TDH RESPONSE

to

Questions from April 2, 2015

CN1407-027 Implanted Pump Management & CN1411-046 Pentec Health, Inc.

The Mission of the Tennessee Department of Health is to protect, promote, and improve the health and prosperity of people in Tennessee. TDH's responses to questions posed by the Health Service and Development Agency regarding the proposed institution of intrathecal pump maintenance services by a home health agency follow.

1. Does the Tennessee Department of Health (TDH) have any way to determine the actual number of intrathecal pumps in Tennessee? For example, is there any type of registry or does the Board of Medical Examiners (BME) keep any type of information?

   TDH Response: TDH is not currently able to determine the number of intrathecal pumps in Tennessee. Neither TDH nor the BME maintains any such registry, and TDH is not aware that any such registry exists in Tennessee.

2. Do physicians prescribing intrathecal pumps for pain management have to meet any additional requirements beyond what a typical physician would have to meet? For example, would physicians prescribing this type of care need specialty board certification such as interventional pain management or would their offices be required to be certified as a pain clinic by the Board of Medical Examiners?

   TDH Response: The Tennessee Home Health Agency rules and regulations (HHA R&R) do not mandate any such certification. The HHA R&R advise that ongoing educational programs be planned and conducted to develop and improve the skills of personnel.

   Insertion of an intrathecal pain pump constitutes interventional pain management under TCA Section 63-6-244 and, as such, a physician engaging in this practice would have to be board certified in one of a few specified areas or meet one of the other qualifications either in statute (TCA Section 63-6-244) or rule (BME Rule 0880-02-.14(14)). Neither TDH nor the BME licenses or credentials for these specified areas. As a result, the BME doesn't have access to information regarding the number of physicians qualified and engaging in this practice. Prescribing the drug to be contained in the pump does not fall under the BME Rules (the usual rules relating to prescribing would apply).

   It is not clear that performing the actual refill also constitutes interventional pain management (the definition in TCA 63-6-244(b) is broad, "...performing invasive procedures involving any portion of the spine..."). The insertion of the needle into the catheter structure that has been inserted directly into the spine may qualify as invasive despite the needle not being inserted directly into the spine itself.

3. A. How often would a physician need to see a patient for an assessment before prescribing refills for the pumps? If a physician is required to see the patient each time before prescribing refills, is there any benefit to this home care model?

TDH Response: HHA R&R do not mandate a face-to-face visit with the physician. The HHA R&R state the plan of care is to be reviewed every 62 days, and a written summary of the patient's status is provided to the physician every 62 days.

There is not a requirement in the BME Rules regarding how often the physician would need to see the patient. Opioids cannot be dispensed in greater than a 30-day supply, although that does not mean that practitioners must see the patient every 30 days. There are also BME Rules 0880-02-.14(6)(e) and (7) that require a physician to conduct a physical exam in order to prescribe, particularly for controlled drugs. However, an exception exists in (7)(b) of that rule for established patients.

B. Does TDH believe the need for this type of service is being met in the physician office setting?

TDH Response: TDH does not have direct knowledge or access to data to answer this question, and is not currently aware of any lack of available services in this regard. A patient receiving this service in a physician office setting is not homebound; initially, all patients initially receive the implanted catheter in a physician's office or surgical setting.

C. If a home option became available, would any physicians be expected to stop providing this service in the office?

TDH Response: TDH does not have information or data that permits it to answer this question. TDH and the BME believe that there is value in the physician seeing andexamining the patient on a regular basis.

D. Who currently provides the refill in the physician office setting? Does the physician do it or a physician extender or registered nurse? Are there any circumstances when someone less credentialed than an RN could provide the refill (such as an assistant)? If someone other than the physician is providing the refill, is direct oversight required?

TDH Response: Since neither TDH nor the BME licenses physician offices or credentials them to engage in this practice, TDH cannot answer this question. It should be noted that TCA Section 63-7-126 only permits an Advanced Practice Nurse or a Physician's Assistant to perform interventional pain procedures under "direct supervision," which means physically present in the same building at the time of the procedure. However, there has not been a determination regarding whether the refill is an interventional pain procedure itself or is instead a maintenance procedure.

4. Can TDH provide any insight from its resources or those of its stakeholders relative to how reimbursable costs of in-home intrathecal infusion pump services provided by the two applicants might compare to the cost of providing the service to patients in the physician office setting? If so, can the data be provided by the major CPT codes that apply to the service? See p. 140, Pentec application, for codes.

TDH Response: TDH does not have access to data by CPT code usage and is thus unable to answer this question.

5. A. Have TDH's concerns about shipping directly to the applicant's staff nurses been allayed [by information in transcript and from applicants? If not, please confirm the federal or state requirements that prohibit this type of activity.

TDH Response: The Tennessee Board of Pharmacy (BOP) is charged with enforcing federal and state laws in this area. BOP staff have spoken with and received emails from the US Drug Enforcement Agency (DEA) indicating that the delivery model does not meet federal requirements, and even though it may be "overlooked" in some areas of the country, if a license application is received the BOP will refer the matter to the Nashville office of DEA for consideration and react accordingly.

B. Please identify the controlling state and federal requirements regarding controlled substances.

TDH Response: US Code of Federal Regulations, Title 21, Chapter II, Part 1306. TCA Sections 39-17-402 (26), 53-10-104, 53-10-105, 53-10-108, 53-11-301, 53-11-302, 53-11-308, 53-11-401, 63-10-204 (12), 63-10-204 (13).

C. Please provide more details regarding state and federal compounding pharmacy requirements. Given the recent concerns regarding the fungal meningitis outbreak due to problems in out-of-state compounding pharmacies, how does the department regulate those pharmacies going forward? Are there any special concerns related to the compounding of the drugs that will be utilized in the implanted pumps? Will TDH approve dispensing by a pharmacy to the applicant home health agency as originally described (direct to staff nurse for transport to home health patient)?

TDH Response: Compounding for intrathecal use via implanted pumps has one of the highest pharmaceutical delivery risk levels, and also contains some of the strongest pain medications available. The BOP aggressively inspects sterile compounders located inside Tennessee at least annually and has a process to allow immediate action should the pharmacy not meet the guidelines of the BOP's pharmacist investigators. TCA Section 63-10-216 requires out-of-state compounders to be inspected by their home state's agency within 12 months of the issue or renewal of their Tennessee BOP License. TDH and the BOP have confidence in the BOP's inspection process for in-state compounders, but do not have the same level of comfort with the inspection of out-of-state compounders by their home state agencies. The TDH response to Question No. 5 A, above, addresses the last question in5 C, immediately above.

D. Are there drug safety concerns regarding the drugs being shipped to the nurse versus being shipped to the home? Is the risk of the drugs being tainted or damaged in some way greater in one scenario than the other? Are there time and/or temperature concerns?

TDH Response: Storage of controlled substances subjects the holder of drugs to risk of burglary, robbery, and other crimes. Pharmacies with major security and advanced alarms are frequently burglarized and robbed; TDH questions whether a nurse's home could be adequately protected so as to make controlled substance storage safe or secure. TDH additionally wonders how a nurse would be able to defend him/herself against patient allegations of theft, tampering, adulteration, or other damage. Regarding temperatures, drugs can be packaged and shipped properly to withstand temperature fluctuations for a short time, but timely retrieval and proper storage of drugs is necessary.

E. How can the receipt and proper use of opiates be monitored and regulated if these applications are approved? How could opiate abuse (illegal use and distribution) by home health personnel be avoided?

TDH Response: The HHA would be expected to have policies and procedures in place to address these concerns. The HHA R&R direct a licensed HHA to have an appropriate and effective pain management program to be in place. TDH has no other way to monitor and regulate the receipt and proper use of opiates, and thus believes that there is currently no way to guarantee that opiate abuse would not occur.

6. A. Could TDH survey states where this process is more common to determine what they have learned about intrathecal pump infusion by a home care agency – for example, the pros and cons of this type of service in the home setting. It would be helpful to learn about the regulatory compliance for these applicants in other states (all states bordering Tennessee except Arkansas; New York and Illinois).

   TDH Response: The following states were reviewed: North Carolina, Virginia, Georgia, Alabama, Mississippi, Missouri, New York, and Illinois. North Carolina and Virginia include intrathecal pumps within the definition of infusion therapy. Each state has specific regulations guiding infusion and intrathecal pump services provided by a home care agency. Alabama code does not appear to address home health agencies. The remaining states do not have rules or regulations in law regarding intrathecal pump services provided by home care agencies. However, these states have rules and regulations in place for home health agencies that may be applicable to intrathecal pump infusion provided by a home care agency.

   a. Kentucky: http://chfs.ky.gov/os/oig/dhcfs.htm

      It isn't clear how Kentucky categorizes services in its home health facilities for regulation; however, it appears unlikely that it singles out in-home intrathecal pumps from other home health regulation.

   b. Virginia: http://www.vdh.virginia.gov/OLC/laws/

      Virginia regulates intrathecal services with other home health agency infusion therapy services. Please see 12VAC5-381-350, Pharmacy Services, for specific information at the above link.

   c. North Carolina: http://www.ncdhhs.gov/dhsr/testrules.htm

North Carolina regulates intrathecal services with other home health agency infusion therapy services. Please see 10a NCAC 13j .1108 INFUSION NURSING SERVICES at the above link for specific information.

d. Georgia: https://dch.georgia.gov/hfr-laws-regulations

Georgia does not appear to regulate intrathecal services separately from other home health agency services.

e. Alabama: http://www.adph.org/HEALTHCAREFACILITIES/Default.asp?id=5344

Alabama does not have regulations for home health agencies.

f. Mississippi: http://msdh.ms.gov/msdhsite/_static/30,0,83,60.html

Mississippi does not appear to regulate intrathecal services separately from other home health agency services.

g. Missouri: http://health.mo.gov/safety/homecare/

Missouri does not appear to regulate intrathecal services separately from other home health agency services.

h. New York: https://www.health.ny.gov/facilities/

New York does not appear to regulate intrathecal services separately from other home health agency services.

i. Illinois: http://www.idph.state.il.us/about/ohcr.htm

Illinois does not appear to regulate intrathecal services separately from other home health agency services.

B. Is compliance information desired from these states on this particular type of service provider?

TDH response: TDH believes this information might help inform the HSDA about specific applicants.

7. The patient to nurse ratio of 40 to 1 seems unrealistic especially since both applicants sought to cover a large geographic area such as Tennessee. Does TDH believe this is a realistic staffing ratio given the nature of the services being proposed?

TDH Response: A concern clearly could arise in the instance of a patient emergency situation and the ability of the nurse to make it to the patient's home within a reasonable amount of time.

8. If all the concerns regarding controlled substances were resolved, is this specialty type singular home health service a better care model than one where an existing full-service agency would contract with a specialty provider? In the former, the specialty provider would notify the patient's physician of any additional problems and assist in coordinating follow-up care under physician's orders with another separately licensed home health agency, as appropriate. In the

latter, a full service agency would contract with the specialty provider to provide the specialized services while the full-service agency would oversee all the care provided.

TDH Response: A plus to the proposed specialty model could be having specialized staff members concentrate on one area of service, contributing to better patient outcomes.

9. Should this application be approved?

   TDH Response: TDH believes the response to this question is the HSDA's responsibility; however, in particular, the responses to Question No. 5 show TDH's level of concern regarding the provision of this service.

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DATE: June 10, 2015

TO: HSDA Members

FROM: Melanie M. Hill, Executive Director

SUBJECT: CN1407-027, Implanted Pump Management, LLC & CN1411-046, Pentec Health, Inc. Response to Agency Questions

On March 25, 2015, the HSDA heard the referenced applications and deferred both so additional information could be obtained. Questions were submitted to both applicants and to the Department of Health. The information below includes a summary of the applicant's responses. Included for you review is a transcript of the March 25, 2015 Agency meeting and each applicant's response to the April 2, 2015 questions. The Tennessee Department of Health's response will be forwarded once it has been received. Please refer to your copy of the original application (which can also be accessed from the agency's website at this link: http://tennessee.gov/hsda/committee_packets/Mar15_packet.html). Pentec has also submitted a response, dated 6/4/15, to IPM's response to Question 13. It is attached directly behind the 5/22/15 Pentec responses.

The table below provides a brief summary of the two projects.

Implanted Pump Management, CN1407-027, and Pentec, CN1411-046

Item	IPM	Pentec
Project Cost	$13,038	$142,028 (100 k for contingency)
Skilled Nursing Services -focuses on medication admin. under physician orders	Refills for Intrathecal pumps only	Refills – Intrathecal Pumps and Meds for Ig-G replacement therapy *(willing to exclude this service)* *Sup 2 -pgs. 241,251,252*
Target Patient Types	Chronic pain, CA pain, CP, MS (YR 1=108 pain, 11 CP, 2 MS) *Sup 2 –p221-224*	Same as IPM YR 1 = 17 in East; 14 in Middle and 8 in West at year end
Est # IP Pumps in TN in CY2014 Projected # IP Patients (Year 1)	300 IP pumps 120 patients	1,976 IP pumps 20 IP patients (avg. per month)

Projected # Visits (Year 1)	1,440 visits (*12 per patient – 1 visit every 30 days*)	120 IP visits (*6 per patient- 1 visit every 60 days*) *Note: Applicant estimates 1,020 IgG patients in TN as of 12/2015*
Compounding Rx Support	By contract- Intrathecal Compounding Specialists (LA) and Basic Home Infusion (NJ) *TN licensed since 2008 and 2009*	Pentec owned/ closed compounding pharmacy at corporate office in Boothwyn, PA. *TN licensed since 2004*
Dispensing *Note: both proposals involve compounding Rx prep, packaging & shipping by pharmacies who hold existing out of state TN pharmacy licenses*	Contract pharmacies (2 identified by applicant) ship to RN or patient. *Note: at March HSDA meeting IPM owner (Putrino) stated they would change model to ship from compounding pharmacy to patient and would use an in-state licensed compounding pharmacy to comply with TDH requirements* *Sup 1-p113;Sup3-p269* *Transcript, p.16*	Pentec's wholly owned pharmacy ships to RN. *Note: at March HSDA meeting, Pentec Rep (Wynd) stated that Pentec' s IP med shipping model of its licensed HHAs in 32 states complies with state and federal (DEA) requirements. Wynd stated Pentec is confident in its delivery system and most likely would not entertain changing the model for the proposed TN service.* *Sup1-p147,165; Sup2-p249* *Transcript, page 97*
Payment Source	Commercial, Private	Commercial, Private (includes partial pay) *Sup 2, p245* *20 of 39 commercial by year end* *See app-p 81 and Sup2-p233 for plans/charges*
Medicare-TennCare – CMS covers Rx & DME only and not skilled nursing home health visits	IPM has no charity policy for these recipients	Will cover recipients as partial pay or charity.
Gross Operating Revenue Average Gross Charge Gross Operating Margin	$288k-$576k $200 per visit 47% of gross rev	$305k-$854k $2,517 per visit 14% of gross rev
Operations History	BHI has pharmacy license in 14 states (*per Putrino at March meeting*) IPM has HHA licensure pending in FL, NJ, UT -No IP patients served yet *TDH sum - BHI Pharmacy infractions in several states*	Pharmacy licensed in 50 states & DC HHA health licensure in 34 states (sup 2, p255) 1,303 IP home patients in 2011 2,177 IP home patients in 2013 (*At March HSDA meeting, Pentec rep stated approx. 2,800 IP patients were served in 2014*) *TDH sum-Pharmacy infraction in Indiana*

Support Letters	2 patients, 3 pump vendors, 2 physicians	I physician (*5 or more initially identified in application –p81*)
Staffing *Both provide 24 hour call center support, secure web portals for patients and physicians, etc.*	1 RN to 40/50 patients (start with 2 FTE) 180 mile radius Mandatory nurse training	1 RN to 40 patients (start with 2.5 FTE) Mandatory nurse training-ANC certified. *Sup2-p254*
Service Area (statewide) Est 2.2 million TN residents with chronic pain, 2,000 with CP, 7,200 with MS	95 counties No existing HHA actively serving IP patients	92 counties
Home Health Need formula	81,600 surplus statewide	80,773 surplus in 92 counties

The following questions were asked of each applicant. A brief summary of their responses follows.

1. Based on the information provided by the Tennessee Department of Health, it appears implantable intrathecal pumps may not be safe. Please provide expert opinion on the safety and efficacy of the pumps.

Pentec - provided opinion from Dr. Stanley Fisher, M.D, St Luke's Neuroscience Institute, Kansas City (bio was included). His comments address the inherent risk of intrathecal pumps (IP), the prevalence of use since FDA approval in 1999 (approximately 80,000 pumps nationwide in 2014), and Pentec's safety protocols for IP medication refills (only in-home service to be provided).

IPM – provided opinion from two sources (a) David Caraway, MD, PhD, Medical Director Center for Pain Relief, St. Mary's Regional Medical Center, Huntington, WV, and (b) overview in clinical/patient literature published by Medtronic (pump manufacturer) dated 4/1/08. Dr. Caraway's letter highlights advantages of IP refills over oral meds for target patient populations (MS, CP, Pain); need for continued oversight by physicians (he recently transferred IP refill management of 200 plus patients to a home health agency. This pain management physician has published reviews of numerous medical studies with colleagues. The Literature Review (Intrathecal Drug Delivery for Chronic Pain Literature Review) defines the use of IPs, its benefits in terms of effectiveness as treatment of last resort by physicians and risks such as complications from wound infections.

2. Describe in detail the safety of refilling the pumps in the home versus a physician office. Who refills the pump in the physician office setting.....is it the physician or a nurse or someone else? If someone other than the physician, detail the oversight provided by the physician.

Note: the responses for this item point out differences between settings. For example, various staff in physician office can be assigned IP refills additional other patient responsibilities (RNs, LPN or med assistants), or physicians may decide to personally administer the refill. Pentec notes that medical pump manufacturers may provide most of the ongoing education support. The key point both make is that the home health agency is inherently the safer setting since they focus on in-home IP refill management as a sole service and RN staff must complete specialized training.

3. Address the risks associated with accessing the spinal port in the home. Provide any statistics for incidents, adverse events, or reported complications over the past 3 years and the outcomes. Both applicants have noted having a national presence in the implanted pump market so additional clarification regarding safety issues is needed.

Note: The responses point out the risks are the same in physician offices with some exceptions such as better infection control in the home setting. Two key risks are described (subcutaneous infection & pump programming errors. Pentec lists safeguards in place to minimize these). Pentec identifies several statistics from its records. For example, it had two patient emergencies during the 3 year period ending April 2015 (partial subcutaneous administration errors) on approximately 28,855 total IP refills during the period (Note: based on information provided in the application and the March 2015 Agency meeting, HSDA staff estimates that approximately 5,800 – 6,000 patients may have been served during this 28 month period)

IPM did not provide the same level of detail, but notes the home health agency error rate is less than 2% of total pump complications.

4. Describe when the procedure is clinically contraindicated (when a refill will not be performed).

Note: both applicants gave specific examples. IPM includes description of notification to physicians. Examples of circumstances include inability to access pump reservoir, infection, fluid accumulation, an inverted pump, or concerns with catheter tubing.

Describe in detail how the medications will be protected from theft, misuse, and/or abuse from the time the nurse receives the medication until it is delivered to the home.

Note: both applicants addressed their medication delivery systems during initial review of the applications. Their responses to this question are consistent with those responses. During the March Agency meeting, IPM agreed to change its shipping protocol to send implanted pump meds direct to patient homes per TDH requirements (page 87 of transcript) and to contract with a Tennessee licensed compounding pharmacy whose preparation and distribution facility is physically located in Tennessee (page 16 of transcript). Pentec notes that it shipped 6,581 implanted pump med packages in 2014. Of these, there were only two circumstances where inaccuracies were noted. Key features used to help control the process include custom designed scheduling systems, cross check of shipping documents by pharmacists and staff nurses, inventory by staff nurse on delivery, and the use of lock boxes and tamper proof caps. Additional detail - Pentec included copies of three existing corporate policies & procedures used by its specialty infusion and pharmacy divisions.

How will the proper use of opiates be monitored and regulated?

In addition to internal protocols by the applicants, IPM notes that Tennessee regulators could track proper opiate use through existing controlled substance tracking systems and MD monitoring.

Have there ever been incidents of opiate abuse by employees of your company in any of the other states in which you operate? If so, please describe in detail how those were handled.

Note: both applicants responded to the question. IPM reported no violations or issues. Pentec identified one instance of diversion by a nurse employee in 2009 and described what was done to report the incident and develop & implement a plan of correction. Since the incidence in 2009, Pentec notes it has performed 50,000 IP refills in six years with no further diversions noted.

5. Emergency procedures were addressed in the applications, but more detail is requested. What are the emergency procedures if there is an adverse reaction during the refill procedure? After the procedure is complete and the nurse is still in the home? When nursing personnel are not in the home? After the procedure, and nursing personnel have left the home?

Note: the additional detail requested was provided by Pentec (copies of 2 corporate policies and physician responsibilities per patient plan of treatment per state law). Otherwise, both applicants provided descriptions of actions staff nurses and patients should take when or if emergencies occur, including notification to physician, the IPM or Pentec 24 hour on call center and calling 911.

6. The patient to nurse ratio of 40 to 1 seems unrealistic, especially since both applicants sought to cover a large geographic area such as Tennessee. How many nurses would it take to provide adequate coverage in Tennessee, and from where would you hire these skilled nurses?

Note: both applicants addressed this in the application and supplemental responses and have a similar 40 to 1 staffing plan. IPM clarified that it would also staff on the basis of a 180-mile radius from the IPM nurse to the patient. Pentec operates in-home skilled nursing IP refill service in approximately 30 states and has experience with this type of staffing plan. Pentec identified state requirements for home health organizations that may otherwise impact its staffing plan such as service areas limited to a 100 mile radius from applicant's parent office (per Kansas and New Mexico requirements). These restrictions are noted in the state-by state analysis Pentec provided on pages 125–132 for question 11 of the letter.

7. During the March 25, 2015 Agency meeting, Mr. Doug Wynd, Pentec National Sales Director of Specialty Infusion, stated there were approximately 80,000 individuals with implanted intrathecal pumps in the U.S, including 75,000 receiving ongoing care from their physicians and 5,000 receiving care in their homes from licensed home health agency nursing staff under physician orders. Mr. Wynd noted Pentec was serving approximately 2,800 of the 5,000 in the home setting (draft transcript, pages 37 and 53). Due to the wide variation in estimates of implanted pumps in Tennessee (IPM used 300 Medtronic implanted pumps while Pentec estimated approximately 1,730 total pumps) please clarify the difference in the two estimates, and document the basis for the estimates.

Note: both applicants described how their estimates were derived and clarified remarks made at the March 2015 Agency meeting. IPM notes that Medtronics sold 621 implanted pumps to facilities in Tennessee in CY 14-15 (595 of the pumps were implanted). IPM also notes that there are another two pump vendors in Tennessee with the result that the current number of pumps in the state could be at least three times higher. Pentec bases its estimate using a population methodology. Specifically, it

multiples Tennessee's population rate (2.05% of US population) by 80,000 exiting implanted pumps in use in the U.S. to arrive at a minimum of 1,640 implanted pumps in the state, increasing to 1,976 pumps when taking Tennessee's health status ranking into account (source of market data is from HMS Holding Corporation).

Please identify the number and source(s) of patients that are presently being treated in a physician's office in Tennessee. Are any physicians expected to stop providing this service in the office if a home health option becomes available?

Note: both applicants appear to agree that 100% of implanted pump patients are being treated in physician offices. Pentec's experience is that approximately 10% of existing pump patients could be referred for in-home treatment support.

8. Please provide testimony (in person or by letter) from physicians with practices in each Grand Division of Tennessee (East, Middle, and West) who would support this specialty service in the home, including the approximate numbers of patients needing this service. Provide sufficient letters to support the service area requested.

   Provide letters of support from patients in each Grand Division of Tennessee not being treated due to not being able to travel to a physician's office as well as from patients who would find this home option more convenient. Provide sufficient letters to support the service area requested.

Note: both applicants provided letters from physician groups and some patients – there are few letters of support as was the case during initial review of the application. One new development is that physician practices have wider geographic service areas with patients from all parts of the state. To help demonstrate this, the applicants used surveys to help identify caseloads of the physician practices. The Pentec response also identified support by Comprehensive Pain Specialists, a physician practice that treats patients through 28 office locations across the state.

9. How often does a physician have to see the patient before these medications can be refilled?

Note: both applicants state that the frequency in most cases is 30 – 60 days. However, they note that frequency will vary as directed by physicians through physician treatment plans that must be updated every 60 days in accordance with state regulations.

10. What is the current estimated cost and payor reimbursement by major CPT codes pertaining to intrathecal implanted pump refill visits in physician offices in TN? How does this compare to your cost and reimbursement?
    IPM projects an average gross charge of $200/visit while Pentec identified $2,517/visit. Although total gross revenue of both applicants is very close in Year 1 (approximately $300K), the difference in projected patient visits results in a wide variance in the projected average gross charge. Please identify the key components of your rate structure with related CPT codes used to bill for implanted pump refills in physician offices, home health, and pharmacy settings. Note: For purposes of comparison, it is suggested the key components of the proposed rate structure identified in the Pentec application be used in the response for this question. Specifically, the rate would include the charges by four basic categories - medications, supplies/materials, nursing time

and a per diem that covers allocated corporate support costs, such as IT, billing, etc. (transcript, Pentec presentation, page 54-55).

Note: there is really no new information provided by IPM – it continues to assert that its $200 rate is for skilled nursing only because it subcontracts for pharmacy services. As a result, the additional detail in the response by Pentec appears to provide further clarification of how its average gross charge was revised to $2,471 per patient visit during HSDA's completeness review of the application, inclusive of charges for medications, nursing labor, supplies, and a per diem charge. Pentec notes that its rate structure has been reviewed and accepted by the nine payers in Tennessee shown on the table in page 20 of the response. Of interest, Pentec states that HCPS codes apply to infusion therapy pharmacy providers (including home health agencies) in lieu of CPT codes that apply to physicians (HCPS = healthcare common procedure coding system). This was confirmed through HSDA communications in April 2015 with Mr. Bill Noyes, Vice President, National Home Infusion Association (NHIA). Mr. Noyes also provided insight on his association's development of legislation to expand Medicare coverage of infusion therapy for patients in their homes (the legislation was recently introduced in Congress under the Medicare Home Infusion Site of Care Act of 2015). As part of the legislation, a study sponsored by NHIA (The Avalere Report) was used to help identify the potential savings to the Medicare program. The report identified an estimated $80 million in savings to Medicare over a 10 year period from 2015–2025 if coverage for in-home care were to be added to existing Medicare coverage of infusion therapy services in hospitals, hospital outpatient departments, physician offices, and skilled nursing facilities. The legislation and the report can be found on NHIA's website at http://www.nhia.org

11. Provide comprehensive state regulations for each state in which you operate this type program. How are these agencies regulated by each state, as home health agencies or pharmacies or as some other type entity? Disclose and discuss any sanctions of existing licenses in other states in which you operate this type program and provide evidence that your company is in good standing.

Note: Pentec provided a state-by-state analysis in a table on pages 125-132 of its response. IPM provided a brief description of applicable requirements and a list showing home health and pharmacy licenses by state currently held by IPM and Basic Home Infusion (BHI), a New Jersey Corporation related to the applicant through ownership by Roy Putrino. With respect to home health licensure only, the list shows that IPM has home health licenses in Florida, Utah, and Virginia while BHI holds licenses in Illinois, North Carolina, and Texas.

According to Pentec, it holds licenses classified as a home health agency in 10 states, under different licensure classifications in five states (e.g. home nursing agency, home care agency), and provides in-home implanted pump services in 14 states, where licensure at the entity or agency level is not required.

Have you ever been denied a certificate of need or a license (home health or pharmacy) in any state? If so, please provide documentation such as staff reports, minutes, denial letters, and/or transcripts.

Note: both applicants answered in the negative. IPM noted it received CON approval from Kentucky in November 2014 to provide intrathecal infusion pump home management services as a "mobile health service" in all but 4 counties of the state.

12. Did either applicant consider contracting with existing home health agencies to provide this service? If not, please explain why. In a contractual situation, the services could be provided under an existing agency's license utilizing IPM or Pentec nurses to provide the service. Discuss the pros and cons of this scenario and how reimbursement would differ.

Note: Of the two applicants, only Pentec appears to have seriously considered the advantages and disadvantages of this scenario with highlights of same fully addressed on pages 24-26 of its response. IPM identified major disadvantages associated with subcontracting with an existing licensed agency stemming from patient safety concerns based on the specialized nature and scope of providing a skilled nursing implanted pump management service in the home setting.

13. Should the Agency determine there is a need for this type specialty home health agency, would the applicants be willing to consider approval for only half of the service area requested so that two agencies would cover the state instead of just one? Would the project still be financially feasible if only a portion of the service area were approved?

Note: both applicants are opposed to this scenario. IPM states this is an unsafe option due to Pentec' s "ongoing FDA investigation that illustrates unsafe pharmacy conditions" (review of the FDA/DEA website by HSDA staff on 6/1/2015 revealed that Pentec' s Boothwyn, PA compounding pharmacy had several citations related to preparation of some renal products used by the company's Renal Division. Please note that Pentec has filed a separate response, dated 6/4/15, to this allegation. This investigation and related actions to correct the situation were addressed in the application and by the Pentec representative at the March 2015 HSDA meeting in Nashville).

Pentec opposes the scenario as a "geographic restriction" that would unnecessarily limit physician referrals of patients who reside in wider geographic areas across Tennessee.

14. The final question is for Implanted Pump Management. In the application and during testimony on March 25, 2015, Mr. Putrino indicated his infusion pharmacy company, Basic Home Infusion, had licensed pharmacies in 14 states and that IPM would be operating home health agencies in three states—Florida, Utah, and New Jersey. Mr. Putrino is quoted on page 16 of the attached transcript as saying "This model has allowed us to grow to a national level via word of mouth, and it is our desire to bring this model to Tennessee" and on page 95 as saying "Let's take this regional contract and make it national." Please explain these comments about going national with only three not yet operational home health agencies. Is IPM or its sister infusion pharmacy company providing direct hands-on skilled nursing services in other states directly to patients via contracts with individual nurses or in some other manner?

Note: Mr. Putrino states that IPM was established with guidance from the Joint Commission to better conform to each state's nursing regulations and to streamline the process. Mr. Putrino also provides some information that may help further appreciate some of the differences between IPM and BHI. A key difference appears to be the scope of BHI coverage in the U.S. based on its licensure as a compounding pharmacy to provide intrathecal therapy in 45 states in accordance with requirements set forth by each state's Board of Pharmacy.

HSDA TRANSCRIPT

MARCH 25, 2015

SIMULTANEOUS REVIEW

CN1407-027, IMPLANTED PUMP MANAGEMENT, LLC

&

CN1411-046, PENTEC HEALTH, INC

MR. WRIGHT: Yes.
MR. AUSBROOKS: Doolittle?
MR. DOOLITTLE: Yes.
MR. AUSBROOKS: Austin?
MS. AUSTIN: Yes.
MR. AUSBROOKS: Fleming?
DR. FLEMING: Yes.
MR. AUSBROOKS: Byrd?
MS. BYRD: Yes.
MR. AUSBROOKS: Johnson?
MR. JOHNSON: Yes.
MR. AUSBROOKS: Ten "yes."
MR. JOHNSON: The motion passes. The certificate of need is approved.
MR. WINICK: Thank you very much.
MR. JOHNSON: Thank you.
We're about to get into a lengthy part of our agenda, and so we're going to take a ten-minute break before we do that.
(Brief recess taken from 9:45 a.m. to 10:05 a.m.
MR. FARBER: Implanted Pump Management, LLC, Knoxville, Knox County, CN1407-027. This application is for the

1 establishment of a home care organization and
2 the initiation of home health services limited
3 to intrathecal pump services. The parent
4 office will be located at 200 Prosperity
5 Place, #102, Knoxville, Knox County. There
6 are no branch offices proposed for this
7 project. The service area includes all 95
8 counties in Tennessee. The estimated project
9 cost is $13,038.
10 This application is opposed by
11 National HealthCare Corporation. This
12 application was deferred from the December
13 2014 meeting. Mr. Mills is recusing on this
14 application.
15 Here on behalf of this
16 application are Melissa Hess and Rachel
17 Nelley.
18 The second application, in the
19 simultaneous review, is Pentec Health,
20 Incorporated, Nashville, Davidson County,
21 CN1411-046. This application is for the
22 establishment of a home care organization and
23 the initiation of home health services limited
24 to intrathecal pump infusion and IgG
25 replacement therapy services in all counties

1 in Tennessee except Hancock, Perry, and Van
2 Buren Counties. The parent office will be
3 located in leased space at 424 Church Street,
4 Suite 2000, in Nashville. There are no branch
5 offices proposed for this project. The
6 estimated project cost is $142,028.
7 This application is also opposed
8 by National HealthCare Corporation, and
9 Mr. Mills will be recusing on this application
10 as well.
11 Here on behalf of Pentec Health
12 are Doug Wynd.
13 MR. JOHNSON: Okay. This is a
14 simultaneous review, which is different than
15 any that most of us have experienced. There's
16 been one since I've been on the Agency. And
17 maybe Mr. Gaither and Ms. Jordan have seen
18 more, but it's a bit unusual for us. So it's
19 going to be done a little differently. We'll
20 hear the application remarks, the opposition,
21 and then we will get into the member
22 discussion as we normally do as opposed to
23 doing it individually.
24 There is opposition for both --
25 I want to make sure that's correct -- right?

1 (Opposition noted.)
2 MR. JOHNSON: All right. So
3 we've got that present. Then we'll go through
4 the process. So first [is] the support
5 presentation.
6 MS. HESS: Hello. My name is
7 Melissa Hess. I'm an RN and Director of
8 Nursing for Implanted Pump Management --
9 MR. JOHNSON: I think you need
10 to get the microphone maybe closer, so we
11 can --
12 MS. HESS: Closer? Is that
13 better, sir?
14 MR. JOHNSON: (Nods head.)
15 MS. HESS: I'm short. Thank
16 you. My name is Melissa Hess. I'm an RN and
17 Director of Nursing for Implanted Pump
18 Management. I have been working in the home
19 intrathecal management portion for nine years.
20 I actually have a passion for the therapy.
21 I've seen how the therapy can assist patients
22 getting to -- who are bed bound, writhing in
23 pain to this pump augmenting them and
24 assisting them to really working a
25 40-hour-a-week position. So it really is a

1 great therapy that you can see tangible
2 results.
3 I want to explain a little bit
4 about the intrathecal pump therapy, if I can,
5 because I'm not quite sure what knowledge
6 level everyone does have of that today. The
7 intrathecal pump is used for two main reasons:
8 Chronic pain and chronic spasticity. So for
9 spasticity, you could look at diagnoses such
10 as cerebral palsy, traumatic brain injuries,
11 spinal cord injuries, and, in some cases, ALS,
12 and then you have a portion of the patient
13 population who suffer from chronic pain.
14 These are those individuals that
15 have had several surgeries, and the doctors
16 have said I can't do anything else to fix
17 this; there's nothing else I can do. And
18 these patients are still in an immense amount
19 of pain and it's affecting their quality of
20 life. They're on a plethora of oral
21 medications. They are unable to participate
22 in their everyday activities as they should be
23 able to. So that's another individual who
24 might benefit from one of these pumps. So you
25 look at chronic pain and spasticity as the two

1 main indicators.
2 It's important to understand
3 that these pumps don't treat chronic pain and
4 spasticity. They don't look at the underlying
5 issue, but they treat the manifestations; the
6 pain and spasticity. And the goal would be
7 for the individuals to have a higher quality
8 of life, to get them maybe out of a wheelchair
9 into a stander, or it may be as simple as for
10 a caregiver to be able to dress them easier in
11 the morning.
12 So the spectrum of patients is
13 very large. You look at an individual who,
14 with a pump, can possibly work a full-time
15 position, or you have an individual who maybe,
16 from a wheelchair, can transfer more easily to
17 the bed.
18 The pump is a titanium pump.
19 It's a closed system. It is implanted usually
20 in the right or left lower abdomen. And a
21 medication, via a catheter is delivered to the
22 spinal column in that intrathecal space. The
23 mind-set and the rationale for this therapy is
24 that the medication enters the cerebral spinal
25 fluid, it does not cross the blood brain

1 barrier, and the manifestations of any sort of
2 side effects that any oral medications would
3 commonly take are not generally presented with
4 an intrathecal pump. So the individuals can
5 have better pain relief, better spasticity
6 relief, and not be dozing off; not have those
7 secondary effects of the two types of
8 medications used to treat the chronic pain and
9 spasticity.
10 The higher quality of life, I
11 think I touched on about five times already,
12 but that really is one of the overall goals of
13 this therapy. And it does require a high
14 acuity. These pumps are not visible from the
15 outside. You could not tell that any of us
16 here might have had a pump. It's not
17 something that any individual can pick up
18 quickly. You have to understand the
19 mechanics, you have to understand how the
20 patient manifests, you have to understand the
21 programming, and you have to really understand
22 the medications and how they affect the
23 patient.
24 The introduction of intrathecal
25 home care management services to the state is

1 something that we have found that is required
2 and actually deficient in the state of
3 Tennessee. The current model is that these
4 individuals who have pumps go to the doctors'
5 offices to have the pumps refilled, to have
6 them increased or titrated, and for any of
7 that management piece.
8 What we look at is, the doctors
9 are saturated with the pumps. So for an
10 individual that -- for example, a doctor who
11 has 20 pumps, that takes a lot or a huge
12 portion of their staff management to manage.
13 And there are actually patients waiting to
14 have pumps. I've had doctors say to me, "I
15 really wish that I could do more pumps, but I
16 just can't take on the additional management.
17 So the home care management
18 piece really takes that --
19 THE COURT REPORTER: Ma'am, you
20 really need to get in front of the microphone.
21 MS. HESS: Oh, I'm sorry. I
22 apologize. I'm moving. I have a little
23 Italian in my. I apologize.
24 I want to go ahead and explain
25 that this introduction of home care management

1 will allow the physicians to offer the
2 treatment more readily. It would give the
3 individuals better access to care. The nurses
4 would go to the patient's home, they would go
5 to a day treatment center, and sometimes to a
6 place of work. The individuals could be
7 filled in their setting.
8 And the idea of the home care
9 piece is very important, because individuals,
10 in their home care setting, generally benefit
11 from that. You take away any sort of burden
12 of travel; you take away higher access to
13 care. If an individual needs a request for an
14 increase or a decrease, the nurse, in the
15 IPM -- or Implanted Pump Management -- model
16 is able to get there generally within 24
17 hours.
18 That same patient who has had an
19 increase in pain and needs an increase in
20 their intrathecal pump dose may have to wait
21 two weeks, based on the doctor's schedule and
22 also a schedule for them to actually get to
23 the physician's office. So I think that's a
24 really important piece to bring up today.
25 There is a full RN assessment.

1 We are there only for the pump. That's
2 something I wanted to really make clear. The
3 Implanted Pump Management model is only to
4 fill the pump, to look at the patient
5 assessment, and to do everything in regards to
6 this intrathecal pump. So we're not here to
7 offer any other type of skilled services.
8 So the idea of us being
9 introduced into the state will really not take
10 away any of the existing licensed home health
11 agencies' resources that they're currently
12 utilizing. I did do, upon the application, a
13 poll of 157 of the licensed home health
14 agencies in the state of Tennessee. And we
15 call them all individually and say "Do you
16 offer this intrathecal home care management?"
17 And one agency said that they were able to,
18 but they have no patients. So I believe that
19 definitely shows that there is a lack of
20 services in this state.
21 We do offer 24-hour on-call
22 availability. Our model works with assisting
23 the doctors, assisting the patients, and
24 really working as that liaison between the
25 two.

1 I would hopefully like to go
2 over some of the patient benefits that this
3 program -- the introduction of this program
4 would bring to the residents of Tennessee who
5 have intrathecal pumps. We, again, have the
6 24-hour on-call service. That's very
7 important. They would speak to a nurse who
8 knows the therapy. They're not brought to a
9 call center. They understand that they will
10 speak to a nurse that understands and does
11 this pump day in and day night [verbatim].
12 The home care approach is more efficacious for
13 the patient due to the location and the
14 availability of the nurses. I spoke about
15 this before.
16 And the idea of the RN doing a
17 full nursing assessment really can lead to a
18 reduction of overall secondary infections for
19 the individuals. If you have an individual
20 who's in the home care setting, who the nurse
21 is there to do a pump refill, and I might
22 identify an area of redness on the right hip.
23 So I would educate. I would let the physician
24 know that we need some more intervention care
25 before we get to a skin breakdown.

1 A lot of these individuals do
2 have a lot of secondary concerns and problems
3 that are going to arise due to their disease
4 processes, so the proactive approach is very
5 important when we're looking at this model.
6 We are the eyes and ears for the physicians
7 while we're in that home care setting, and we
8 can bring anything to them that we feel is out
9 of the normal. And that is the policy and how
10 we will introduce the system.
11 I do want to quickly go over the
12 benefits for the physicians, because not only
13 is it a benefit for the patients, but it's a
14 benefit for the physicians and their office.
15 It allows them to really increase the patients
16 that they can service with this intrathecal
17 pump. It allows the increase in modality; it
18 allows the increase of secondary eyes and ears
19 in the home care setting.
20 And I am going to go over -- I
21 know, in part of the application, there was a
22 question regarding TennCare residents. I know
23 part of the State Health Plan really is
24 specific that TennCare residents need to be
25 identified and any introduction of the model

1 would be required to service those
2 individuals. So Mr. Putrino was hoping to
3 speak quickly regarding Medicare and our
4 pathway that we have developed for that.
5 Thank you.
6 MR. PUTRINO: Good morning. My
7 name is Roy Putrino. I am the owner of both
8 BHI and IPM. As a pharmacist, I've been
9 providing intrathecal home care services since
10 1991.
11 Our organization has developed a
12 very strong Medicare program. With the help
13 of CMS, we've been able to access the MAP
14 programs -- which is the Medicare Advantage
15 programs -- to provide enhanced services to
16 this population. We help -- we assist them in
17 finding the proper MAP for them. We also have
18 the MAP companies, like Humana and United, go
19 to their home and explain the benefits, and if
20 they choose to go ahead, they can. And at any
21 time, they can revert back to Medicare, if
22 they would like.
23 As a pharmacist, I'm licensed in
24 14 states, one of which is Tennessee. As the
25 owner, I take full responsibility knowing that

1 the -- knowing all the specific laws from the
2 state, in the development of all the clinical
3 programs of our organization. Over the last
4 14 years, my organization has developed a
5 unique clinical program that is both proactive
6 and cost-effective. This model has allowed us
7 to grow to a national level via word of mouth,
8 and it is our desire to bring this model to
9 Tennessee.
10 We understand your concern
11 regarding the state compounding pharmacies.
12 And although our organization has a Tennessee
13 pharmacy license and I am a licensed
14 pharmacist, we have no problem in making the
15 use of an in-state compounding pharmacy as a
16 condition of the CON. Currently, we have this
17 model set up. We are currently working with
18 pharmacies in other states, like West
19 Virginia, Ohio, Louisiana. It actually works
20 quite well, and it's great to have the people
21 on the ground.
22 I understand you have over 200
23 compounding pharmacies in this state. We'd be
24 happy to find one to work with us. Thank you
25 very much.

1 Oh, Melissa will do the summary.
2 MS. HESS: I believe -- do we
3 do --
4 MR. PUTRINO: Now or later?
5 MS. HESS: Is pro and support,
6 and then summary after?
7 MR. JOHNSON: Pardon me?
8 MS. HESS: The summary is after
9 the other part, because we're doing a
10 simultaneous review; is that correct, sir?
11 MR. JOHNSON: There will be an
12 opportunity right now for people who support
13 the application who are not a part of it.
14 MS. HESS: Okay.
15 MR. JOHNSON: I didn't call for
16 that earlier, but I will now.
17 MS. HESS: Okay. Thank you.
18 MR. JOHNSON: So now is the time
19 to do that. Are there those who wish to
20 speak? Anybody else?
21 MS. HESS: I think it's just us.
22 (None noted.)
23 MR. JOHNSON: I don't think so.
24 MS. HESS: Okay. Thank you.
25 MR. JOHNSON: Mr. Elrod, the

1 opposition's presentation?
2 MR. ELROD: Thank you,
3 Mr. Chairman and members of the Agency. I'm
4 Dan Elrod, here on behalf of NHC HomeCare,
5 which, through its affiliated agencies,
6 operates throughout the state, except for
7 three counties: Scott, Hancock, and Lake
8 Counties. NHC is a provider of comprehensive
9 home care, including infusion therapy.
10 This application, we submit,
11 suffers from multiple deficiencies, including
12 the following: No need has been established.
13 The applicant requests authority to serve 95
14 counties in the state, but readily admits it
15 has no information about how many patients in
16 each county, if any, actually need this
17 service. Using the Guidelines for Growth as a
18 starting point, there is clearly no need for
19 additional home health in the state, and the
20 staff report establishes that.
21 In the face of that, it's really
22 up to the applicant to show, through
23 documentation, that patients are not being
24 served now; that patients are going without
25 adequate service now. And they have

1 completely failed to do so. They have
2 produced two letters from physicians -- two
3 physician letters -- one from Nashville and
4 one from Hendersonville, and two patient
5 letters -- one from Lebanon and one from
6 Gainesboro -- none of which say that there's a
7 failure to get service now. They're
8 supportive of the application, but they don't
9 say that they're going without service. And
10 we submit that that's not sufficient to
11 establish need in one county, much less 95
12 counties.
13 The application also fails to
14 meet the criteria of orderly development of
15 health care. The limited service proposed in
16 this application is the fragmentation of
17 health care to the extreme. Patients with
18 intrathecal pumps are medically complex, with
19 comorbidities. And it really defies common
20 sense and it's contrary to where health care
21 is headed to create a model of care that
22 addresses only one aspect of patient care.
23 And this is really kind of
24 highlighted in the application because there
25 was -- there's a real contradiction in the

1 application between what it says and actually
2 what was said this morning, because in the
3 application, in one place, they say, "We're
4 gonna take care of the whole patient." On
5 page 46 of the application, it says that it
6 will, quote, "focus on the patient as a whole;
7 not on the implanted intrathecal pump."
8 But then on page 43, when
9 attempting to show how this is not going to
10 affect other home health agencies, they say,
11 quote, "IPM focuses only on this one therapy."
12 And that's what was said here this morning:
13 "We're gonna only do the intrathecal pump."
14 That's not a good model of health care,
15 because it doesn't look at the patient as a
16 whole. It's just a flawed model, we submit.
17 And we appreciate what's being
18 said here in terms of -- about the change now
19 from what was in the application to their
20 willingness to use an in-state compounding
21 pharmacy. We submit that that condition is --
22 I'm not sure how that would be enforced by the
23 Department of Health or how you would police
24 that.
25 But in any event, the pharmacy

1 part of this organization has a shaky
2 regulatory history. And this was pointed out
3 in the Department of Health report which
4 summarized numerous violations in other
5 states, including South Carolina, Colorado,
6 and Illinois. And one of the compounding
7 pharmacies that the applicant relied on
8 actually had a problem in Louisiana with a
9 diversion of 22 pints of codeine cough syrup
10 and 10,000 hydrocodone pills. And we're
11 talking about an opiate substance in this
12 situation.
13 This disciplinary history is
14 really a good segue into our final point. And
15 that's Commissioner Dreyzehner's letter,
16 which, in my history of doing this in front of
17 the Agency, is unprecedented, in terms of
18 having that kind of letter from the
19 commissioner of health. And, remember,
20 Commissioner Dreyzehner is a physician and
21 he's also a public health expert.
22 And his letter includes the
23 following concerns: The model of care may not
24 be consistent with the rules relating to the
25 dispensing of controlled substances. He's

1 concerned about the reliance of out-of-state
2 compounding that's been somewhat addressed,
3 but we submit how that would be policed is
4 still uncertain.
5 Commissioner Dreyzehner's letter
6 also notes a recent practice guideline from
7 the American College of Occupational and
8 Environmental Medicine that casts serious
9 doubt on the appropriateness of the
10 intrathecal pump procedure itself. And that
11 article -- that practice guideline --
12 concluded with this quote (as read): "Thus,
13 with a lack of documented efficacy,
14 invasiveness, serious adverse effects, and
15 marked costs, these devices are not
16 recommended."
17 Commissioner Dreyzehner ends his
18 letter of concern with this statement (as
19 read): "On balance, we have concerns
20 regarding the unintended consequences that may
21 result from these services and the overall
22 impact they may have on the population and
23 health in Tennessee."
24 One other point I want to
25 make -- it relates to the presentation they

1 just made to the Agency -- is that, in the
2 application, it says repeatedly "We're not
3 gonna be Medicare certified," but yet part of
4 the discussion this morning has been how they
5 serve Medicare patients. That, to us, doesn't
6 really -- the two statements are not
7 reconcilable, and it certainly needs to be
8 something that's taken into account by the
9 Agency.
10 We submit that we have presented
11 numerous reasons why this application should
12 be denied. It hasn't -- it does not meet the
13 criteria. But, in any event, Commissioner
14 Dreyzehner's letter alone is really a reason
15 for the Agency to deny this application, and
16 we urge you to do so.
17 MR. JOHNSON: Were there others,
18 Mr. Elrod, or is that it, in terms of the
19 opposition?
20 MS. WEIR: Hi. My name is
21 Scarlett Weir, and I work with a company
22 called ContinuumRx Home Infusion. We have a
23 joint venture with Saint Thomas Hospital and
24 we service all of those patients, and [we]
25 work very closely with NHC to provide the

1 whole continuum of care for patients. So we
2 are greatly concerned. We do provide
3 medications for patients going out of the
4 hospital, be it IV antibiotics, IgG, or pain
5 medicine.
6 We have a very secure pharmacy.
7 It's very controlled. We work with the
8 hospitals and NHC to make sure that the
9 patient -- not only the medication, but the
10 whole service of care for the patient is
11 provided. And so we think this would be a
12 very bad idea. Thank you.
13 MR. JOHNSON: Thank you.
14 Is that all?
15 MR. ELROD: (Nods head.)
16 MR. JOHNSON: All right. Now we
17 have rebuttal, up to five minutes.
18 MR. PUTRINO: My name is Roy
19 Putrino. I'd like to go over a few of the
20 points. First of all, addressing the Medicare
21 issue. Medicare does not cover home infusion,
22 so it doesn't cover any, but we try to address
23 it. So at this point, you know, saying that
24 we're not a certified agency really doesn't
25 make a difference at this point. So what

1 we're looking at here is finding a pathway for
2 these people so that they're not ostracized
3 from this therapy.
4 As far as the therapy not being
5 efficient, you know, you just have to see a
6 multiple sclerosis person who is rolled up in
7 a pretzel get this pump, and then your mind
8 will change and they are able to start caring
9 for themselves again and move back into
10 society.
11 What basically brings -- what
12 IPM brings to the table here is something
13 bigger than that though. We have a national
14 network. If this person travels anywhere in
15 the country, there will be an IPM nurse to
16 care for them. Whether they go to Orlando or
17 Alaska or anywhere in the country, we will be
18 there for them.
19 When you go into an emergency
20 room with a problem with this pump -- and you
21 have over 200 here in Tennessee -- there will
22 be no programer there and there will probably
23 be no person that will be able to handle it.
24 This is why national -- major insurance
25 companies sign national contracts with us. We

1 are out there protecting these patients.
2 In the hospital setting, the
3 patient has to be -- has to travel there.
4 Every time there is an issue, they have to get
5 an ambulette or have a family member to bring
6 them there. We can settle 90 to 95 percent of
7 the issues, through our monitoring center,
8 with a simple dispatching of a nurse. It has
9 been effective for over 14 years, and we have
10 been brought all over the country, word of
11 mouth from physicians who have had excellent
12 experiences.
13 And I see the problem where he's
14 saying that the results haven't been good, but
15 our outcomes from the home care piece far
16 exceed those. We have people with reduced or
17 eliminating oral medications, and by not
18 getting the tremendous pronounced side effects
19 from some of these drugs, the patient's
20 quality of life has gone, you know, much
21 higher. Let's remember there's no cure for
22 these things. We can only look at the quality
23 of life. Thank you.
24 MS. HESS: My name is Melissa
25 Hess. I was hoping to address some of the

1 concerns from the gentleman, and the woman
2 from ContinuumRx Infusion. I understand the
3 concern that they're worried that these
4 patients are medically complex and that we're
5 there to do one thing. I think I wanted to
6 clarify in my presentation -- I'm not sure if
7 I came across efficiently in explaining that
8 we are there to do a full nursing assessment.
9 We are not going to disregard a wound and we
10 are not going to disregard signs and symptoms
11 of a urinary tract infection, but our model
12 does not do that ourselves. We assist -- we
13 use the physician. We call the physician and
14 say, "This individual has X, Y, and Z. How do
15 you want us to follow up? Do you want to come
16 see them? We think that they may have a
17 urinary tract infection," for example.
18 So the idea for us being
19 there -- we do the pump because it's very
20 specific, but we always look at the whole
21 patient. And I think nursing always looks at
22 the whole patient. I think to go in and look
23 at only the pump and not do a full nursing
24 assessment would be negligence in nursing.
25 The idea that we're there to look at every

1 aspect of the patient -- it's always very
2 important. It's just that IPM does not
3 service every aspect of the patient.
4 So I hope that clarifies what I
5 had presented before or that that makes better
6 sense, but our model is to identify any
7 abnormal findings, alert the physician, and
8 the physician will use -- if there's other
9 skilled services required for this individual,
10 the physician will use the existing licensed
11 home health agencies for those additional
12 skilled services. Our skilled services will
13 only be specific to that intrathecal pump. I
14 hope that clarifies that.
15 And I understand the concern
16 that the model is different. And it is
17 different from a lot of other home care models
18 and medical models. But the fact that these
19 pumps are delivering high doses of morphine,
20 high doses of Dilaudid, very high
21 concentrations of Lioresal, there is no room
22 for error. So as a nurse -- and I think I'm a
23 pretty good nurse. But for me to go in a home
24 care setting to do an IV IgG or to go do a
25 wound care, and then to do a pump, my focus

1 isn't going to be on that pump. And if the
2 focus isn't primarily on this intrathecal
3 pump, errors are going to occur.
4 So the focus is created on the
5 intrathecal pump to reduce and -- I can't say
6 eliminate, but to greatly reduce that error.
7 So I hope that clarifies, also, that model.
8 And ContinuumRx Infusion, the
9 idea of them being a very strong pharmacy I'm
10 sure is very true, but do they provide
11 intrathecal medications. When you look at
12 narcotics, it doesn't -- the intrathecal
13 medications are so different than oral
14 narcotics. So I think we have to look at the
15 distinction between the intrathecal pump and
16 the rest of the care that the individuals have
17 and require. Thank you.
18 MR. JOHNSON: Okay. Thank you.
19 Okay. Applicant 2's
20 presentation -- I have it listed as Doug Wynd
21 who is going to do that. And we'll go through
22 the same procedure for you as we did for the
23 first one, and then we will get into questions
24 by the members.
25 MR. WYND: Yes. Thank you.

1 Actually, my name is Doug "Wynd," like you
2 "wind" a clock, but 90 percent of the people
3 guess "Wind" and I live with that. So no
4 offense taken. I also have with me three
5 other people from Pentec Health. I, myself --
6 I am the national sales director with Pentec.
7 MR. JOHNSON: Before you go --
8 are there others that plan to speak as well,
9 in support --
10 MR. WYND: Yes, sir.
11 MR. JOHNSON: -- that either are
12 a part of it or those that are not a part of
13 the application?
14 MR. WYND: Yes, sir.
15 MR. JOHNSON: Both?
16 MR. WYND: Not -- the people
17 that are planning on speaking in favor are
18 part of the application.
19 MR. JOHNSON: [They're] with
20 you?
21 MR. WYND: Yes.
22 MR. JOHNSON: Okay. Please
23 continue.
24 MR. WYND: So I have three other
25 people from my company with me. I have

1 Michelle Hiidel. Michelle is the regional
2 nurse manager. She will be responsible for
3 home health care here in Tennessee if we get
4 the privilege to work here. She is a
5 registered nurse. She's also licensed as a
6 nurse here in Tennessee herself. I have Chip
7 Slavin. Chip is a 15-year pharmacy --
8 pharmacist with Pentec Health. And he can
9 answer and address any of the pharmacy
10 questions that may come up. And then I have
11 Amy Toresco, who is an account executive on
12 our IVIG side of our business that's part of
13 that application as well. So they'll be here
14 to address any questions that may come up in
15 the process.
16 But we as a company are thrilled
17 to be here in Tennessee before you asking for
18 approval in the CON process. We have had
19 referrals come in to our company -- four
20 patients that are living here in Tennessee --
21 and unfortunately we've had to refuse those
22 referrals because we are not licensed to be
23 here, and they have found sometimes other
24 companies who would be able to take care of
25 those pumps, but that's outside of our

1 regulatory approval.
2 Ms. Hess did a good job of
3 talking about the therapy itself. I want to
4 talk specifically about the pump. This is the
5 pump that both companies are talking about
6 (indicating). You can see that it's about the
7 size of a hockey puck, and it's a very
8 complicated machine. There's a reservoir in
9 here. This pump is implanted in the patient,
10 and a catheter is run up through the spinal
11 cord in the intrathecal space of the spinal
12 cord, and then the pump continuously pushes
13 out highly concentrated narcotics or
14 antispasticity medication to provide the
15 relief to a patient.
16 The target for this pump is
17 about the size of your button -- I don't know
18 how many of you have a cell phone. The button
19 on your cell phone is about the target size of
20 this pump. And, again, it's implanted under
21 layers of skin and muscle and fat, and it's a
22 very difficult site to access. Every patient
23 that has one of these pumps -- and there's
24 about 80,000 of these pumps in patients across
25 the country. Every patient who has one of

1 these pumps is committed for the rest of their
2 life or until this pump is removed to
3 continually get this pump refilled.
4 By and large, those refills
5 happen in the physician's office, and he or
6 she will refill the pump themselves, or their
7 staff will, but as demonstrated -- and as you
8 can appreciate -- these patients are either
9 wheelchair bound or in severe pain or have to
10 travel great distances to their physician to
11 get their pump refilled. And that creates a
12 burden upon society that Pentec Health can
13 alleviate. We can go make house calls to the
14 patients and refill the pumps there.
15 If a pump runs dry -- if it's a
16 pain pump, those patients will go into
17 withdrawal, which is a miserable experience,
18 as you can appreciate. If the patient is
19 being treated for spasticity and the pump runs
20 dry and they no longer get their
21 antispasticity medicine, that can be
22 potentially fatal.
23 So, again, the patients are
24 committed to getting these pumps refilled.
25 Whether we do it in the home or the patients

1 are forced to go back to their physician's
2 office, the pumps will get refilled. If it's
3 filled improperly -- again, the target is very
4 small. If it's filled improperly and highly
5 concentrated narcotics are shot into the body
6 outside of the pump -- that's called a "pocket
7 fill" in the industry, and that is also
8 potentially fatal. You get highly
9 concentrated narcotics that can shut down the
10 respiratory system and a patient could expire.
11 So it's a very risky procedure,
12 a very specialized procedure, and one that
13 most home health care agencies, as Ms. Hess
14 stated, too, they certainly -- a lot of times
15 they aren't even aware that these pumps exist,
16 and if they are aware of them, they really
17 don't want to touch them, because it is a very
18 high-risk procedure and one that, if you're
19 going to do this procedure, you really need
20 the expertise to do that.
21 So that's the pump (indicating),
22 and let me speak to our expertise and why
23 Pentec Health would be a good person to allow
24 into the state.
25 MR. JOHNSON: Let me just

1 interrupt you a second.
2 MR. WYND: Yes, sir.
3 MR. JOHNSON: You have a
4 ten-minute presentation, which includes your
5 other folks, so . . .
6 MR. WYND: Yeah. And, actually,
7 they're here to address questions. They're
8 not part of this initial salvo, so this is me
9 and the salvo.
10 MR. JOHNSON: Okay. You're it.
11 All right.
12 MR. WYND: Yeah. But I
13 appreciate that. So Pentec has been in the
14 business for about 30 years. We are the
15 largest provider of home health care service
16 in the intrathecal pump space. We have about
17 2,800 patients on service across the country.
18 We are appropriately licensed in 30 states.
19 We are not licensed here in Tennessee, and we
20 are not seeing any patients here actively in
21 Tennessee. We've been referred patients but
22 have turned them away.
23 Our nurses -- the training for
24 our nurses is second to none. The nurses that
25 we hire oftentimes have expertise in critical

1 care before coming to us. Oftentimes, they
2 have experience filling pumps in a physician
3 office. They come to us and regardless of
4 their training and past experience, we put
5 them through a rigorous three-month training
6 program. That is the only training program
7 that's ANCC accredited. "ANCC" is the
8 American Nursing Credentialing Council. They
9 accredit our training programs, so our nurses
10 come out knowing stuff.
11 In fact, we hired two nurses
12 that came from Medtronic, the manufacturer of
13 this pump, and their previous job was to
14 instruct people how to fill the pump. They
15 went through the training program and at the
16 end, they said, you know, that they learned
17 things that they probably should have known
18 and definitely wished they would have known
19 when they were teaching other people how to
20 deal with these pumps. So our nurses are
21 second to none, in terms of their experience
22 and their training, and we'd be thrilled to be
23 here.
24 Our pharmacy -- we're held to
25 the very high standards of a 797-compliant

1 pharmacy. Now, oftentimes, your compounding
2 pharmacies at a local level may not reach the
3 797 standards. It's just -- they're higher
4 standards than normal non-high-risk
5 compounding, or low risk or moderate risk.
6 797 guidelines are pretty strict, and we
7 certainly meet those and exceed those in doing
8 some proprietary things in our pharmacy that
9 kind of set us apart in the market space.
10 But the last thing I'll touch on
11 is the insurance piece. And it was spoken to
12 in the previous presentation about really the
13 orderly development of health care and whether
14 or not a company will provide service to
15 TennCare patients or Medicare patients. In
16 our application, throughout -- if you've
17 read it -- it talks [about] and describes our
18 philosophy about that and our willingness to
19 take not only TennCare patients, but also
20 Medicare patients across the country.
21 Again, we're not in Tennessee so
22 we don't have TennCare-specific patients, but
23 other states who have TennCare-like insurance
24 coverage for patients, we do accept those
25 patients on a compassionate care basis. We

1 also accept Medicare patients who may -- you
2 know, as a federal program, Medicare does not
3 cover the home visits of our nurse, so that --
4 we don't get fully paid for that. So we will
5 provide that on our nickel. We'll go and take
6 care of those patients, because it's the right
7 thing to do.
8 My national book of business --
9 about half of my business are patients that do
10 not fully pay us. And those are patients
11 that -- elsewhere, outside of Tennessee, other
12 companies are not taking those patients, and
13 we fill that need. And we'll take those
14 patients, because those patients are in great
15 need too. Depending on whether or not they
16 have insurance is really irrelevant to most
17 people in the company. I manage that. From a
18 business perspective, I've got to make sure
19 that we can't just, you know, have all people
20 who aren't paying us. It's a business that I
21 run, but it's something that -- again, half of
22 my business is not patients who fully pay.
23 And that was, I think, a clear difference in
24 the applications before you.
25 The last thing I'll state is

1 that -- and we don't have anybody here to
2 support us in person. Like I say, we've got
3 2,800 patients across the country. Every
4 year, we survey the patients. We ask them for
5 their feedback and ask them if there's
6 anything that we can do better. And we get
7 volumes of information where patients will
8 give us feedback on how thrilled they are with
9 what we do. And anything they're not thrilled
10 about, we delve into that and fix it.
11 But one thing that came through
12 from a patient -- she had volumes to say about
13 her nurse that she couldn't fit in the small
14 space that we gave her, so she wrote a letter.
15 And I'll just read two paragraphs (as read):
16 "Technically, Connie" -- who is the nurse --
17 "is a godsend. Having a needle inserted in my
18 abdomen and finding where it has to fit" -- or
19 "go to fit into the pump is not a pleasant
20 process. Connie can put that needle into me,
21 and I don't even feel it. I compare it to the
22 times when somebody at the doctor and somebody
23 else has hurt me with the needle and had to go
24 fishing to find the right spot on the pump."
25 Again, if you're looking for that little bitty

1 thing -- you're in there and you start fishing
2 around until you get in. That is a painful
3 process, I can imagine.
4 (As read) "It may not seem like
5 a big deal to you, but it's a huge thing to
6 me. I'm already in so much pain that every
7 little thing that avoids pain means everything
8 to me."
9 And then she goes on to say that
10 she was in the process of changing
11 medications, which is often a laborious
12 process, where you have regular visits by a
13 nurse to check or most likely the patient will
14 have to go to the physician office to adjust
15 the medication and adjust the response. It's
16 a -- and they keep a diary through the whole
17 process, and she said that our nurse was
18 willing to go make those house calls regularly
19 and volunteered to do so, even though it was a
20 three-hour round trip to go take care of that
21 patient.
22 And that patient, who had
23 glowing comments and a glowing response, it
24 really changed her life or at least that
25 aspect of her life in a medical situation that

1 none of us want to trade places with. That
2 was a patient that was not a full-paying
3 patient for us. That was a patient that was
4 on my dime. That was something that -- that
5 was a patient -- not knowing the rest of the
6 story that would happen, but that was a
7 patient that elsewhere would not have been
8 treated. And if there are other patients in
9 Tennessee like that, they're not gonna be
10 dismissed out of hand by our company. It'll
11 be with a full business-enterprise approach to
12 taking on those patients.
13 So that, I think, is the end of
14 my time, and we'll go to the next step. Thank
15 you, sir.
16 MR. JOHNSON: Okay. Mr. Elrod?
17 MS. NELLEY: Rachel Nelley here,
18 on behalf of the applicant who opposes
19 Pentec's competing application. I wanted to
20 bring to your attention -- I'm not sure that
21 your materials included a warning letter from
22 the FDA with respect to Pentec. And,
23 basically -- let's see. The warning letter
24 was dated March 7th, 2014. You know, during
25 their presentation, they indicated they were a

1 979 pharmacy, subject to high standards.
2 Well, basically, the FDA
3 inspection of the pharmacy, between March
4 18th, 2013 and April 1st, 2013, found -- and I
5 quote -- "serious deficiencies in practices
6 for producing drug products that were intended
7 or expected to be sterile, which put patients
8 at risk," unquote. 163 units of product had
9 to be recalled. Their products -- I mean,
10 their products were produced in an environment
11 found to have significant contamination risks.
12 There were adulterated products, again, that
13 had been recalled.
14 They took corrective action in
15 response to the initial letter from the FDA,
16 but -- and I quote from this letter (as read):
17 "We acknowledge your action on May 15th, 2013,
18 to recall all sterile products that were
19 intended or expected to be sterile, with an
20 expiry [verbatim], that were produced in a
21 certain hood. Your planned corrections do not
22 appear to be sufficient to remedy the
23 insanitary conditions at your firm." And the
24 FDA strongly recommended (as read) "that your
25 management immediately undertake a

1 comprehensive assessment of operations,
2 including facility design, procedures,
3 personnel, processes, materials, and systems.
4 In particular, the review should assess your
5 aseptic processing operations."
6 And I think we're all, here in
7 Tennessee, very aware of what can happen when
8 an out-of-state compounding pharmacy is used
9 and it's producing and sending to Tennessee,
10 for use in Tennessee patients, unsterile
11 products. We've seen what this -- what a
12 disaster can happen with a situation like
13 this.
14 Again, I don't think this --
15 this letter is very lengthy. And I don't
16 think it was included with your materials
17 today, but I'm happy to go through, in
18 additional detail, the findings enunciated in
19 the letter, if you want me to. Thank you.
20 MR. CHRISTOFFERSEN: May I make
21 a comment, Mr. Chair?
22 MR. JOHNSON: Sure.
23 MR. CHRISTOFFERSEN: Ms. Nelley,
24 do you have copies to submit to the Agency,
25 for the record?

1 MS. NELLEY: I have "a" copy
2 that I can submit to the Agency, for the
3 record, and I'd be happy to.
4 MR. CHRISTOFFERSEN: Okay.
5 Well, if you wish to, whenever you're ready
6 to, Mr. Ausbrooks would be the one to receive
7 it.
8 MS. NELLEY: Okay.
9 MR. CHRISTOFFERSEN: Thank you.
10 MR. JOHNSON: Mr. Elrod, for the
11 remaining time?
12 MR. ELROD: Thank you,
13 Mr. Chairman and members of the Agency. Dan
14 Elrod again, on behalf of NHC HomeCare. This
15 application has really the same deficiencies
16 as the IPM application, and maybe even some
17 more.
18 Again, no need has been
19 established. It has not documented the
20 failure of any patient to get this service.
21 In fact, in their presentation, they've said
22 when they've gotten referrals now, because
23 they can't do business here, those patients
24 have gotten the service elsewhere. So
25 patients are getting this service mainly from

1 a physician's office, and that's the model
2 for -- in which this service is now being
3 delivered. And we submit, based on
4 Mr. Dreyzehner's letter and the concerns he
5 raises, that that remains the best option for
6 these patients.
7 But if, in fact, there does need
8 to be a home solution for this, it needs to be
9 for a home care agency who is going to address
10 all of the patient's needs, not just this
11 narrow part of the patient's needs. And,
12 again, this application suffers from that same
13 problem with a fragmentation of care. They
14 clearly state that they're only gonna
15 deal with the intrathecal pump, and if the
16 patient has other problems, they'll just send
17 them to another provider. That's not a good
18 model of care.
19 And with regard to how they have
20 handled Medicare patients -- just to put this
21 into perspective, Pentec is a pharmacy; it's a
22 compounding pharmacy. They get paid for the
23 pharmaceutical part of this, even if they
24 don't get paid for the nursing part of it, so
25 it's to their economic benefit to sell as many

1 pharmaceuticals as possible. And so the
2 easier they make that to get to the patients,
3 then they still come out okay, in terms of the
4 finances of it.
5 It's not even a machinary
6 (phonetic) undertaking on their part to
7 provide the pump management for Medicare
8 patients without getting paid. There is a
9 payment mechanism for that.
10 Finally, there's another
11 financial aspect of their application that's
12 frankly just mystifying. They propose to
13 charge $71 for a nurse's visit and a so-called
14 per diem charge of $1,775. And they never
15 really explained what that per diem charge is
16 for. They indicate that patients are going to
17 be seen six times a year, so the total patient
18 charges would be $11,076.
19 The IPM application says they
20 gonna charge $200 for a nursing visit, and
21 each patient is seen an average of 12 times a
22 year, so a total of $2,400 per year. And the
23 fact that Pentec's per patient charge is
24 projected to be four-and-a-half times that of
25 what IPM charges create -- I don't know. It's

1 inexplicably, frankly, in terms of why there's
2 such a great disparity.
3 But all of that, frankly, we
4 would suggest, undermines any idea that this
5 is more cost-effective than the alternatives,
6 which really are two: One, the physician's
7 office and where the physician sees these
8 patients on a face-to-face basis when they're
9 getting this highly technical situation for a
10 patient who is very sick and has
11 comorbidities, and if that needs to be
12 supplemented with being seen at home, then it
13 needs to be done by a home health agency who
14 can take care of all of the patient's needs.
15 Commissioner Dreyzehner's letter
16 applies to this application just as much as it
17 did the first one, and that alone really, we
18 would suggest, again, would require that this
19 application be denied. Thank you.
20 MR. JOHNSON: Thank you.
21 Rebuttal up to five minutes,
22 Mr. Wynd, or a substitute.
23 MR. SLAVIN: Good afternoon. My
24 name is Cliff Slavin. I am the pharmacy
25 manager for Pentec Health in Boothwyn,

1 Pennsylvania. I'm also a licensed pharmacist
2 here, and I want to address the 483 findings
3 that we had a few years ago.
4 We were inspected by the FDA in
5 response to what happened with NECC. They
6 inspected us as though we were a
7 CGMP-compliant pharmacy -- or facility, as
8 though we were Merck or AstraZeneca or a
9 rather large manufacturer, which we are not.
10 We are not designed -- we were not set up to
11 do large repetitive compounding of
12 multiple-ingredient identical products.
13 So when they came in and
14 inspected us, they were sort of looking at
15 us -- it was an apples and oranges kind of
16 thing. Regardless, in all respect to their
17 findings, we did take them seriously and we
18 made serious progress in terms of what we've
19 done for corrective measures. The first thing
20 is being a -- establishing a quality unit. We
21 have our own microbiologist on staff; we have
22 our own in-process testing where we've done
23 initial qualifications, process
24 qualifications, ongoing qualifications of
25 everything that we do. So we did take it

1 seriously.
2 With regard to the product that
3 was recalled, when we went through, as part of
4 our routine maintenance annual -- I'm sorry --
5 biannual surveys of our hoods, we found that
6 we had a laminar flow hood that was leaking
7 outside of the cabinet. It was not in
8 anything that could have affected the
9 sterility of the product; however, the piece
10 of equipment was out of specifications by the
11 manufacturer. The responsible thing to do was
12 to recall the product that was just made in
13 that particular hood.
14 That's all I have to add to that
15 at this point.
16 MR. WYND: Thanks, Cliff. And
17 I'll add just one thing about the product that
18 was recalled. There was 163 units that were
19 recalled with the -- because we didn't know if
20 there was contamination in the product --
21 MS. HILL: Sir, can you state
22 your name, please.
23 MR. WYND: Oh, I'm sorry. Doug
24 Wynd again. So sorry.
25 Those products were recalled,

1 and we replaced the products on a different
2 side of our business, at the renal side; renal
3 division. Patients received replacement
4 product, and no patient lost a dose because of
5 this recall. The products that were recalled
6 were put on a shelf to see if we could grow
7 out a contamination, and no contamination was
8 drawn out from those products that we
9 recalled.
10 So we recalled it because we
11 weren't sure. And we sat it on a shelf, and
12 we did not grow out anything that would cause
13 patient harm, even if it was given to a
14 patient, and no patient was at risk for that
15 issue. And Cliff gave the explanation, as a
16 pharmacist, when the issue is brought up by
17 our competition in the marketplace, we explain
18 exactly what happened, and our customers
19 understand the lingo and they get the fact
20 that our pharmacy is above the standards and
21 they get the whole process and, in fact, will
22 deepen their relationship with Pentec because
23 of the issues being raised and being addressed
24 by us.
25 In terms of the concerns by

1 NEC -- or NHC, in terms of the need, when I
2 did say that the patients were referred to us
3 and we couldn't fill them and service them,
4 they were seen by another company, but it was
5 Roy's company with Basic Home Infusion. So
6 Basic Home Infusion is operating here in your
7 state without your agency's approval, without
8 licensure, and that's something that we
9 wouldn't do. We had the opportunity to and we
10 said we're not going to do it, and then those
11 patients found another home.
12 Other examples where patients
13 were on vacation seeing a daughter here in
14 East Tennessee, their pump was alarming and
15 needed to be refilled, we had to say we
16 couldn't fill that patient because we weren't
17 licensed in Tennessee. And there were other
18 patients who were cancer pain patients being
19 treated in Georgia that were residents of
20 Tennessee, asking us to take care of them when
21 they got home from -- after getting their pump
22 implanted, and we had to refuse those
23 patients. I don't think those patients have
24 found somebody to go to the home, but we would
25 love to be that service provider.

1 In terms of the narrow part of
2 the needs and this being pump-refill specific
3 instead of, you know, why not let a home
4 health agency that can do everything do this
5 instead of just the pump -- and I'll use this
6 analogy: The interventional pain medicine
7 offices that we call on, the nurses who refill
8 the pump oftentimes do the pump refill, and
9 they might do it every week, and they're
10 scared to death to do that. And that's part
11 of their job.
12 So they're an interventional
13 pain medicine office nurse and they do all
14 kinds of things that are done in
15 interventional pain medicine offices, but they
16 are intimidated by the risks associated with
17 filling this pump and being wrong in doing
18 that. So to suggest that somebody who doesn't
19 have the interventional pain management focus
20 could be kind of an all -- you know, a handy
21 man to do everything is, I think, outside of
22 the understanding of the risks that are
23 associated with this pump.
24 And, frankly, that's probably
25 why, when we interview the home health

1 agencies and ask them if you're taking care of
2 any patients who have intrathecal pumps, they
3 oftentimes don't know what intrathecal pumps
4 are, because a physician, frankly, isn't going
5 to refer out the treatment of this pump -- or
6 the refill of this pump and the management of
7 this pump without knowing we have the
8 expertise.
9 Again, there's 80,000 patients
10 who have these pumps, and they're being
11 refilled regularly. And the entire market of
12 our industry, there's about 5,000 patients
13 being seen in the home. The other 75,000 are
14 being treated by his or her physician because
15 that's the -- you know, that's the only option
16 they have. So we can go in there and meet
17 that need.
18 And then, finally, from an
19 economic model perspective, it was suggested
20 that, you know, why our costs, in terms of the
21 per diem and the overall cost to a payor is so
22 much higher than what IPM is suggesting. What
23 was left out of the IPM presentation is that
24 Basic Home Infusion -- you know, Roy's other
25 company -- would be charging all those other

1 fees. They would be charging the per diem fee
2 that was discussed, an average of $1,700
3 dollars or so, and all the other fees.
4 There are four main components
5 to the fee collection schedule in this market.
6 There's the medication, so we can make a
7 margin on the medication, but if that's all
8 the money we're making, we are losing money in
9 providing this service and having our
10 full-time nurses go to the patient's home and
11 provide the service to them and make those
12 house calls. That is a losing endeavor for
13 us, but we are making money on the medication.
14 But we would not stay in business if that's
15 all we were doing.
16 The second component is the
17 materials affiliated with the refill. There's
18 the nursing time that can be billed
19 separately, and then there's this per diem
20 that encompasses everything from our
21 electronic medical records, to our ability to
22 do telepathic medicine, to our ability to do
23 drug utilization reviews, to having our
24 pharmacies review the very complicated
25 formulations that are oftentimes required with

1 these patients, to everything else that we do
2 at the back end that's kind of all
3 encompassing the management of this patient.
4 Those fees are negotiated
5 between a company like Pentec and the
6 insurance company. And we tell them what we
7 do, and they tell us what it's worth to them,
8 and we talk about where we meet in the middle,
9 and that's the value that they place on our
10 service to provide this service to their
11 patients.
12 So I'm sensing that, I think,
13 that was over five minutes in total, but I
14 hope that addresses the questions.
15 MR. JOHNSON: We can deal with
16 that collectively.
17 So questions by the members of
18 either applicant or their folks?
19 MS. HESS: Excuse me. I'm not
20 sure if this is out of order and just let me
21 know if this is --
22 MR. JOHNSON: I can't hear you.
23 MS. HESS: I'm sorry.
24 MR. AUSBROOKS: State your name.
25 MS. HESS: Melissa Hess. I'm

1 not sure if this is out of order. I was
2 hoping to address something that Mr. Wynd had
3 brought up, actually, I think, in his
4 rebuttal, but it was a direct -- of impact to
5 Implanted Pump Management and the owner of the
6 company, Roy Putrino. Is that something I can
7 address now, sir?
8 MR. JOHNSON: I think we'll do
9 it through the questions and answers.
10 MS. HESS: Okay. Great.
11 Thanks.
12 MR. JOHNSON: Questions by the
13 members? Ms. Jordan.
14 MS. JORDAN: I'll start with
15 Ms. Hess. Obviously, the question of need is
16 something that we have to be satisfied that
17 there is a need that exists. And that's true
18 for both applications. I'm concerned that the
19 application did not include more specifics
20 about patients who currently have these pumps
21 but are unable to receive this service in
22 their home.
23 MS. AUSBROOKS: Ms. Jordan,
24 speak into the microphone.
25 MS. JORDAN: Oh, I apologize.

1 Tell me why we don't have more information
2 either from patients who haven't been able to
3 obtain this service or --
4 (Microphone turned on.)
5 MS. JORDAN: Okay. Can you hear
6 me now? All right. Why don't we have more
7 specifics in the application, either from
8 patients or from doctors who are using these
9 pumps that this is an unmet need?
10 MS. HESS: Melissa Hess. That's
11 very good question and one that I think I can
12 pretty adequately address for you. One of the
13 main reasons that we don't have even a lot of
14 the pump numbers for the volume of Tennessee
15 is that the numbers are very proprietary to
16 Medtronic. Medtronic is actually the number
17 one pump manufacturer. I think it was
18 Mr. Wynd had said that there was approximately
19 80,000 pumps in the U.S.; intrathecal pumps.
20 I think Mr. Wynd would also probably agree
21 that the majority of them are made by
22 Medtronic; is that correct? And Medtronic is
23 a huge corporation, and that information is
24 very proprietary to Medtronic.
25 So we actually did go to

1 Medtronic to ask them specifically how many
2 individuals in the state of Tennessee; can you
3 give me specifics regarding counties. And
4 that was information that they were not
5 willing to provide to us, for that reason.
6 They felt it was proprietary and that it would
7 allow their competitors to have information
8 that could potentially damage them.
9 As far as the patients not
10 knowing about the service, I think that's
11 really, Ms. Jordan, a lot of times what
12 happens. The patients don't often know that
13 another model, the home care model, is
14 available. Through my experience, they said,
15 I've been going to the doctor for six years,
16 and I didn't even know you could do this in
17 the home. So a lot of the individuals -- and
18 I would assume that that's the way in
19 Tennessee -- they don't know that this is an
20 option.
21 So to answer the other part of
22 your question, we have had a lot of interest
23 from physicians regarding -- when we go to
24 different conferences, they say: "Well, why
25 aren't you in Tennessee? I have a whole bunch

1 of patients. I could really use your service.
2 Right now, I have five that I'm thinking of
3 that have to take an ambulette in to my office
4 to get filled. It just shouldn't have to be
5 like that."
6 So that's really how we compiled
7 some of our data, but it's just -- it's not
8 hard-and-fast data that I was able to provide
9 you. I'm not sure if that answers your
10 question.
11 MS. JORDAN: Well, I guess if
12 there are doctors that have expressed that
13 interest, I don't understand why you couldn't
14 have gotten those doctors to write a letter
15 saying: I have five patients that would be
16 better served in their home.
17 MS. HESS: That probably would
18 have been a better way. You know, if I had
19 gone through the experience again, I can see
20 where that would have been a better effective
21 tool to provide you to show more of a need. I
22 was actually scrambling at the end of it. I
23 had worked on the application myself, and I,
24 you know, was just struggling to get all of
25 the information together. So, you're right,

1 that would have been a better way to present
2 it to the committee to show that need.
3 MS. JORDAN: Okay. Another
4 question: Help me understand -- I believe
5 your application says that you project 120
6 patients the first year.
7 MS. HESS: That's correct.
8 MS. JORDAN: But yet the
9 application indicates that there would only be
10 one RN in the first year -- but you're going
11 to be serving patients on a statewide basis --
12 and each patient would be seen once per month.
13 I don't understand how one nurse could serve
14 that many patients per month on a statewide
15 basis.
16 MS. HESS: You're right.
17 There's actually another place in the
18 application where it talks about patient
19 caseload. And, ultimately, when we get our --
20 our goal would ultimately be 120 patients with
21 a projected volume of around two to three
22 hundred patients in the state of Tennessee.
23 Not all of those individuals are gonna be a
24 good fit for home care. There are gonna be
25 some that don't want to use home care. There

1 are gonna be some physicians that don't want
2 to use the model. You know, not every
3 physician that works with these intrathecal
4 pumps would be willing to give all of their
5 patients over to a home care model. So that's
6 why our goal would be 120.
7 Our goal after the first year
8 would be to get 120, but I believe there's
9 also a part -- and I can pull the page up. I
10 don't have it in front of me, Ms. Jordan --
11 that talks about the census to RNs, and it
12 would be between 40 and 50 patients per RN,
13 based on demographics. For example, a lot of
14 times what we use is a catchment area of
15 between 120 and 180 miles, regarding the
16 nurse's home or central location. So those
17 patients -- any of those patients in that area
18 would really fall into that certain RN's
19 census.
20 So it's very feasible that if a
21 patient has to be seen, you know, once a month
22 or once every two months, for a nurse to do
23 that Monday through Friday, specifically if
24 they're very close geographically. The actual
25 visit takes approximately an hour or maybe an

1 hour and a half, depending on whether an
2 admission is being done, or if there's other
3 concerns that the patient might have, the more
4 education the patient might need on that day.
5 So it's very feasible for a
6 patient -- you know, a nurse, excuse me, to be
7 seeing a patient up to maybe three patients a
8 day and still have a pretty full day and get
9 all of those visits required on a weekly
10 basis.
11 MS. JORDAN: Okay. Thank you.
12 MS. HESS: You're welcome.
13 MS. JORDAN: I now have a
14 question for Mr. Wynd. And it's really the
15 same question that I just asked Ms. Hess. Why
16 don't we have more specifics in the
17 application about the need that you assert is
18 out there but is not being met?
19 MR. WYND: In terms of patients?
20 MR. AUSBROOKS: State your name.
21 MR. WYND: Oh, I'm sorry. Thank
22 you. I'm Doug Wynd, with Pentec.
23 In terms of patients stating "We
24 want this service"? Or more specifically --
25 MS. JORDAN: Both; both doctors

1 and patients.
2 MR. WYND: Yeah. So our -- so
3 we are not practicing here in Tennessee. So
4 what we find is that when we talk -- if we
5 go to a patient -- and we don't do this
6 anywhere in the country. We don't go to a
7 patient first and say, you know, "Ms. Jordan,
8 we have this great service. And if we could
9 see you in the home, would you be interested?"
10 Because that -- by and large, the patients
11 would love to have that service, but it also
12 requires a physician referral.
13 And your physician may not be
14 wanting us to do the referral -- or the
15 service in their home. The physicians make
16 money on refilling the patients in their
17 office. There's great risks associated with
18 refilling the pumps, and they -- you know,
19 I've discussed that already.
20 So there's a lot of reasons why
21 a physician wouldn't want our service, but
22 patients, by and large, definitely want our
23 service.
24 MS. JORDAN: So tell me, then,
25 if the physicians aren't going to refer, then

1 how are you going to get those patients?
2 MR. WYND: They will refer. And
3 not all of them, but a good number of them.
4 Like I said, there's about 80,000 pumps --
5 patients with pumps in the country, and the
6 industry to see them in their home has about
7 5,000 of those pumps. But to every single one
8 of those patients, that changes the outlook of
9 their day; of them living with their disease;
10 or the management of it.
11 Whatever it takes for them to
12 get from wherever they are, the transportation
13 to the office, waiting for a high-volume
14 office, you know, going through the procedure
15 can take, you know, an hour or two, and the
16 travel the roads back home. That whole part
17 of their living with the disease goes away.
18 So the patients -- the patients will do that.
19 MS. JORDAN: I understand that,
20 but why did doctors not write letters of
21 recommendation saying, as I asked Ms. Hess,
22 "I have five patients that would benefit from
23 this -- or ten patients -- that it would
24 improve their quality of life if they could
25 have this service in their home"?

1 MR. WYND: Right. My judgment
2 was that it would be best to have those
3 letters of recommendation come from Tennessee
4 physicians, and since I'm not here in the
5 market, I was not asking them -- I wasn't
6 knocking on their door explaining this service
7 to them. Because some physicians will say:
8 "I love this service. I want to do this
9 service. Where have you been all my life,"
10 and they'll want to refer patients over. And
11 since we weren't willing to take patients yet,
12 I didn't want those to go elsewhere.
13 Likewise, not knowing the
14 opinion of this committee and the agency -- or
15 the licensing procedure, I didn't want to
16 invest the resources to explain that the
17 service exists and get them excited, other
18 than what Dr. Muench did. When we met with
19 him here in Nashville -- Comprehensive Pain
20 Specialists -- he was very in favor of it and
21 is supportive of it, and if we get licensed
22 appropriately, he'd be happy to send patients
23 over.
24 MS. JORDAN: I noticed that in
25 2012 your company had a big write-off of

1 goodwill. Can you explain what brought that
2 about?
3 MR. WYND: Sure. Pentec, as a
4 company, has three divisions. A renal
5 products division -- and they basically take
6 care of end-stage renal disease patients who
7 are undergoing dialysis. And we provide a
8 nutritional supplementation to those patients
9 who are undergoing dialysis. So this
10 write-off was on the other side of the
11 company.
12 The Medicare reimbursement for
13 that line of business took about an 81 percent
14 decrease in the reimbursement for our products
15 overnight without notice. We thought it was a
16 mistake, and it was not. And it stunk. So we
17 had all the appropriate meetings, all the way
18 up to CMS, all the way up to the very top
19 levels, nationally, and had centers involved.
20 But at the end of the day, we
21 took about an 81 percent haircut on our
22 reimbursement on about 80 percent of our line
23 of business on the renal side. So that
24 significant write-off in 2012 was all about
25 our reimbursement from Medicare on a very

1 important line of our business.
2 MS. JORDAN: Thank you.
3 MR. WYND: Sure.
4 MS. JORDAN: One more question,
5 Mr. Chair.
6 MR. JOHNSON: Certainly.
7 MS. JORDAN: Mr. Elrod, can you
8 tell me if your client, NHC, has been
9 approached by any physicians for them to
10 provide this service in-home that they've had
11 to turn down?
12 MR. ELROD: This is Dan Elrod,
13 on behalf of NHC. I have actually asked that
14 question myself, and I've been told no, they
15 have not been approached by anybody about
16 providing this service.
17 MS. JORDAN: Thank you.
18 MR. JOHNSON: Other questions?
19 We've got two -- and I want to ask one as
20 well -- or three. Let me do mine first,
21 because there's been some discussion about the
22 Department of Public Health and the letter
23 they had written. So I don't know who, from
24 the Department, wants to address it, but you
25 expressed a number of concerns and those are

1 concerns that I think the members of the
2 Agency might have. And rather than ask
3 individual questions, perhaps you can do that
4 and then we'll ask questions of Health,
5 because it's unusual for us to get such a
6 letter, and so we want to give the Department
7 ample time to respond.
8 MS. BAYLES: Thank you. Good
9 morning. Julia Bayles, with Health Planning.
10 Jeff sends his apologies for not being able to
11 stay. He had a legislative meeting he needed
12 to attend.
13 We'd like to start by mentioning
14 the Tennessee Department of Health's mission
15 to protect, promote, and improve the health
16 and prosperity of the people in Tennessee.
17 And Commissioner Dreyzehner's letter sets out
18 the Department's concerns regarding the
19 unintended consequences that may result from
20 providing these services in the home. As it
21 has been pointed out, they are currently
22 provided in physician offices. But the
23 Department is concerned about the unintended
24 consequences that may result from providing
25 these services in the home, as well as the

1 overall impact it may have on population
2 health in Tennessee.
3 We do have representatives here
4 today from the Department of Health who will
5 state those concerns and can answer your more
6 specific questions. We have Libby Lund, from
7 the Board of Nursing; we have Jerry [sic]
8 Grinder, from the pharmacy board; we have Ann
9 Reed, from Health Facilities; and we have
10 Andrea Huddleston, who is the attorney for the
11 professional boards here today.
12 And so I will now let them come
13 and speak more directly to the points made in
14 the letter that deal with their expertise.
15 Would you like to start, Libby? Or Andrea?
16 Whoever would like to start. Andrea
17 Huddleston.
18 MS. HUDDLESTON: Good morning --
19 or afternoon. I'm not sure, actually. [I'm]
20 Andrea Huddleston, with the Office of General
21 Counsel for the Department of Health. I
22 supervise an office of attorneys, and we all
23 work with the various professional boards:
24 The Board of Medical Examiners, the Board of
25 Nursing, the Board of Pharmacy, et cetera.

1 And I know, as a group, we were all asked to
2 look at this application. There were lots of
3 things that piqued our interest, and it was an
4 unusual situation and did raise several
5 concerns.
6 You have the letter from
7 Dr. Dreyzehner in your materials, I believe.
8 One of the concerns -- and possibly the
9 biggest concern -- had to do with the drugs
10 that are going to be used in the intrathecal
11 pain management [and] how they're going to be
12 dispensed and distributed. So that was part
13 of the concern.
14 Generally speaking, there is
15 federal law -- and there's state law on this
16 as well -- that pharmacies are to dispense
17 directly to ultimate users; to the patients
18 themselves. And I don't know -- it was never
19 clear to us, I don't think -- and I don't know
20 that it's been addressed today -- if that's
21 what's going to happen. We have some
22 information that that's not the plan and
23 that's not the approach, at least from the IPM
24 entity and perhaps from both.
25 Our understanding is that these

1 drugs will be shipped to the nurses themselves
2 who will pick them up from Fed-Ex or some
3 entity like, keep them in their homes, and
4 then transport the drugs to the patients. We
5 have lots of concerns about that process. We
6 have concerns about the nurses. These are
7 dangerous drugs. These are drugs that end up
8 being stolen and diverted. They have a high
9 street value. And, again, we're not sure that
10 that's consistent with federal or state law.
11 If the plan is for the drugs to
12 be shipped directly to the patients
13 themselves, that, I think, would probably be a
14 preferable model; however, I think that might
15 then involve the pharmacies needing to be
16 licensed as manufacturers rather than
17 pharmacies. Dr. Grinder --
18 (Inaudible off-the-record
19 consultation between
20 Ms. Huddleston and unidentified
21 speaker.)
22 MS. HUDDLESTON: I understand
23 for them to ship it to the nurse, they would
24 have to be licensed as a manufacturer, which I
25 don't believe either of these entities are

1 right now. And, again, under any
2 circumstances, there are concerns about
3 diversion and safety in that situation.
4 We did not have available to us,
5 at the time, policies related to issues about
6 personnel training and oversight. We've heard
7 a little bit about that training, but it
8 doesn't sound like there's an extensive
9 training program. And I don't believe we've
10 heard anything about oversight, particularly
11 as regarding drug diversion and drug screening
12 for the nurses who will be perhaps
13 transporting these medications and injecting
14 them.
15 I do believe there has been some
16 discussion about which compounding pharmacies
17 will be used and whether they'll be out of
18 state. At least with the IPM entity, it's
19 understood that there will be an out-of-state
20 compounding pharmacy, in which case our Board
21 of Pharmacy inspectors -- they cannot travel
22 out of state to inspect those compounding
23 pharmacies.
24 You've already heard from
25 Mr. Elrod about the recent article and study

1 from the American College of Occupational and
2 Environmental Medicine that indicates that
3 these devices are really not recommended,
4 because there are questions about their
5 efficacy.
6 In addition, I believe you have
7 heard some comments about whether or not the
8 IPM entity has been operating without a
9 certificate of need and without a license for
10 some period. I don't know if they would care
11 to answer questions about how long they've
12 been practicing. I know there were questions
13 about numbers of patients and the need for
14 this service, and it seems to me, if they've
15 already been servicing patients, they probably
16 have additional information to provide in that
17 regard.
18 So, again, we have Libby Lund,
19 from the Board of Nursing, Ann Reed, from the
20 Board of Health Care Facilities, and Dr. Terry
21 Grinder, from the Board of Pharmacy if you
22 have any additional questions.
23 MR. JOHNSON: Well, there may be
24 some. We had -- let's see. Dr. Fleming had a
25 question, Ms. Burns, and Mr. Doolittle.

1 If you have one pertinent to the
2 Department of Health, why don't you ask it
3 now.
4 MR. DOOLITTLE: Yes, I do. The
5 Pentec applicant says that they have, if my
6 notes are correct, 2,800 patients in other
7 states in the United States. Presumably, they
8 are operating under whatever the regulatory
9 guidelines are of these several states. And I
10 don't think I have any information on that,
11 but in the course of your examination of this
12 application and in raising your concerns, do
13 you know of anybody in the Department of
14 Health that contacted other states where
15 either of these applicants provide services to
16 find out, you know, how things work, what the
17 protocols are, you know, regulatory issues, or
18 otherwise?
19 MS. HUDDLESTON: Andrea
20 Huddleston, with the Department of Health.
21 I'm told our -- the IPM application came
22 first, and that is the application that we
23 looked thoroughly at. I understand the Pentec
24 application came later. So we have not had
25 any conversations with any other licensing

1 entities across the country to see about
2 whether or not they're using similar models
3 and whether or not they believe those models
4 meet federal and state rules.
5 MR. DOOLITTLE: But as a general
6 point, I mean, in your examination of this
7 business segment, was there any working
8 knowledge of other jurisdictions that allow
9 this, and the pros and cons incurred in . . .
10 MS. HUDDLESTON: For the IPM
11 application, I know there were some
12 conversations with -- the Massachusetts Board
13 of Pharmacy, I believe?
14 UNIDENTIFIED SPEAKER: New
15 Jersey.
16 MS. HUDDLESTON: -- the New
17 Jersey Board of Pharmacy.
18 Dr. Grinder, can you address
19 those conversations?
20 DR. GRINDER: Terry Grinder. I
21 am a pharmacist and an investigator with the
22 Tennessee Board of Pharmacy. I have had
23 conversations with the New Jersey Board of
24 Pharmacy, as well as some different offices of
25 the DEA. And as far as the delivery process,

1 the DEA has issued a statement to me saying
2 that if they deliver to the nurses, then they
3 would have to be licensed as a manufacturer;
4 however, as a compounding pharmacy, they are
5 supposed to dispense to the patient.
6 Now, I was told that there was
7 an understanding in New Jersey with their
8 local DEA office that they viewed this model
9 as more beneficial to the patient, so it was
10 basically not enforced there.
11 MR. DOOLITTLE: Okay. Anything
12 else on any other jurisdictions? You know,
13 general research or otherwise.
14 DR. GRINDER: (Shakes head.)
15 MR. DOOLITTLE: Thank you very
16 much.
17 MR. JOHNSON: Dr. Fleming.
18 DR. FLEMING: Just to clarify,
19 while I really appreciate the commissioner's
20 letter about the issue of efficacy of the
21 pump, obviously, in 80,000 instances in the
22 country, the physicians felt that they were
23 efficacious, because they put them in. I
24 mean, so the question of efficacy is
25 debatable, depending on the patient's unique

1 situation and unique needs.
2 So as a physician, I just want
3 to throw out there that I appreciate their
4 opinions -- and maybe time will tell that they
5 aren't as helpful in the long-term as we think
6 they might be, but if you have one more
7 patient with chronic pain that doesn't have to
8 go to the doctor every month, that's not a
9 small deal, just to throw that out as a
10 commentary. And just from a federal oversight
11 standpoint, these are FDA-approved pumps.
12 They are FDA-approved for implantation into
13 patients for pain control. Correct?
14 DR. GRINDER: Yes.
15 MR. JOHNSON: Ms. Burns.
16 MS. BURNS: My questions will be
17 for Ms. Hess, please. Ms. Hess, can you
18 provide a brief overview of your training
19 program for the nurses? Pentec provided a
20 little bit more of an overview in their
21 application than you did in yours.
22 MS. HESS: Yes. Melissa Hess.
23 Yes, absolutely. I'd be happy to do that. We
24 use our training protocol based on Medtronic's
25 guidelines, because, I think as I spoke

1 before, Medtronic is the largest manufacturer
2 of the pumps. And the SynchroMed, which is
3 the Medtronic-manufactured pump really has the
4 lion's share of those 80,000 pumps throughout
5 the country.
6 So we really we emulate
7 Medtronic's training. We look at the pump
8 mechanics; we look at the patient; we look at
9 all the medications; we look at refills; we
10 look at programming. You know, everything
11 that we utilize to train is straight from
12 Medtronic. And the reason being is because
13 Medtronic made the pump. They have set the
14 guidelines; they had to seek FDA approval. So
15 there's no reason for us to change the
16 training as to how Medtronic has set it forth.
17 In addition to that, I have made
18 a lot of extra safety checks in addition to
19 what Medtronic has recommended in their
20 policies for the pump. For example, the
21 nurse, if they do any sort of programming
22 other than a simple change in reservoir, any
23 programming out of the norm, the nurse is
24 going to call the on-call nurse and review
25 that. Because the nurses are in the home by

1 themselves. You know, even though we're doing
2 a great thing in the home, we don't have a
3 nurse, as on a hospital floor, to check a
4 heparin drip. We don't have one to run
5 somebody a calculation by. But the model with
6 IPM does offer that. We offer nursing and
7 pharmacist's assistants at just via a phone
8 call.
9 So part of our training is to
10 really look at how else we can eliminate
11 potential errors. Because nurses are humans,
12 and we have -- we're gonna make mistakes. You
13 know, I can't stand here and, in good
14 conscious, say that I have never made an
15 error, but the safety checks that IPM has in
16 place really make it impossible to leave the
17 patient's house without identifying and being
18 able to fix the error.
19 For example, we have what's the
20 telemetry. It's a printed version of what the
21 nurse has done to that pump. Once they've
22 read it and if they've done any programming
23 and then updated the pump. Basically, the
24 pump doesn't do anything without us being
25 programmed [verbatim]. So it looks at flow

1 rate, calculations, and dosages and things
2 like that. It's a huge math equation is what
3 the intrathecal pump really, in essence, is.
4 So when the nurse is in there
5 doing any programming -- if they're making any
6 changes to the initial programming that was
7 initially read when the nurse got there and
8 read the pump, then what the nurse does is to
9 review, line by line by line, that telemetry.
10 And that sounds very simple, but for me to go
11 through every line -- and there's, I would
12 say, you know, 50 lines -- it's reviewed with
13 the patient or it's reviewed with the
14 caregiver if the patient isn't able to really
15 cognitively understand the review.
16 So as a last line before that
17 nurse walks out of that house, the IPM nurse
18 reviews every portion of that telemetry to
19 make sure it's perfect. And if, by a slim
20 chance, you know, the reservoir volume should
21 have been 19 and for some reason I push 17
22 because the lighting is dim, that's found
23 then. So we have that chance.
24 We also review all of the
25 medications with the patient. We look for

1 color, we look for clarity, we look for
2 concentration, we look for concentration, we
3 look for any sort of sediment. It's reviewed
4 with the pharmacy when the nurse gets to the
5 patient's home.
6 So we have a lot of actual
7 safety checks. And really what we teach our
8 nurses at the very end of it -- I'm not sure
9 if anyone is a nurse here -- as a nurse, if
10 there's anything -- any portion of you that
11 doesn't think something is right, they're
12 instructed to stop. And that sounds really
13 basic, but everything has to be perfect.
14 And I think I said it before:
15 There's no room for error with this therapy.
16 We're looking at a catheter -- I mean, an
17 access port, roughly, I'd say, usually, the
18 tip of a pencil head or a pencil eraser. So
19 everything has to be exactly the way it should
20 be expected, and if it's not, the nurses stop.
21 MS. BURNS: So what is the
22 length of your training before you actually --
23 MS. HESS: The length of --
24 MS. BURNS: -- have a person go
25 out?

1 MS. HESS: Using three to six
2 weeks, depending on the nurse. Yeah. And
3 then, you know, some nurses need longer. And
4 then I'll be honest with you: Some nurses
5 just never fully get what I need them to get.
6 But it's definitely three to six weeks. And,
7 you know, for the first week, it's book
8 training. They have to understand every
9 component of the pump. They have to
10 understand why there's a .22 micron filter in
11 the pump.
12 They need to understand not just
13 the refill procedure but how it works with the
14 patient. And they need to understand the
15 potential red flags that could occur with this
16 therapy. Every once in a while a catheter
17 will become dislodged. So if a patient has
18 had a couple of increases and they're not
19 getting pain relief, the nurse needs to sit
20 and do some critical thinking and call the
21 doctor and say: "Geez, I've just done two 10
22 percent increases and they're still at a
23 seven. I think maybe, you know, we're gonna
24 recommend they come in and see you, because I
25 think something -- I think you want to look at

1 this more." So that's really what our nurses
2 are trained to do.
3 (Inaudible off-the-record
4 consultation between Ms. Hess
5 and unidentified speaker.)
6 MS. HESS: (Directed at
7 unidentified speaker.) Yeah. Good call.
8 Thank you.
9 I also want to just let everyone
10 know the training protocol, once the nurses --
11 we've actually graded the level of access for
12 our pumps. You could have a bump, ma'am,
13 Ms. Burns -- and you're lean, you know, so a
14 pump could be visible. And then a doctor
15 could put a pump in an individual who has a
16 little bit more adipose tissue in this
17 abdominal area and you don't even know it's
18 there. So the level of difficulty plays a
19 huge factor on the success of -- of
20 successfully accessing these pumps.
21 So IPM has graded them -- Level
22 1, 2, and 3 -- and that's based on palpation,
23 it's based on being able to palpate all three
24 sides, depth, and things like that. So until
25 the nurse is able to go fully on their own,

1 they have to be witnessed three times with
2 each access level. And that's something we've
3 added on, in addition to Medtronic.
4 MS. BURNS: Another question:
5 How frequently do you actually see the
6 patients? Mr. Elrod pointed out that you had
7 said 12 times a year and Pentec said six times
8 per year. So how many times are patients
9 actually seen?
10 MS. HESS: Good question. I'm
11 Melissa Hess, again. Sorry. Well, really it
12 depends on the patient and how long they've
13 had their pump. I don't like a patient to go
14 more than two and a half, three months without
15 seeing a nurse, because they have that full
16 nursing assessment if there's some things we
17 didn't catch. If a pump is new, it could be
18 every week. If a pump has been established,
19 it could be every two months based on, again,
20 medication concentration and the volume of the
21 pump and the daily dose.
22 So I estimated 12. Some
23 patients are gonna be under; some patients are
24 gonna be over. But that was my estimation,
25 for that reason. A newer pump really is gonna

1 take more time to what we call titrate it or
2 to get to a therapeutic level, and when you're
3 dealing medication directly into the spinal
4 column, you really want to go slow.
5 So a doctor in a doctor's office
6 might say, "Ms. Smith had a really hard time
7 getting here. I'm gonna go ahead and do a 30
8 percent increase, because she's here," but an
9 IPM model I could have a nurse go every week
10 and do a 10 percent increase and maybe she
11 only needs a second one because we brought her
12 pain level down two points which was our
13 therapeutic goal to begin with. So the model
14 is a little different, but -- I hope that
15 answers your question.
16 MS. BURNS: And you have, but I
17 guess my concern is, based on Ms. Jordan,
18 you're not planning on having a lot of nurses,
19 and you're covering 95 counties. I can't
20 imagine that you could go see a patient every
21 week. And then that begs the question, as far
22 as patient assessments: Seeing a patient
23 every month or two months, to me, is really
24 not giving a full assessment of the patient
25 versus a home health agency, routinely -- you

1 know, patients are seen every week. So just a
2 little bit of contradiction there, you know,
3 is what I'm seeing there.
4 And I don't know if you or
5 Mr. Putrino need to explain your actual
6 process -- the Department of Health brought
7 this up -- you know, the transporting, the
8 dispensing, the pharmacy consultation, the
9 administration; just that whole process. I
10 really have a lot of concern and questions
11 about that.
12 MS. HESS: Yeah. Absolutely.
13 MR. PUTRINO: Let me do that.
14 MS. HESS: Oh, okay.
15 MR. PUTRINO: Hi. I'm Roy
16 Putrino. First of all, in addition to the
17 nursing, this is not training that the nurses
18 would get in the doctor's office, so you'll
19 have a higher skill level in the home, and,
20 also, all of our nurses get follow-up training
21 every six months. So they must come to New
22 Jersey, and they must go through the training
23 again and again, and we look for little flaws.
24 As far as the distribution of
25 the drug, this is a highly sensitive drug.

1 There's no preservatives in this. So anybody,
2 if they open that box -- if I send it to the
3 patient's home and they leave it in an exposed
4 area, it could be a problem. Now, here in
5 Tennessee, they want us to send it to the
6 patient's home. We have already wrote that
7 policy, and it's in the application.
8 So we have already complied with
9 that. We feel it's perfectly acceptable, and
10 it will be sent directly to the patient. It's
11 still a doctor's order, and we will be
12 delivering it on, you know, an as-needed
13 basis. So they won't be sitting there with
14 three prescriptions. They'll be -- it'll be
15 time for their refill in maybe a day or two,
16 so it'll be delivered to their home. But if
17 we use an in-house -- in-state pharmacy, that
18 procedure will be even easier.
19 Did you want to say something?
20 MS. HESS: Yeah. I was just
21 hoping --
22 MR. PUTRINO: [This is] Melissa
23 Hess.
24 MS. HESS: Yeah. I'm Melissa
25 Hess. Ms. Burns, I was hoping -- I should

1 have said this before, and I apologize -- to
2 expand on the training and to just maybe give
3 you a better understanding of the level of
4 training that the IPM nurses have. The
5 doctor's office nurses are wonderful. You
6 know, they look at a lot of different
7 therapies, and they run back and forth all day
8 long, but they don't have the knowledge level
9 that the IPM nurses are gonna have, just
10 because they aren't able to focus on it like
11 the IPM nurses do.
12 The idea of the sole focus with
13 the IPM model, I think, is really one of the
14 most important things that we do. The idea of
15 understanding all those mechanics, like I
16 talked about, understanding the three levels,
17 understanding the medications, understanding
18 the potential red flags. The doctors -- the
19 nurse in the doctor's office, and even
20 sometimes the NPs and the PAs, they can't
21 immerse themselves in it like an IPM nurse
22 can.
23 So I think that's really, really
24 important for me to bring up; that, you know,
25 patients can go into a doctor's office and

1 sometimes, you know, we can run doctor -- the
2 programming. You know, I have often gone in
3 and helped the doctor do the complex
4 programming. Just because I have the luxury
5 of doing it Monday through Friday, and I
6 happen to love it -- but also they, you know,
7 the doctors, do just a small portion of this,
8 generally, in their practice -- that the level
9 of nursing and the level of expertise that IPM
10 can bring can really be invaluable. So I hope
11 that helps. Thanks.
12 MS. BURNS: Back to, I guess,
13 Mr. Putrino -- I assume you'll come back and
14 explain the dispensing and the pharmacy
15 consultation that's required in Tennessee and
16 that type of thing. Just explain the process
17 for that, please.
18 MR. PUTRINO: Well, the
19 pharmacy --
20 MR. AUSBROOKS: Please state
21 your name.
22 MR. PUTRINO: Oh, Roy Putrino.
23 The pharmacy has just received, from the Joint
24 Commission, the consulting dispensary
25 accreditation, just this month. Our

1 pharmacists and nurses in our monitoring
2 center work very closely with the physicians
3 on tailoring these prescriptions. We also use
4 the input from the patients. So we are
5 constantly on the phone with them determining
6 what levels of pain they are having, what was
7 their reaction from the last changes, and
8 along those lines.
9 We monitor their oral
10 medications as well, and we also are -- we
11 also work with the PTM machines -- which is
12 "Patient Therapy Manager" -- which is
13 basically the bolus piece of this external
14 pump. Basic Home Infusion programs it,
15 marries it to the pump, and monitors it so
16 that we can go ahead and, you know, use that
17 to determine the basal rate of the therapy and
18 how many boluses they should be having.
19 So there's a lot of consultation
20 going back and forth. And we didn't really
21 apply for that consulting degree
22 accreditation. They came back with it to us.
23 And so as far as dispensing, again, to
24 Tennessee, which is the only one that actually
25 requires us to go to the -- send it to the

1 patient's home, we're more than happy to do
2 so. But I just want to forewarn you that this
3 is a preservative-free item, and it goes in
4 the spinal cord.
5 You know, my nurses will have in
6 their home a particular safe area, that
7 we supply with cabinets, where that stuff will
8 be stored safely. Even before they go to do
9 it -- to do the refill -- they must call the
10 pharmacy and go over each piece again over the
11 phone as the final check. So there's a lot of
12 things that get involved there, but we'll do
13 it from the home. We'll call from the home
14 when we get there and make sure that
15 everything is done properly.
16 That's really the whole scope.
17 Is there something -- was there something
18 else?
19 MS. BURNS: That's okay. I'm
20 just -- you know, routinely, when you go in
21 and pick up a prescription, you know, [they'll
22 say], "Are there any questions?" and the
23 pharmacist is available to answer that. Is
24 the doctor providing the overview of the
25 medication prior to the patient even --

1 MR. PUTRINO: Well, the doctor
2 definitely introduces the situation -- so the
3 pump; a change of drug; a change of a
4 combination drug -- and you have to remember
5 that of the seven drugs that we use, only
6 three are approved by the FDA. And of those
7 three, once they are put into combination with
8 other drugs, they are also off label.
9 So over the 14 years that I have
10 been doing this therapy, since the early
11 trials in '91, we have compiled tremendous
12 data; compendiums of them. So physicians feel
13 it necessary to call us even when it's not
14 their patient on conversions from morphine to
15 fentanyl; the ingredients that can be mixed
16 with them; what are the increased gradients;
17 what are the boluses.
18 So we have a lot of data, and
19 we've even taken it a step further. We are
20 now drawing back what's in the reservoir,
21 taking it back to New Jersey, and we're doing
22 stability testing, which is going to be coming
23 down, I think, in the 800 Standards. But
24 we're already doing that, so we can go back to
25 them. Since there's no compendium that will

1 tell you the stability of this -- if I mix two
2 drugs together that are 60 days and 60 days,
3 it's -- you know, some people think it's 60
4 days, but it's not. It's more like 40 days.
5 And we have now the methods
6 with -- you know, with analyzers and mass
7 spectrometers that will now tell us the
8 stabilities of these drugs, and we're giving
9 that information back to the physicians. And
10 what we're seeing is even better outcomes,
11 because, now, what they thought was hopeless
12 was the fact that the drug wasn't getting
13 there and they were, in their minds, thinking,
14 "I have 20 cc's. That's good for 100 days" --
15 because that's the volume -- but it was really
16 only good for 40. And one by one, people are
17 dropping off of Percocet and all of the other
18 oral meds; even the baclofen. You know,
19 that's really where we found that from.
20 MS. BURNS: Okay.
21 MR. PUTRINO: Thank you.
22 MS. BURNS: And changing
23 subjects now, can you explain your charges?
24 Mr. Elrod, again, pointed out that your
25 charges appear to be much less than Pentec's.

1 Can you --
2 MR. PUTRINO: Yes, they are. We
3 don't bill for materials, first of all. It's
4 all included in our per diem. Unlike our
5 competitor, all are -- I'd say 90 percent of
6 our cases are all under contract, which means
7 the prices are dictated to us. They're much
8 lower than carving out. And I don't know if
9 you know what that term means. It means that
10 if you don't have a contract, you go out of
11 network and you bill outside of there.
12 So they can bill maybe twice
13 what we bill, but we are under contract
14 with -- our organization is under contract
15 with all of the major insurance companies: --
16 Humana, United, the Blues, Aetna -- and the
17 reason that they have chosen us is that our
18 model works. Our hospitalizations on our
19 census is 0.2 per year compared to whatever
20 theirs are, and some vary from two to three
21 times a year. So we're going in the hospital
22 once a year, and they're going in the hospital
23 two or three times a year. So that model
24 drives those insurance companies to say:
25 "Let's take this regional contract and make it

1 national." And that's exactly how this rolled
2 out for us.
3 You know, we realize that it's
4 more than just filling the pump. It's
5 everything around it. And I want to address
6 what the gentleman said there regarding not
7 having a full picture. We do have a full
8 picture, but we don't want to impact all of
9 the other agencies in this state or in any
10 state. That's why we bring them in when there
11 are issues. And they are the experts in those
12 issues, and that's why we bring them in.
13 They know how to handle wound
14 care, and UTIs, and things like that. We are
15 focused on this, but our nurses do a full
16 assessment. But other than that -- I'm sorry.
17 I went off topic there.
18 MS. BURNS: All right. I'm
19 almost through.
20 Mr. Wynd, please.
21 MR. PUTRINO: Thank you.
22 MS. BURNS: Thank you.
23 MS. HESS: Can I -- I'm sorry.
24 I'm not sure if this is the time --
25 MR. AUSBROOKS: State your name.

1 MS. HESS: Melissa Hess. Sorry.
2 I was hoping -- it really ties into the
3 training. I was hoping just to get another 30
4 seconds. When Mr. Wynd had spoke regarding
5 doctors wanting them -- Pentec -- to come to
6 Tennessee and they're not able to -- that, you
7 know, Roy was seeing patients in that area --
8 how that rolled out is that a doctor's office
9 oftentimes don't have the training, the
10 nursing staff, to really effectively assist
11 these patients. They have often sometimes
12 inherited them from doctors who have retired,
13 or who have left the area, and they're really
14 trying to help the individual, but they don't
15 have the resources to do that.
16 So in that situation, what Roy
17 and Basic Home Infusion did decide to do was
18 to use an independent contractor, in addition
19 to the MD needing the services. So I was just
20 hoping to clarify that. I didn't want that,
21 like, a big elephant in the room, because, you
22 know, our goal to be here for IPM is to really
23 introduce this and to be effective and to work
24 within your State Health Plan. Thank you.
25 MS. BURNS: Thank you.

1 Okay, Mr. Wynd.
2 MR. JOHNSON: Do you have
3 others?
4 MS. BURNS: For Mr. Wynd.
5 MR. JOHNSON: Oh, okay. I'm
6 sorry.
7 MS. BURNS: So you've heard IMP
8 talk about the availability to use compounding
9 pharmacies within the state of Tennessee.
10 Have y'all considered that or are you still on
11 using the out-of-state pharmacies?
12 MR. WYND: Hi.
13 MR. AUSBROOKS: State your name.
14 MR. WYND: Doug Wynd. No. We
15 have not considered that. And, most likely,
16 we would not entertain that model. We feel
17 very confident in our delivery system. And
18 Cliff can talk more about that, if you're
19 interested in how we particularly do it and
20 how -- our nurses are an extension of our
21 company and our pharmacy.
22 So the regulations who state
23 that you have to deliver it to the end user in
24 a state, through our legal advice, through the
25 channels and the regulatory processes that we

1 have asked, you know, about our model -- about
2 our nurses, you know, hand-delivering it to
3 the patient and saying, "Here's what it is,
4 this is what I'm gonna do, and that's the
5 delivery of the medication to the patient" --
6 that's been sufficient.
7 And, frankly, in the industry,
8 the idea to ship the medicine to a patient and
9 then have the patient brown-bag it back
10 into -- either to the physician's office or to
11 have it waiting there for a nurse to show up
12 to inject it is fraught with high levels of
13 concern. So everything from diversion,
14 obviously, to the product becoming riddled
15 with all kinds of infection or contaminants,
16 and you just -- you lose control of that
17 thing.
18 So while there may be some
19 bodies that suggest that's a right way to go,
20 regardless of whether it's a physician -- and,
21 frankly, the patients themselves -- the
22 patients don't want highly concentrated
23 narcotics in their house, because they live in
24 the wild. They live wherever they live. And
25 if people know that there's highly

1 concentrated narcotics with street values of
2 who knows what, that then subjects them to
3 safety risks.
4 And so we heretofore have not
5 considered that, and those would be our
6 initial concerns with doing a brown-bag
7 situation with these types of medications for
8 those patients. We'd be happy to, you know,
9 discuss that further, but I think that's where
10 we will probably net out, because that's,
11 again, in the industry, brown-bagging these
12 medications. And having it sit around in
13 uncontrolled situations, you lose that,
14 especially in light of the fact that our
15 model, where our nurses are an extension of
16 our pharmacy delivering it to the end user,
17 kind of settles that issue.
18 MS. BURNS: Okay. And one more
19 quick question for you, and then I want to ask
20 Mr. Grinder and Ms. Huddleston what their
21 thoughts are on that. You have in your
22 application that Coram had announced recently
23 that it's discontinuing this service
24 nationwide. Do you know why? Would you have
25 any comments on that?

1 MR. WYND: They didn't state
2 publicly -- well, now off the record, now on
3 the record [verbatim], it's because it wasn't
4 profitable for them to reach the critical mass
5 to do. Everything it takes to manage these
6 patients appropriately, even from the pharmacy
7 level, to do all the things that Roy just
8 spoke to in terms of the calculations and the
9 medications and all the background knowledge
10 that is required of a pharmacy, just to create
11 the medication -- an appropriate medication,
12 to go in the syringe -- is a challenge.
13 And then to have the nursing
14 staff -- if you don't have the nurses that
15 have enough patients to do this regularly,
16 it's a very intimidating procedure, not only
17 just to find that little bitty access port but
18 to inject the medication, hoping that you're
19 in the port. And if you're not, you could --
20 you're looking for signs of, you know,
21 respiratory distress. And then when you push
22 the "Go" button on the program -- you know,
23 you have to program everything in and then you
24 hit "Go," and if you didn't do that right and
25 if you don't have the expertise to do that

1 every day, it's very intimidating.
2 So off-the-record comments from
3 the Coram folks that I have spoken to at the
4 national level, they have said that that's why
5 they're getting out.
6 MS. BURNS: Okay. Thank you.
7 And I just wanted to give Dr. Grinder or
8 Ms. Huddleston either one an opportunity to
9 respond to that in regard to medications being
10 dispensed to the home versus to the nurse.
11 MS. HUDDLESTON: Andrea
12 Huddleston, for the Department of Health.
13 Yes, diversion from the patient is always a
14 concern. That's the traditional model, of
15 course. The patient goes to the pharmacy and
16 has oxycodone pills dispensed; takes that home
17 and puts it in their medicine cabinet.
18 Obviously, that's the
19 responsibility of the physician to educate the
20 patient about that concern, and we're -- I
21 think the pharmacists, as well, probably try
22 to engage in education about that. But when
23 you dispense to the nurse, now you've added
24 another way for diversion, and in multiple
25 levels, I would imagine.

1 I'm not sure, again, how the
2 drugs get to the nurse and then how the nurse
3 keeps them. I've heard some conversation
4 about that, but I've also heard from some
5 other folks that perhaps the nurses are just
6 told to -- generally speaking, that they
7 should just secure them in their home and are
8 not provided appropriate facilities to do
9 that. And then, of course, when the nurse is
10 transporting the drugs in their car. There
11 are multiple levels of diversion danger there
12 as opposed to just the patient having the
13 drugs at home.
14 MS. BURNS: Okay. That's all.
15 MR. JOHNSON: Dr. Fleming, and
16 then Ms. Austin.
17 DR. FLEMING: I've got a quick
18 question for the NHC HomeCare folks. Is there
19 anybody in your home care agency with the same
20 level of training and comfort to do this care
21 in the home?
22 MS. OWENS: Pam Owens, [with]
23 NHC HomeCare. We haven't had any call to
24 train our nurses or to -- I've just started
25 investigating, with these applications, this

1 whole provision of this service. But not at
2 this time; we don't have anybody.
3 MR. JOHNSON: Ms. Austin.
4 MS. AUSTIN: This question is
5 for IPM. Can you-all speak to the accusation
6 of your company already servicing patients in
7 Tennessee without -- [with] the lack of a CON?
8 MS. HESS: Absolutely. My name
9 is Melissa Hess. IPM is not seeing patients
10 at all in Tennessee. But I think I tried to
11 explain that before, and I apologize if I
12 didn't do it succinctly.
13 Basic Home Infusion, who Roy is
14 also the CEO of -- and, I believe, a 70
15 percent owner -- does independently contract
16 with a nurse and a couple of physicians in
17 Tennessee for the provision of intrathecal
18 services. But IPM isn't, no. No, ma'am. And
19 that would be against our plan, definitely.
20 Thank you.
21 MR. JOHNSON: Mr. Doolittle.
22 MR. DOOLITTLE: Just a couple of
23 quick questions, starting with Mr. Elrod. I
24 don't think I heard you say that NHC provides
25 this service; is that correct?

1 MR. ELROD: Oh, no. And, in
2 fact, I think we made it plain that we don't.
3 I'm sorry. Dan Elrod, on behalf of NHC.
4 Ms. Owens just answered Dr. Fleming's
5 question, that they have not had any calls to
6 do so, so they haven't done so.
7 MR. DOOLITTLE: Got it.
8 MR. ELROD: Right.
9 MR. DOOLITTLE: Okay. The first
10 application indicates that there are about 300
11 users of these pumps in the state of
12 Tennessee. And I'm going to ask the other
13 two, but is there any reason to believe that
14 most of those are done somewhere other than
15 the physician's office? I mean, is there
16 obviously another company floating around
17 whose name hasn't been mentioned today?
18 MR. ELROD: I don't think
19 so, Mr. Doolittle. I think the physicians'
20 offices are where they're being done. And
21 it's interesting, on that point, that the
22 Pentec application actually listed five groups
23 of physicians, including four neurology
24 groups, that they had been in contact with,
25 and yet they could produce no letters from any

1 of those physicians documenting that somehow
2 these patients weren't getting served. So I
3 think it is happening in physicians' offices,
4 basically.
5 MR. DOOLITTLE: Okay. Well,
6 what I want to focus on very quickly is the
7 economics of this. Do you have any way of
8 estimating what it costs to provide this
9 service in physicians' office? Because we
10 have, you know, apples and oranges comparisons
11 in the application, which I'm going to get to
12 with the other -- with the applicants in just
13 a second.
14 MR. ELROD: We don't have any
15 information about what the physicians' charges
16 are. No, we don't. I'm sorry.
17 MR. DOOLITTLE: Okay. Thank you
18 very much.
19 Ms. Hess -- economics,
20 quickly -- the number that I see in the
21 application is a $200 fee, and it specifically
22 excludes the cost of the compounding. And
23 then I think in either your testimony or the
24 other gentleman's, you mentioned that it -- it
25 was mentioned a per diem. Add it all together

1 and tell me what the aggregate cost is per
2 visit on an average basis.
3 MR. PUTRINO: Well, let me --
4 MR. AUSBROOKS: State your name,
5 please.
6 MR. PUTRINO: Roy Putrino. Let
7 me just begin by saying that this is a wide
8 spectrum you're asking, because it's not just
9 the refill. It's all of the other pieces
10 around it: The hospitalizations, the
11 emergency rooms, the transportation. So you
12 have to get all of those numbers together. I
13 don't think that UnitedHealthcare would have
14 given us a contract if it wasn't
15 cost-effective at this point.
16 So for me to answer that
17 question, I would have to get stuff -- a lot
18 of stuff here, but I don't -- I mean, Humana,
19 as well [as] BlueCross, I don't think they
20 would engage me if it was going to cost them
21 more money.
22 MR. DOOLITTLE: Well, here's the
23 issue: I am one of three consumer reps on
24 this panel.
25 MR. PUTRINO: Okay.

1 MR. DOOLITTLE: And so I am, of
2 course, concerned about consumers, about the
3 payors, and the cost of health care in the
4 state. I am going to try to get an estimate
5 of what it costs to have this done in a
6 doctor's office. Your opposition over there
7 has given us a number which I think is
8 something on the order of $2,343 as an average
9 cost. So what I'm trying to find out is, it's
10 not 200 versus 2,300 or whatever the correct
11 number was --
12 MR. PUTRINO: That's correct.
13 And we're --
14 MR. DOOLITTLE: Give me a zip
15 code.
16 MR. PUTRINO: Okay. Probably
17 about half, I'm gonna say, because we don't
18 have the same per diems. My per diem is
19 contracted, so it's much lower. So we work
20 within the realm of that.
21 MR. DOOLITTLE: Okay.
22 MR. PUTRINO: So we don't really
23 have those higher per diems.
24 MR. DOOLITTLE: I got it.
25 MR. PUTRINO: Oh, sorry.

1 MR. DOOLITTLE: Yeah. I'm not
2 pointing fingers.
3 MR. PUTRINO: No. I understand.
4 MR. DOOLITTLE: I'm just trying
5 to get apples and apples and apples.
6 MR. PUTRINO: I'm sorry. I --
7 MR. DOOLITTLE: And I'm missing
8 the physician piece, but --
9 MR. PUTRINO: Yeah. I don't
10 have the physician piece. And, you know,
11 there's a study being done now called "The
12 Burden of Care," and there's a lot of stuff
13 that the physician does that doesn't get paid
14 for.
15 MR. DOOLITTLE: Let me ask
16 you --
17 MR. PUTRINO: Like the
18 oversight.
19 MR. DOOLITTLE: Let me ask you
20 one other additional questions. What other
21 states would this sort of service be much more
22 pervasive, since it doesn't exist, to any
23 great extent, in the state of Tennessee? You
24 know, what are the other states -- whether or
25 not you all are there, because I'm gonna ask

1 Mr. Wynd the same thing -- what are the other
2 states that we could benchmark our information
3 on this?
4 MR. PUTRINO: West Virginia;
5 mostly if you went to the northern states,
6 because, apparently, multiple sclerosis seems
7 to be in the colder areas. More densely
8 populated areas, like Chicago, New York City,
9 Philadelphia, those kind of areas, it would be
10 even more.
11 MR. DOOLITTLE: So you would say
12 that those -- you know, you could hold those
13 states out as where this is a more routine
14 service than it is in the state of Tennessee?
15 MR. PUTRINO: I would say it's
16 more common. It's still an orphan therapy.
17 MR. DOOLITTLE: All right. Got
18 it. Thank you very much.
19 MR. PUTRINO: You're welcome.
20 MR. DOOLITTLE: Mr. Wynd?
21 MS. HESS: I was just -- this is
22 Melissa Hess. I was just hoping to add
23 something onto what Roy said. When you look
24 at the cost at their doctor's office, we'd
25 also have to remember not just what the

1 doctor's office bills, but the ambulette that
2 the individual has to take to and from their
3 home to have that done. So there are a lot of
4 other costs that are involved with the MD
5 office model that are very hard to
6 extrapolate. So I just wanted to bring that
7 to your attention.
8 MR. DOOLITTLE: No. I
9 appreciate that.
10 MS. HESS: Thank you.
11 MR. DOOLITTLE: Unfortunately,
12 we don't have that information. But, you
13 know, $1,500 per diems -- I mean, the nurses
14 could be riding in limos.
15 MR. WYND: They are not.
16 MR. DOOLITTLE: Or flying in
17 private planes.
18 Mr. Wynd?
19 MR. WYND: Yes, sir.
20 MR. DOOLITTLE: Is my $2,343
21 estimate -- or your average in your
22 application -- is that an all-in number?
23 MR. WYND: Doug Wynd, with
24 Pentec Health. It is an all-in number, and if
25 that number varies from -- we gets zero

1 reimbursement for providing the exact same
2 care with the exact same medication to
3 probably in excess of that, depending on what
4 the insurance company deems the value of the
5 services that we're providing to be for their
6 particular patients. So they figure out what
7 it's worth, and they tell us what they're
8 willing to pay for it, and then we reach an
9 agreement as to what those payments are.
10 MR. DOOLITTLE: So you have a
11 contract model much like --
12 MR. WYND: Absolutely, yeah. We
13 have, I'm sure, similar and, if not, greater
14 contracts, because we're licensed in more
15 states. But one thing that was not addressed
16 was, you know, what does it cost the patient.
17 For Pentec, as a general rule, it never costs
18 the patient any more for us to go to their
19 home than it would be for them to pay a co-pay
20 in the physician's office.
21 So they're all in. So they
22 don't have to do whatever it takes for their
23 caregiver to take off work, or take an
24 ambulance or whatever to get to the doctor's
25 office. We do all of that for them.

1 So for a patient-specific, what
2 does it cost, it's no more than it would have
3 cost in the physician's office, but -- [if]
4 you ask what they would be willing to pay for
5 it, it's substantially more, but we never ask
6 them to pay more than what they would in the
7 doctor's office.
8 MR. DOOLITTLE: The last
9 question --
10 MR. WYND: Sure.
11 MR. DOOLITTLE: -- is [about]
12 geography.
13 MR. WYND: Yes, sir.
14 MR. DOOLITTLE: What are the
15 states that you would hold out as having
16 these -- not orphan, but, you know, slightly
17 more common than the state of Tennessee?
18 MR. WYND: So let me address the
19 number that is being tossed around. It was
20 estimated that there might be two or three
21 hundred patients in the marketplace on IPM's
22 application. The reality, in terms of our
23 proprietary market research that we have done
24 in the state, is -- it's closer to 2,000.
25 There's about 1,900-plus patients that we

1 referenced, in our application, that we've
2 uncovered, via proprietary market research,
3 are patients who have those implanted pumps in
4 the state.
5 In terms of reference sources,
6 like when the Department of Health was -- if
7 they wanted to talk to other people that are,
8 you know, using our model or they were using
9 our model in their states, every state that
10 borders Tennessee is a state that Pentec is
11 currently licensed and doing business in, with
12 the exception of Arkansas.
13 So every other state that
14 borders Tennessee, we're doing it. We have
15 gone through the surveys, and the next step in
16 the process is to get a license, and then
17 their whole policies and procedures get
18 investigated and looked through, sifted
19 through. And we have been approved in every
20 other state that borders Tennessee. And I
21 hope that is a good reference point for you.
22 MR. DOOLITTLE: And what about
23 states that you're not even seeking business?
24 In other words, they mentioned New York, and,
25 you know, Chicago; the state of Illinois. I

1 mean, with regard to Pentec, are those states
2 where this is a more common procedure?
3 MR. WYND: Correct. And it's
4 very interesting. I live in St. Louis myself.
5 In St. Louis, even though we have two major
6 medical centers there, in neither medical
7 center, with their interventional pain
8 management fellowships, do they use the pumps.
9 They don't -- they don't do it. And it may be
10 that it's more like what the commissioner's
11 comments were on line 8 of his comment; that
12 the therapy might -- you know, it is still in
13 question. In other parts of the country, it
14 is more readily used.
15 So it varies. And sometimes the
16 place is where you would not really suspect,
17 because it's not necessarily geographically
18 based where there's a high density in
19 population. But it's more so where the
20 physician -- where he or she trained, and what
21 he or she brings back to the community, and
22 their passion for getting patients off of
23 these, you know, high doses of oral products,
24 who tend to create great toxicity, and implant
25 a pump which could then reduce the toxicity

1 and give better outcomes for the patient.
2 MR. DOOLITTLE: Thank you very
3 much.
4 MR. WYND: Certainly.
5 MR. JOHNSON: Other questions?
6 Ms. Jordan.
7 MS. JORDAN: This is for the
8 Department of Health. In the opening
9 comments, you mentioned the concern about the
10 unintended consequences of providing these
11 services in the home. Have we adequately
12 addressed that? Is that basically the concern
13 about how these drugs are dispensed, if
14 they're dispensed to the nurses or directly to
15 the patient, or are there other concerns that
16 the Department of Health has?
17 MS. BAYLES: Julia Bayles,
18 [with] Health Planning. The unintended
19 consequences is very much based in the article
20 from the American College of Occupational and
21 Environmental Medicine. That is an
22 association that Dr. Dreyzehner is a fellow
23 of, and that is an article that he found
24 helpful as a reference point. As it seems --
25 based on comments from the applicants, there

1 seems to be, you know, certain doctors [who]
2 are more likely to pursue this service in the
3 home, but we did have information from at
4 least one doctor in Tennessee who does
5 intrathecal pump services who was not
6 interested in the home health intrathecal
7 model.
8 So there are certainly diversion
9 concerns, whether it's to the nurse, or
10 directly to the patient, or -- I mean,
11 diversion is a problem with these types of --
12 these opiates and very dangerous medications,
13 no matter what, but there are also safety
14 considerations, and quality considerations,
15 and those sorts of questions, [that] are
16 difficult to control if they're in the home.
17 So that's another really
18 important aspect of it, and that's kind of
19 encapsulated in that quote from the article as
20 well. The article specifically -- I mean, it
21 talks about the costs and the invasiveness of
22 the therapy and other adverse effects.
23 So it is about diversion, but
24 it's also about those safety and quality
25 issues, and it's this, kind of, big picture of

1 concerns. And it looks like Andrea Huddleston
2 would also like to comment.
3 MS. HUDDLESTON: Andrea
4 Huddleston, from the Department of Health.
5 And also just to mention the concern raised by
6 Mr. Elrod, we were also concerned about the
7 fragmentation of care here. And this is not
8 particularly on point, but given that we don't
9 have a lot of information about the number of
10 physicians that would be willing to refer to
11 this kind of service, and given that we -- I'm
12 not sure how much information we have about --
13 accurate information that we have about the
14 number of pumps being used in Tennessee, the
15 number of physicians who implant those pumps,
16 the number of physicians who have really
17 excellent knowledge about those pumps and
18 their ability to service them on their own in
19 their office, much less having this done at
20 home where the physician is not able to
21 exercise that level of supervision.
22 So, again, that sort of
23 fragmentation, I think, we were also concerned
24 about that as well.
25 MS. JORDAN: Okay. One

1 follow-up: I think I probably know the answer
2 to this, but, obviously, there is a lot of
3 well-founded concern about compounding --
4 compounded medications. Does the Department
5 of Health have any idea where the medications
6 are coming from now that these doctors who use
7 these pumps -- where they're obtaining these
8 compounded drugs? Do we have any idea?
9 MS. HUDDLESTON: I don't know
10 that we have an ability to find out that
11 information.
12 MS. JORDAN: I didn't think you
13 did, but I just wanted to ask. Thank you.
14 MS. HUDDLESTON: And, also, back
15 to your original question, we had talked
16 earlier, I think, about the training for the
17 nursing who will be engaging in this activity.
18 There's been some discussion about that. I
19 believe the application -- the IPM
20 application -- acknowledged that this is very
21 technical, very invasive, and requires an
22 excellent skilled base. And given that there
23 are not formal training programs, currently,
24 that's part of the concern for this to be
25 particularly done in a home health

1 environment.
2 MR. JOHNSON: Other questions?
3 (None noted.)
4 MR. JOHNSON: Other questions.
5 (None noted.)
6 MR. JOHNSON: Well, seeing none,
7 it's time for summation. Mr. Elrod? First of
8 all, [it's] three minutes max, and we need to
9 stick to that because of the timing. And you
10 are to do or your designate is to do
11 application number two first and then the
12 first application.
13 MR. ELROD: Okay. So let me
14 just -- excuse me. Do I do both summations
15 now?
16 MR. JOHNSON: You can do them
17 both at the same time or separately.
18 MR. ELROD: Perfect.
19 MR. JOHNSON: Either way.
20 MR. ELROD: Both at the same
21 time. And I'm Dan Elrod, on behalf of NHC
22 HomeCare, and I appreciate the Agency's close
23 attention to this. And I really think that
24 the volume of questions that have been asked
25 really kind of make our point. And there are

1 so many questions about this, including a
2 number of which that are unanswered, as
3 demonstrated by the exchange between the
4 Department of Health and Ms. Jordan, that
5 that, by itself, justifies -- well, it fails
6 to justify approval, and so it would thus
7 justify denial.
8 Going back also to Ms. Jordan's
9 questions, she asked about why couldn't they
10 come up with physicians who would somehow
11 quantify what we're talking about. And as I
12 indicated earlier, the Pentec application, on
13 page 81, lists five physician groups that they
14 talked to; four neurology groups and one other
15 group of physicians in Knoxville, Memphis, and
16 Chattanooga. And none of those physicians
17 produced any letters to quantify patients, or
18 say "We have a need for this," or "We want the
19 home health model," even though they've been
20 in touch with them.
21 Both of these are extensions of
22 compounding pharmacies who have an incentive
23 to, you know, really sell as many of their --
24 as much of their product as they can. There's
25 nothing wrong with that, but I think the

1 Agency needs to understand the kind of -- what
2 underlies this model.
3 You know, IPM says they're
4 gonna -- that they would use an in-state
5 compounding pharmacy, but based on the
6 questions by Ms. Jordan about where the
7 doctors are getting their drugs now, I don't
8 think there's any way for the Department of
9 Health to actually police that condition, if
10 it were there. And so, you know, that -- I'm
11 not suggesting that they would deceive the
12 Agency. I'm just saying, after it -- if it
13 were approved, there would be no way to really
14 know that for sure going forward.
15 Both result in fragmentation of
16 care. And, you know, IPM says, Oh, they will
17 be happy to work with home health, but they
18 have, heretofore, not been made any outreach
19 to home health, and as far as we know, they
20 haven't been in contact with NHC which
21 operates statewide. They haven't indicated
22 they've had any conversation with any other
23 home health agency about how they would
24 coordinate care. And, in fact, they say
25 repeatedly in the application and otherwise,

1 "We focus on the intrathecal pump, and that's
2 it."
3 If the need emerges for this in
4 a home setting, in a home care model -- if the
5 physician community in the state gets behind a
6 home care model, the home health agency, which
7 is very -- or home health agency industry,
8 which is very vibrant and strong in this
9 state, will emerge organically to address that
10 need. And that's the way this should happen,
11 because that's the model in which the whole
12 patient would be taken care of and not just a
13 very narrow focus.
14 And so for all those reasons, we
15 would encourage the Agency to deny both of
16 these applications. Thank you.
17 MR. JOHNSON: Okay. Thank you.
18 Mr. Wynd, you're up; a maximum
19 of three minutes.
20 MR. WYND: Yes, sir. Doug Wynd,
21 with Pentec Health. And I'll just summarize
22 it this way: I hope you've heard that there
23 is a need for this service in this state.
24 Again, there's about 2,000 patients who have
25 these pumps. We're forecasting that there's

1 about 40 patients that will end on service
2 with us at the end of our first year. And 40
3 patients may not sound like a whole lot to a
4 lot of people in the room, but those 40
5 patients matter, and the impact that we can
6 have on any and every one of those individual
7 40 patients in that first year will be
8 dramatic. And if they were here to stand up
9 and tell you that, they would urge you to
10 allow us to come see them in their home.
11 Our training for our nurses is
12 second to none. If it's a 90-day training
13 program, a lot of nurses don't make it out,
14 but at the end of the day, when they get
15 through that ANCC-accredited training program,
16 our nurses know their stuff, and it's a
17 tremendously valuable service to provide to
18 the patients.
19 Our pharmacy, again, is a
20 closed-loop system, in terms of risk for
21 diversion. And all of our policies and
22 procedures -- I'm sure those would be
23 investigated if we move through the CON
24 process and go to the licensing stage, and
25 when we go through our surveys, you-guys --

1 I'm sure the State will look at all of our
2 policies and procedures, and they'll be
3 satisfied, like all of the other states that
4 we're in, about the way we control diversion
5 and risk of diversion for the patients.
6 And, lastly, in terms of orderly
7 development of health care, for broader access
8 to health care for patients, I'll go back to
9 what I said in my initial comments about the
10 way that we view the patient market. We're
11 not gonna carve out your TennCare patients.
12 We're not gonna carve out the Medicare
13 patients.
14 Our book of business across the
15 country are in markets in which both companies
16 compete, but just my business selective -- or
17 my business solely, about half of my patients
18 I don't get fully reimbursed on. And that's
19 something that we will do here in Tennessee,
20 and I think that, you know, contributes to the
21 orderly development of health care to these
22 patients who, right now, have to go to --
23 [from] wherever they live or wherever they
24 reside, however they need to get there -- to
25 their physician to get refilled.

1 And we would love for the
2 opportunity to come here, with the appropriate
3 regulatory approval, to be here in the state
4 to service the patients here in Tennessee. So
5 thanks for your consideration and thanks for
6 your patience, all of y'all.
7 MR. JOHNSON: Ms. Hess?
8 MR. PUTRINO: Roy Putrino, to
9 address some of the issues from the Board of
10 Health. Probably the majority of the drugs
11 are from Florida. That's where we see that
12 they come from. I am not familiar if there
13 are any compounding pharmacies that provide
14 this service in Tennessee.
15 Also, as far as the article
16 goes, they have one article. I could probably
17 bring you at least five that show the
18 significant importance of having this therapy.
19 I don't want to leave without
20 telling you the importance of the nursing
21 network across the country. If you use, as
22 this gentleman here has said, a local
23 community physician to handle the patients,
24 what happens there is that when that -- that
25 patient is trapped now in that area. They

1 can't leave that area, because this is a
2 continuous infusion.
3 In addition, if that physician
4 goes on vacation, what are they to do?
5 What's -- the hospital is not going to be able
6 to handle it. That's why this network works
7 so well. That's why it's great to have these
8 nurses trained through the whole -- throughout
9 the country.
10 And there were a lot of
11 problems, and those companies are gone. And
12 that's where you see those problems; that's
13 where you see the pocket-fills; that's where
14 you see the wrong drugs given. And the Corams
15 and the Walgreens and the Aprias are all gone.
16 They all have left this field. There's only a
17 few of us left, and the few that are here are
18 doing a great job. And we -- you'll see those
19 values start to increase.
20 And, basically, you know, the
21 big issue here now is patient care. And,
22 again, I don't want you to think it's
23 fragmented. It's actually coordinated far
24 better than it would have been. These
25 patients normally would stay at home and not

1 say anything. They would say, I can't go to
2 the doctor's office, so I'm not gonna do it.
3 But, meanwhile, if they know they can get to
4 the monitoring center and they can get that
5 information, they can get that problem
6 coordinated. And that's what we do. Thank
7 you very much.
8 MR. JOHNSON: Thank you.
9 Discussion by the members? Dr. Fleming, and
10 then Ms. Burns.
11 DR. FLEMING: I'm sorry. I
12 can't hesitate to at least insert that, from a
13 physician's perspective and from a patient
14 advocacy perspective, there's a small group of
15 patients who are in desperate need for help.
16 Chronic pain is one paramount in the national
17 health organizations in the country now as a
18 need. It's the fourth vital sign. I mean, so
19 pain management is not a small deal, and for
20 folks in chronic pain, this opportunity could
21 be life-changing.
22 I'm not a pharmacy regulatory
23 person -- and this is not a legal statement --
24 but from a physician's perspective, I can
25 guarantee that there are patients that would

1 benefit from this concept, and I am an
2 advocate for them.
3 MR. JOHNSON: Ms. Burns.
4 MS. BURNS: I'm honestly having
5 a hard time with this application. I really
6 don't think we have enough information. And
7 that's not to say we didn't have tons of paper
8 to review, but it would have been really nice
9 if the applicants had provided information
10 from the states where this is going on, or if
11 they could have had a doctor come in and talk
12 to us, or if they could have provided, you
13 know, information from those physicians. It
14 could have been really nice if the Department
15 of Health had gone out and talked to other
16 states to have more information for us.
17 I'm just having a really hard
18 time knowing, you know, what we need to do.
19 Is it right for the patient? Probably, it is.
20 Do our home health agencies need to be doing
21 this? Probably not. As a nurse, I cannot
22 imagine being a home health nurse and only
23 doing this two or three times a -- you know, I
24 mean, once every two or months. My competency
25 level would not be there, and it would

1 probably be of more harm to the patient than
2 good for them.
3 So I'm really having a hard time
4 with this application, not knowing if we
5 really have enough information to really make
6 an informed decision.
7 MR. JOHNSON: Mr. Doolittle.
8 MR. DOOLITTLE: I'd like to echo
9 Ms. Burns' concerns. What bothers me the
10 most -- and I inherently think that this is
11 probably a good service that ought to be
12 licensed in the state, but it does strike me
13 that the Department of Health does not have
14 nearly enough information to get comfortable
15 with it, and also to see, most particularly,
16 where it is being done successfully in other
17 states in volume, what the pros and cons are,
18 and what are the things to look out for.
19 And so I really do think that it
20 is tough for us to license a new service which
21 is only being performed, apparently, by
22 physicians on a home health basis, without
23 having the overall regulatory authority in the
24 state feel comfortable that when it goes into
25 service, it's going into service in the

1 correct manner. And we can learn from other
2 state's mistakes. Thank you.
3 MR. JOHNSON: Other discussion
4 by the members? Mr. Wright.
5 MR. WRIGHT: And I think I would
6 just add to that: On a scale of 95 counties,
7 it would be problematic with the information
8 we have.
9 MR. JOHNSON: I'll just make one
10 comment. I think Ms. Jordan brought it up
11 originally and others had amplified the need
12 question. That's not well-defined. We don't
13 really know. Usually in these kinds of
14 things, there's an outcry publicly before we
15 ever see it and before, perhaps, the
16 Department of Health would see it. And there
17 may be an outcry, but if it is, it's hidden.
18 And I think that gets back to the lack of
19 information that we have. And so I too am
20 conflicted.
21 I understand as a consumer rep
22 that patients do need this service, and some
23 are probably not capable of getting to
24 doctors' offices regularly. And they're the
25 ones that need the help the most. The others

1 can make it and it works for them. They're
2 getting help now. It may not be convenient
3 for them. Also, I think the cost numbers have
4 been all over the board.
5 As we get into this, we have
6 some options in terms of what we do as an
7 agency. And this is part of the discussion,
8 so I just want to sort of lay it out; what our
9 opportunities are. We could approve one, two;
10 one or two of the applications. We can deny
11 both or one. Or the one we haven't ever
12 discussed, as far as I'm concerned, is we can
13 defer this until we get more information.
14 I think that would --
15 Mr. Counsel, is that a legitimate motion, if
16 we choose to do that?
17 MR. CHRISTOFFERSEN: It can be
18 done.
19 MR. JOHNSON: Pardon?
20 MR. CHRISTOFFERSEN: It can be
21 deferred for -- or they can be deferred for up
22 to 90 days.
23 MR. JOHNSON: For how many?
24 MR. CHRISTOFFERSEN: Up to 90
25 days.

1 MR. JOHNSON: Thank you. So
2 those are our options, as I see it. And at
3 this point, I haven't seen anything that would
4 convince me to vote for either applicant right
5 now. There are a few things that would
6 convince me to vote against it, just because
7 of the lack of information. However, I don't
8 want to -- I don't feel like I would want to
9 decline a service that's needed because I'm
10 reluctant to get the information to make it
11 possible.
12 So those are our options, as we
13 go forward. So further discussion by the
14 members? Mr. Wright, and then Mr. Gaither.
15 MR. WRIGHT: Mr. Chairman, the
16 other thing I'd like to add: The need is not
17 something I struggle with as much as I do with
18 the lack of information that helps me make a
19 determination about the orderly development.
20 I think that's my biggest concern.
21 MR. JOHNSON: Mr. Gaither.
22 MR. GAITHER: This is for legal
23 counsel. So if we defer, are they allowed to
24 present -- how does that work? Does everybody
25 get to present more information, or does the

1 application stand on its own and you ask
2 questions? I'm just trying to understand.
3 Because the need would have to be addressed
4 with additional information, not just more
5 input from the Department. That's got to be
6 some additional paper or something?
7 MR. CHRISTOFFERSEN: If this
8 were to be -- or if one or both of these -- I
9 assume both -- were to be deferred for a
10 period of time, there wouldn't be any point in
11 doing it without looking at new information;
12 therefore, I would expect that the applicants
13 and the opposition and the Department of
14 Health and Agency staff would all have the
15 opportunity to explore some of the questions
16 raised by the Agency.
17 As a matter of fact, the more
18 guidance the Agency could give, if they were
19 to do it, as to exactly what they want
20 answered -- though I think if that evidence
21 had been clear anyway, it would be helpful.
22 MR. GAITHER: I think that's
23 where I was going, is we would have to tell
24 you what we really want to know on that.
25 MR. CHRISTOFFERSEN: That would

1 be helpful.
2 MR. JOHNSON: Other discussion?
3 (None noted.)
4 MR. JOHNSON: Well, one further
5 comment, that the Department addressed that we
6 haven't talked much about, is the abuse issue.
7 Tennessee is not the most abusive drug state
8 in the country, but it's one of them. It's
9 probably in the top ten. And that's a
10 concern.
11 MS. HILL: We're ranked two.
12 MR. JOHNSON: We're ranked two?
13 MS. HILL: I think so.
14 MR. JOHNSON: Okay. So it is a
15 concern and a big concern. And I don't see --
16 unless we're able to regulate this situation
17 in a reasonable way, I don't see that getting
18 any better because of what we might do. So I
19 think that needs to be addressed too, if we
20 should agree to defer.
21 Ms. Austin?
22 MS. AUSTIN: I guess it's just
23 my understanding that we've already deferred
24 these applications once for extensive
25 questions by the Department of Health and by

1 the HSDA staff. I'm just not sure -- and they
2 weren't able to provide, still, the
3 information that was outstanding. I just
4 don't know how much more they're gonna be able
5 to give us at this point.
6 MR. JOHNSON: Well, I don't know
7 either, but I suspect that they probably have
8 a better direction of what questions the
9 Agency has after today than they had before we
10 talked about it. So it seems to me the
11 questions are pretty specific now. Probably
12 less than five or so big theme-type questions
13 that need to be answered. And I think the
14 minutes will show what those are, and we can
15 summarize those.
16 Other discussion?
17 (None noted.)
18 MR. JOHNSON: Well, if there is
19 none, a motion is in order to do one of three
20 things. We can one, two, defer, neither --
21 and/or approve neither. So those are our
22 options. So a motion is in order.
23 MS. HILL: For Implanted Pump
24 Management first.
25 MR. JOHNSON: Pardon?

1 MS. HILL: IPM is the first one.
2 MR. JOHNSON: Oh, I'm sorry. I
3 need to say that we need to deal with these
4 separately, not collectively. So we'll deal
5 with Implanted Pump Management first, and then
6 we will do Pentec separately.
7 So a motion is in order.
8 MR. DOOLITTLE: May I ask --
9 MR. JOHNSON: Mr. Doolittle.
10 MR. DOOLITTLE: I have a
11 question of the chairman. I think it's only
12 fair that we try to delineate exactly what
13 we're looking for. Is it possible for us to
14 supplementally deliver a letter to the
15 applicants and say: We've got the following
16 five areas that we'd like -- and the
17 Department of Health -- five areas we'd like
18 you to elaborate on? Is that possible, or do
19 we have to invent this right now?
20 MR. JOHNSON: Ms. Hill?
21 MS. HILL: Certainly,
22 Mr. Doolittle. If your decision is to defer
23 the application, then it certainly would be
24 appropriate to delineate the information that
25 you are looking [for] from them; otherwise,

1 you would be, you know, voting to approve or
2 deny something.
3 MR. DOOLITTLE: Okay. Well,
4 that's my question. Can we supply it, you
5 know, in writing supplementally?
6 MR. JOHNSON: Mr. Christoffersen,
7 do you have additional -- you looked like you
8 were about to answer.
9 MR. CHRISTOFFERSEN: Yes.
10 MR. JOHNSON: Other questions or
11 discussion?
12 (None noted.)
13 MR. JOHNSON: A motion is in
14 order for Applicant No. 1, which is Implant
15 [Pump] Management. Mr. Doolittle.
16 MR. DOOLITTLE: Regarding
17 Implant Pump Management, CN1407-027, I move
18 that we defer this application for up to 90
19 days to solicit additional information on
20 specific subjects to be transmitted to the
21 applicant in writing within the next week, and
22 the same set of questions for possible
23 additional information be transmitted to the
24 Department of Health for additional research
25 on their part.

1 MR. JOHNSON: That's a proper
2 motion. Is there a second?
3 MS. BURNS: Second.
4 MR. JOHNSON: All right.
5 [Seconded by] Ms. Burns. Please call the
6 roll.
7 MR. AUSBROOKS: Jordan?
8 MS. JORDAN: Yes.
9 MR. AUSBROOKS: Flora?
10 DR. FLORA: Yes.
11 MR. AUSBROOKS: Gaither?
12 MR. GAITHER: Yes.
13 MR. AUSBROOKS: Wright?
14 MR. WRIGHT: Yes.
15 MR. AUSBROOKS: Doolittle?
16 MR. DOOLITTLE: Yes.
17 MR. AUSBROOKS: Burns?
18 MS. BURNS: Yes.
19 MR. AUSBROOKS: Austin?
20 MS. AUSTIN: Yes.
21 MR. AUSBROOKS: Fleming?
22 DR. FLEMING: Yes.
23 MR. AUSBROOKS: Byrd?
24 MS. BYRD: Yes.
25 MR. AUSBROOKS: Johnson?

1 MR. JOHNSON: Yes.
2 MR. AUSBROOKS: Ten "yes."
3 MR. JOHNSON: The motion passes.
4 The application is deferred for up to 90 days.
5 And I will ask the Department to put a time on
6 it, based on other applications to be heard,
7 and the timing that you think the information
8 can be gathered. I don't think it'll be 30
9 days, but it may not need to be 90. So we
10 will address that question with the staff.
11 All right, then. A motion is in
12 order for Pentec. Mr. Doolittle.
13 MR. DOOLITTLE: Regarding Pentec
14 Health, Inc., CN1411-046, I make the same
15 motion that the application be deferred for
16 consideration for up to 90 days to allow the
17 applicant to address a few additional requests
18 for information and that a similar request,
19 perhaps with additional things, be transmitted
20 to the Department of health.
21 MR. JOHNSON: That's a proper
22 motion. Is there a second?
23 MS. BURNS: Second.
24 MR. JOHNSON: Seconded, again,
25 by Ms. Burns. Please call the roll.

1 MR. AUSBROOKS: Jordan?
2 MS. JORDAN: Yes.
3 MR. AUSBROOKS: Flora?
4 DR. FLORA: Yes.
5 MR. AUSBROOKS: Gaither?
6 MR. GAITHER: Yes.
7 MR. AUSBROOKS: Wright?
8 MR. WRIGHT: Yes.
9 MR. AUSBROOKS: Doolittle?
10 MR. DOOLITTLE: Yes.
11 MR. AUSBROOKS: Burns?
12 MS. BURNS: Yes.
13 MR. AUSBROOKS: Austin?
14 MS. AUSTIN: Yes.
15 MR. AUSBROOKS: Fleming?
16 DR. FLEMING: Yes.
17 MR. AUSBROOKS: Byrd?
18 MS. BYRD: Yes.
19 MR. AUSBROOKS: Johnson?
20 MR. JOHNSON: Yes.
21 MR. AUSBROOKS: Ten "yes."
22 MR. JOHNSON: The motion passes.
23 The application is deferred for up to 90 days,
24 with the same stipulations about
25 communication.

Response to Agency Members Questions

Pentec Health, Inc.

CN1411-046

MAY 22 '15 AM 11:30

PENTEC HEALTH, INC.

RESPONSE

TO

REQUEST FOR ADDITIONAL INFORMATION

IN CONNECTION WITH

CERTIFICATE OF NEED APPLICATION CN1411-046

MAY 2015

1. **Based on the information provided by the Tennessee Department of Health, it appears implantable intrathecal pumps may not be safe. Please provide expert opinion on the safety and efficacy of the pumps.**

A letter from Stanley P. Fisher, M.D., Co-Director of St. Luke's Marion Bloch Neuroscience Institute, Kansas City, Missouri, along with a biographical sketch for Dr. Fisher, is attached to this Response as Attachment to Question 1.

2. **Describe in detail the safety of refilling the pumps in the home versus a physician office.**

Pentec protocols for refilling pumps in the home versus the physician's office setting are the same. The pump manufacturer's guidelines are followed for refill procedures. For any complications that may arise, the protocols are also the same in both settings and include calling 911, performing CPR if indicated, and administering Narcan if needed. Pentec standards of care that focus on patient safety in the home care setting include:

- Pentec nurses remain and monitor the patients after the refill procedure is completed. Patients who receive a physician refill in the office setting typically leave when the procedure is completed and are not monitored.

- Pentec nurses specialize in intrathecal pump management and perform the refill procedure daily. Physicians, or their staff, not only perform intrathecal pump refills, but also various other patient care procedures. In many cases they may perform the pump refill procedures only intermittently.

- In the home setting, there is a focus on infection prevention and aseptic technique as the patient is not exposed to other environmental factors that they may be in a physician's office. There have been no intrathecal pump infections related to Pentec's nursing care.

- Pentec nurses are required to successfully complete an ANCC-accredited 90-day training program and examination prior to performing independent patient care. This training program requires completion of 460 hours of classroom and hands-on field training. In addition, all nurses are required to have at least 3 years of clinically-relevant practice with ICU or ER experience preferred prior to hire. Copies of (i) Pentec's Administration Policy and Procedure – *Nurse Training Program*, and (ii) Pentec's accreditation letter from the ANCC regarding the training program are attached to this Response as Attachment to Question 2.

- In addition to the initial training program, all Pentec nurses are required to complete annual competency screening and continuing education related to their practice. In 2014, each primary care nurse completed 40 hours of continuing education, and about half of the nurses completed additional special training or attended one- or two-day practice-related conferences.

Who refills the pump in the physician office setting ... is it the physician or a nurse or someone else?

All Pentec personnel with direct patient contact are Registered Nurses with specialized training in intrathecal pump management. Physicians, on the other hand, may employ and utilize Registered Nurses or (if permitted under applicable law) Medical Assistants or Licensed Practical Nurses for pump management in their office, or they may perform refills themselves. Pentec believes that many of these physicians and office personnel have received training on intrathecal pump refills and maintenance from Medtronic, the largest intrathecal pump manufacturer. Medtronic offers online distance learning courses, classroom programs, on-site training and seminars in connection with academic conferences for physicians, nurses and other professionals at various skill and

experience levels. Such training would be at the discretion of the physician or the practice group.

If someone other than the physician, detail the oversight provided by the physician.

Any oversight done by the physician is varied based on their preference and what state laws or guidelines they need to follow.

3. Address the risks associated with accessing the spinal port in the home.

The risks associated with accessing the intrathecal pump in the home setting versus the physician's office are generally the same. These risks include items such as possible subcutaneous administration and the possibility of programming errors. However, the risk of introducing an infection is lower in the home setting because of Pentec's focus on infection prevention and aseptic technique and the fact that the patient is not exposed to other environmental factors that may be present in a physician's office.

To minimize these risks, Pentec has developed and implemented policies and procedures addressing the administration of intrathecal medications. These include:

- Infusion Policy and Procedure – *Medication Safety*. This policy sets forth the steps that Pentec's primary care nurse must follow before and after each pump refill to ensure that the correct medication is administered.

- Infusion Policy and Procedure – *Synchromed Infusion System Refill*. This policy sets forth in detail each of the steps that Pentec's primary care nurse must follow to perform any necessary pump programming, access the patient's pump in a sterile manner, withdraw fluid from the pump reservoir, prepare medication for the refill procedure, refill the pump, dispose of medical waste, and review information pertaining to the medication, dosage, rate and next refill with the patient.

- Infusion Policy and Procedure – *Patient Safety Checklist*. This policy sets forth the check points to be observed by the primary care nurse to confirm the accuracy of medication delivered for administration to the patient, to re-confirm the accuracy of the medication prior to pump access, and to review all changes with the patient or caregiver. The policy includes an actual checklist to be completed by the primary care nurse and signed by the nurse and the patient or caregiver.

- *Infection Control Policies and Procedures*. Pentec has developed and implemented a series of policies and procedures to identify and reduce the risk of infection in patients (and Pentec staff) by means of surveillance, prevention, reporting and control. Specific policies address (1) control of blood-borne pathogens; (2) hepatitis B vaccination; (3) post-exposure evaluation and follow-up; (4) broken skin and skin infections; (5) upper respiratory infections; (6) identification of healthcare associated infections in patients, e.g., pump and catheter site infections, sepsis and pneumonia; (7) patient infection reporting guidelines; (8) reportable diseases; (9) tuberculin testing; (10) standard precautions to prevent hepatitis B and HIV infection; (11) use of personal protective equipment and clothing; (12) disposal of hazardous waste; (13) storage and labeling of biohazardous materials; (14) handwashing; (15) tuberculosis patient care; (16) patient vaccination vs. influenza and pneumococcal pneumonia; (18) surveillance (i.e., gathering of infection data).

For further information, copies of all of the above policies and procedures are attached to this Response as Attachment to Question 3.

In addition to the Pentec policies currently in place to address any risks that may arise, Pentec continually trains and reviews information with its nurses on managing any possible concerns or events. This continuous training and review includes practice in programming medications and changes, weekly review of case studies, a bimonthly

educational newsletter, and in-person competency and educational meetings throughout the year.

Provide any statistics for incidents, adverse events, or reported complications over the past 3 years and the outcomes. Both applicants have noted having a national presence in the implanted pump market so additional clarification regarding safety issues is needed.

During the 3-year period ending April 30, 2015, Pentec has experienced zero nosocomial infections.

During the 3-year period ending April 30, 2015, two inadvertent partial subcutaneous administrations have occurred. The first occurred in Texas in 2013 and the second in Florida in 2015. In each case, 911 was called, CPR was initiated, Narcan was administered, and the patient was transported to the hospital. In each of these instances, the patient outcome was full recovery without any further issues.

The total number of pump refills performed by Pentec was 12,007 in 2013, 11,924 in 2014, and 4,942 for the four-month period from January 1 through April 30, 2015.

4. **Describe when the procedure is clinically contraindicated (when a refill will not be performed).**

Contraindications of the pump refill procedure include:

- Fluid accumulation over the pump site.
- Localized or systemic infection.
- The intrathecal pump is inverted.
- Catheter site assessment indicates possible concerns such as a kink in the catheter tubing or a granuloma.
- The intrathecal pump is deep under the fascia and possibly a difficult access that would be better suited for ultrasound or fluoroscopy guided access.
- The home environment may be deemed inappropriate or unsafe.

Describe in detail how the medications will be protected from theft, misuse, and/or abuse from the time the nurse receives the medication until it is delivered to the home.

Pentec has numerous system controls to maintain the security and prevention of theft, misuse, and/or abuse of any medications. Pentec's shipping, storage and delivery protocol is designed to ensure continuous Pentec custody of all medication from the time it leaves Pentec premises until the time it is delivered to the residence of the patient (by an agent of the pharmacy, as authorized by the Tennessee Board of Pharmacy Rules at § 1140-03-.12(5)) and then administered to the patient, thereby keeping the risk of loss, theft or diversion to an absolute minimum. These controls include:

- Scheduled medication deliveries in conjunction with the next scheduled patient visit, reinforced with an email notification to the primary care nurse including tracking number, when medication will be delivered.
- Delivery of medication to the nurse to maintain chain of custody. Delivery can include to the nearest FedEx facility if needed.
- Shipping manifest (including patient name, delivery date, physician name, nurse name and medication description) accompanying medication delivered.
- Verification by Pentec nurse that package contents match shipping manifest.
- Medication storage in a locked box in a refrigerator before administration and transported by Pentec nurse in a delivery bag to the patient's residence on the day of administration.
- Tamper-evident cap on all medication syringes placed at the time of compounding and not opened until in front of the patient.

- Patient signs the delivery ticket verifying volume received and is provided with a copy of the delivery ticket.

- Documentation of residual volume verifies that the previous refill had the correct volume.

- Patient interviews regarding pain relief and verification that they witnessed disposal of residual medication.

- Medications wasted as per DEA recommendations to prevent diversion.

- Documented witness to narcotic waste.

- Process Improvement monitoring of alarms. Patients would present with withdrawal if incorrect medication was given.

- Nursing documentation is accessible on the Physician's Portal and EMR within 24 hours after the refill.

- Annual drug diversion training, including recognizing symptoms and behaviors of a possible chemically dependent person, ethical and legal obligations to report, and the review of mandatory reporting laws.

- All nurses complete a drug screen upon hire.

- Random drug screen for reasonable suspicion.

- On occasion two nurses will complete a visit.

Pentec's pharmacy (which is licensed in Tennessee) has developed and implemented policies and procedures to ensure that all patient medications, including controlled substances, are properly ordered, documented, tracked, stored and delivered. These policies and procedures include:

- Pharmacy Policy and Procedure – *Prescription Requirements and Review*. This policy establishes procedures for determining acceptability of prescriptions received by the pharmacy, required prescription information, recordkeeping, pharmacy review of prescriptions received and offers of counseling by a pharmacist.

- Pharmacy Policy and Procedure – *Controlled Drug Substance*. This policy addresses DEA registration requirements and establishes procedures for the handling and oversight of controlled drug substances, including storage, security, inventory management, ordering, receipt, return to manufacturers, dispensing, distribution to other dispensers, accidental loss or destruction, planned disposal, loss reporting, and return of unused controlled drug substances.

- General Policy and Procedure – *Narcotic Waste Disposal*. This policy outlines the procedures to be followed by Pentec's primary care nurses for disposal of medical waste removed from the pump reservoir at the time of refill and excess

new medication, and the return to the pharmacy of unused controlled drug substances not delivered to the patient.

For further information, copies of these policies and procedures are attached to this Response as Attachment to Question 4.

Pentec's pharmacy shipped a total of 6,581 packages of intrathecal medications in 2014. Of these 6,581 shipments, only 2 inaccuracies were noted – in each case, a package shipped on a Friday was delivered by Federal Express on a Monday, rather than the preceding Saturday as requested. In both cases, the package was returned to the pharmacy and the pharmacy re-compounded and replaced the medication. Most importantly, Pentec has never experienced a lost shipment of intrathecal medication. Pentec strongly believes that its proven model for handling intrathecal medication is superior to any alternative, and provides the best protection against diversion, abuse, loss and spoilage.

How will the proper use of opiates be monitored and regulated?

Patients who are prescribed narcotics via intrathecal drug delivery devices have much better compliance than other patients. The medications are in a closed system which effectively prevents patient access – medication is contained in a reservoir inside the pump, which is implanted in the patient's body. Based on a thorough patient assessment, the pumps are programmed very precisely as per the physician orders, specifying the medication type, amount, and frequency. Intrathecal drug delivery provides the physician with much more control of how and when the medications are delivered than they are able to do if oral medications are prescribed. Patient compliance is simply not a variable with the intrathecal pump.

Have there ever been incidents of opiate abuse by employees of your company in any of the other states in which you operate? If so, please describe in detail how those were handled.

There has been one incident of opiate diversion by a nurse employee, which was discovered in 2009. Pentec reported the incident to the appropriate DEA Field Division Office, and thereafter Pentec executives worked with the DEA in implementing future safeguards. Pentec's action plan in response to this incident, which involved strengthening existing pharmacy, nursing and billing policies and procedures, was completed in 2009 and has been fully implemented. There have been no other incidents of diversion in the past six years, although more than 50,000 pump refills have been performed, and a similar number of deliveries of intrathecal medication have been made, during that time.

5. **Emergency procedures were addressed in the applications, but more detail is requested. What are the emergency procedures if there is an adverse reaction during the refill procedure?**

The emergency procedures if an adverse reaction should occur include calling 911, performing CPR if indicated, and administering Narcan (an FDA-approved opioid antagonist used to reverse an opioid overdose) if needed. Annual emergency training and review of mock emergencies are performed. Pentec nurses also complete hands-on CPR recertification every two years. Emergency response cards, with detailed information about intrathecal pump medications, are carried by Pentec nurses for reference. Also, Pentec nurses carry Narcan at all times for emergency use as noted above.

In addition to the *Medication Safety* policy discussed in the response to Question 3, Pentec has implemented specific policies to address inadvertent subcutaneous administration and emergency administration of Narcan:

- Specialty Infusion Policy and Procedure – *Management of an Inadvertent Subcutaneous Administration of Medication (Pocket Fill) During an Intrathecal Pump Refill Procedure*. This policy establishes the response procedures to be followed by the primary care nurse in the event that an inadvertent subcutaneous administration of medication occurs or is suspected.

- Specialty Infusion Policy and Procedure – *Emergency Administration of Naloxone*. This policy establishes the protocol for the emergency administration of Naloxone (Narcan) and related response procedures to be followed by the primary care nurse in the event of an opioid overdose.

For further information, copies of these policies and procedures are attached to this Response as Attachment to Question 5

After the procedure is complete and the nurse is still in the home?

In addition to the measures noted above, the nurse would also immediately notify the patient's physician and the appropriate Pentec Nurse Manager. The nurse would remain with the patient until EMS arrived, then accompany the patient to the hospital emergency department.

When nursing personnel are not in the home?

This situation would be the same whether the patient is treated in the physician's office or by Pentec in the patient's residence. However, to address this situation, Pentec nurses provide education with each interaction they have with the patient. Patient, caregiver, and family teaching regarding safety and signs or symptoms of complications are reviewed. Educational materials are given to the patient. Teaching includes basic home safety, detailed medication information, including signs and symptoms of withdrawal and overdose, when to call 911, and the availability of a nurse and pharmacist at all times via Pentec's 24-hour on-call system.

After the procedure, and nursing personnel have left the home?

This situation would be no different than if an adverse reaction occurred after the patient departed the office of a physician performing a refill, except that the risk is reduced under the Pentec model because of the additional time spent by the primary care nurse monitoring the patient after completion of the refill procedure and the training described in the responses above.

Beyond the items mentioned above, Pentec has a "high touch" model where the patient and nurse interact more frequently than when a patient is cared for directly by a physician or his or her staff. Also, if any programming or medication changes are performed, the nurse will follow up with the patient within 7 days of the change. Patients, caregivers, and families are taught and reminded to contact their primary care nurse with any concerns, questions, or changes at any time through Pentec's 24-hour on-call system.

It should also be emphasized that in every case, the treating physician determines whether intrathecal pump care by Pentec in the residential setting is appropriate and safe, remains responsible for the patient's case after the referral to Pentec is made, and will continue to examine the patient in the office as frequently as indicated. All Pentec patients have a plan of treatment that is approved by the treating physician, and the physician reviews this plan of treatment in accordance with the requirements of applicable law (in Tennessee, once every 62 days per Tenn. Comp. R. & Regs. § 1200-08-26-.06(3)). In addition, the primary care nurse enters his or her visit notes into the patient's chart in Pentec's EMR system within 24 hours after the visit (or sooner, if required by applicable law), and those notes are provided to the physician. The primary care nurse will also contact the physician directly as needed. This frequent communication and review allows physicians to make adjustments to the patient's plan of treatment – or to discontinue in-home treatment – as they determine necessary or appropriate. In short, the care provided by Pentec in the patient's residence is an extension of that provided by the treating physician.

6. **The patient to nurse ratio of 40 to 1 seems unrealistic, especially since both applicants sought to cover a large geographic area such as Tennessee. How many nurses would it take to provide adequate coverage In Tennessee, and from where would you hire these skilled nurses?**

Pentec would expand its patient/nurse coverage utilizing its proven staffing techniques for new markets. Pentec's highly skilled and knowledgeable nurse trainers will relocate to the regions in Tennessee where patient needs present, until two nurses can be hired to initiate patient care in Tennessee. Experienced registered nurses will be hired and trained in the areas where patient needs present and will complete Pentec's previously-mentioned training program. The 40:1 patient to nurse ratio is a guideline; where and how many nurses will be available is based on such factors as the location and the acuity of the patients. Additional nurse staffing considerations are the experience level of the nurses and the amount of time required for travel to patients' homes.

It is important to reiterate that, unlike the traditional home health agency whose nurses may need to visit a patient several times weekly or even daily, intrathecal pump management requires patient visits much less frequently – every 30 to 60 days in the majority of cases. For this reason, statewide coverage has not proved to be difficult in any state in which Pentec operates. Pentec has established the target patient-to-nurse ratio of 40:1 in its operations in other states and has determined through experience that statewide coverage at that ratio is manageable, even in large states such as Texas.

Pentec has implemented a policy to guide its regional managers in ensuring adequate nurse staffing in the regions for which they are responsible. This policy provides for regular assessment of primary care nurses' caseloads and adjustment of the target patient-nurse ratio as needed. A copy of this policy, entitled Specialty Infusion Policy and Procedure – *Evaluation of Staffing*, is attached to this Response as Attachment to Question 6.

7. **During the March 25, 2015 Agency meeting, Mr. Doug Wynd, Pentec National Sales Director of Specialty Infusion, stated there were approximately 80,000 individuals with implanted intrathecal pumps in the U.S, including 75,000 receiving ongoing care from their physicians and 5,000 receiving care in their homes from licensed home health agency nursing staff under physician orders. Mr. Wynd noted Pentec was serving approximately 2,800 of the 5,000 in the home setting (draft transcript, pages 37 and 53). Due to the wide variation in estimates of implanted pumps in Tennessee (IPM used 300 Medtronic implanted pumps while Pentec estimated approximately 1,730 total pumps) please clarify the difference in the two estimates, and document the basis for the estimates.**

For planning purposes Pentec uses commercial market data provided by HMS, a unit of HMS Holdings Corp. HMS Holdings and its affiliates provide coordination of benefits and payment integrity services for payers, including health and human services programs in 45 states and the District of Columbia; commercial insurers, including Medicaid managed care, Medicare Advantage, and group health plans; the Centers for Medicare & Medicaid Services (CMS); and Veterans Administration facilities. Data provided by HMS are derived from its claims database, which is the largest in the industry.

In its CON application, Pentec provided an estimate of 1,976 intrathecal pump patients in Tennessee. This estimate was derived from HMS data, and it is consistent with U.S. Census Bureau data estimates for 2014. The Census Bureau estimates that Tennessee's population in 2014 was 6,549,352, representing 2.054% of the estimated total US population of 318,857,056. Applying this percentage to the estimated 80,000 total pump patients in the US, the share attributable to Tennessee would be 1,643 pump patients. The fact that the HMS data indicate a higher number of pump patients in Tennessee may be a reflection of overall health status – according to the 2012 Update to the Tennessee State Health Plan, Tennessee ranked 39th of the 50 states in health status, so it would not be unreasonable to find a higher number of pump patients per capita. In any event, the estimated population data suggest that the number of pump patients in Tennessee is well above the figure of 300 provided by IPM.

Pentec has recently engaged in discussions with two medical practices in the Chattanooga area (Consultants in Pain Management and Specialists in Pain Management), which, combined, have an estimated 175 to 200 intrathecal pump patients. While it is possible that some of these patients may be Georgia residents, these numbers suggest that the total number of pump patients residing in Tennessee is much higher than the figure of 300 provided by IPM.

Please identify the number and source(s) of patients that are presently being treated in a physician's office in Tennessee.

If no licensed home health agencies are providing intrathecal pump services in Tennessee, then it is reasonable to assume that 100% of these patients are being treated in a physician's office or similar health care facility. At present, these patients do not have the option of seeking, and their physicians do not have the option of making a referral for, intrathecal pump services in the home.

Are any physicians expected to stop providing this service in the office if a home health option becomes available?

On the basis of its experience in other states, and as indicated by the national numbers cited in Question 7, above, Pentec reasonably expects that about 10% of all existing pump patients would be referred by treating physicians for in-home treatment. Pentec does not solicit patients directly, but it does call on physicians and practices that treat intrathecal pump patients to provide education on the services that Pentec can offer. The decision to refer any given patient is in the discretion of the physician.

8. **Please provide testimony (in person or by letter) from physicians with practices in each Grand Division of Tennessee (East, Middle, and West) who would support this specialty service in the home, including the approximate numbers of patients needing this service. Provide sufficient letters to support the service area requested.**

The following letters are attached to this Response as Attachment to Question 8:

1. Letter dated April 28, 2015, from Gregory Ball, M.D., Consultants in Pain Management, Chattanooga, Tennessee.

2. Letter dated December 1, 2014, from Richard Muench, M.D., Comprehensive Pain Specialists, Hendersonville, Tennessee. Comprehensive Pain Specialists is a statewide provider in Tennessee, with offices in Athens, Bartlett, Camden, Centennial, Chattanooga, Clarksville, Cleveland, Columbia, Cookeville, Dayton, Dickson, Franklin, Gallatin, Germantown, Hendersonville, Hermitage, Jackson, Knoxville, Lenoir City, Maryville, Morristown, Mt. Juliet, Murfreesboro, Oak Ridge, Savannah, Skyline, Tullahoma, Union City and White House.

As noted above, Pentec calls on physicians and practices that treat intrathecal pump patients to provide education on the services that Pentec can offer. However, it typically would not begin this process until the state home health agency license has been issued. Although Pentec has been in contact with several Tennessee physicians who treat pump patients, it cannot reasonably begin its usual physician education process before issuance of a certificate of need.

Provide letters of support from patients in each Grand Division of Tennessee not being treated due to not being able to travel to a physician's office as well as from patients who would find this home option more convenient. Provide sufficient letters to support the service area requested.

The following letter is attached to this Response as Attachment to Question 8:

Letter dated April 10, 2015, from Paula Pennington (inpatient at St. Thomas Hospital, Nashville, Tennessee). Please note that Ms. Pennington is a permanent resident of Kentucky who has traveled to Tennessee for other medical treatment and to visit family members, and who was unable to have her pump refilled during a stay in Nashville in October 2014.

Because Pentec is not presently licensed as a home health agency in Tennessee, it has no Tennessee patients. Pentec does not solicit patients directly – its patient referrals come from physicians who treat patients with intrathecal pumps. Consequently, Pentec takes the position that it would be ethically impermissible to contact directly any Tennessee residents with intrathecal pumps to solicit support for its CON application, even if it were possible to obtain these patients' contact information (e.g., from a treating physician) without a HIPAA violation. Rather, any such letters would need to be offered voluntarily, which is unlikely given that these patients would not know Pentec and may not even be aware that in-home intrathecal pump services are a treatment option.

Results of Pentec patient satisfaction surveys suggest that Tennessee patients, like those elsewhere, would be very supportive of Pentec's services. Pentec conducts these

surveys annually. The survey asks patients to assign a rating, on a scale of 1 (lowest) to 5 (highest), in 10 different areas. The survey is based on a large sample of the patient population – for 2014, 820 out 2,312 intrathecal pump patients, or 35% of the total, were surveyed. For the years 2011 through 2014, the average overall rating has been 4.8 out of 5.0.

9. How often does a physician have to see the patient before these medications can be refilled?

The intervals for intrathecal pump refills vary from patient to patient based on physician ordered medication concentration, daily dosage, and pump capacity. In most cases, the refill interval is between 30 and 60 days. However, in some cases the interval can be as frequent as every 10 days or as seldom as every 180 days. How often a physician needs to see a patient would be up to the physician's discretion based on the patient's needs, diagnosis, and assessment, and as mandated by applicable state law.

Regardless of the frequency of physician visits, communication between Pentec and the physician is regular and frequent. The physician reviews the patient's plan of treatment in accordance with the requirements of applicable law (typically, once every 60 days). In addition, the primary care nurse enters his or her visit notes into the patient's chart in Pentec's EMR system within 24 hours after the visit (or sooner, if required by applicable law), and those notes are provided to the physician. Pentec also has the capability of conducting secure, HIPAA-compliant videoconferencing between the physician, on the one hand, and the patient and the Pentec nurse, on the other, in the patient's residence at the time of the pump refill. Through this proprietary technology, the physician has the ability to observe both the patient and the procedure.

10. What is the current estimated cost and payor reimbursement by major CPT codes pertaining to intrathecal implanted pump refill visits in physician offices in TN?

Payer reimbursement varies; rates are largely dependent upon the codes that are billed, negotiated rates (which may differ between providers with the same payer), and specific patient circumstances. This question specifically requests CPT (Current Procedural Terminology) codes, which are commonly used by physician practices. However, it is important to note that home infusion therapy providers often use a separate coding set known as HCPCS (Healthcare Common Procedure Coding System).

Pentec has performed a review of major payers within the Tennessee and surrounding markets and has identified the following CPT codes which would apply to the refill and maintenance of patients with intrathecal pumps.

Code	Description	Rate
CPT 99601	Nursing visit, up to 2 hours	$94.00
CPT 99602	Nursing visit, each additional hour	$48.00

Pentec has also performed a review of major payers within the Tennessee and surrounding markets and has identified the following HCPCS codes which would apply to the refill and maintenance of patients with intrathecal pumps.

Code	Description	Rate
HCPCS A4220	Refill kit for implantable infusion pump	$50.00
HCPCS S-code	S-codes pertain to per diem; specific code is dependent upon the payer and the patient's condition being treated. S-codes pertain to infusion therapy and include administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment.	$57.00
HCPCS J-code	J-codes pertain to drugs; specific code is dependent upon the payer and prescribed product(s).	AWP less discount

How does this compare to your cost and reimbursement?

Pentec would be reimbursed for refill and maintenance of patients with intrathecal pumps substantially in accordance with the tables above. However, as noted above, reimbursement rates may be negotiated with a payer and may vary from payer to payer.

IPM projects an average gross charge of $200/visit while Pentec identified $2,517/visit. Although total gross revenue of both applicants is very close in Year 1 (approximately $300K), the difference in projected patient visits results in a wide variance in the projected average gross charge. Please identify the key components of your rate structure with related CPT codes used to bill for implanted pump refills in physician offices, home health, and pharmacy settings. Note: For purposes of comparison, it is suggested the key components of the

proposed rate structure identified in the Pentec application be used in the response for this question. Specifically, the rate would include the charges by four basic categories – medications, supplies/materials, nursing time and a per diem that covers allocated corporate support costs, such as IT, billing, etc. (transcript, Pentec presentation, page 54-55).

It should be noted that in Supplement No. 1 to its CON Application, in its answer to Section A, Applicant Profile, Item 13, Pentec revised its estimated gross charge per patient visit to $2,471, consisting of the following components:

Medication:	$ 588
Nursing Services:	71
Supplies:	37
Per Diem:	1,775*
Total:	$2,471

* The per diem charge covers the services necessary to render this type of care. A detailed list of items covered by the per diem charge is attached to this Response as Attachment to Question 10.

Regardless of whether the pump refill is being performed in the home, in a physician's office or in another setting, charges for medication will be dependent upon whether the service provider is compounding the medication independently or purchasing it directly from a supplier, and will vary.

Charges for nursing services are likely to be consistent from one setting to another. However, the charges in a physician's office setting will vary depending upon any procedures the physician is performing and whether the physician is performing the service vs. a nurse or other health care professional. The CPT codes that could be billed by a physician and that relate to the maintenance and refill of the pump are captured in the table below. However, Pentec does not have access to any of the corresponding reimbursement rates.

CPT Code	Description
62367	Analyze spine infusion pump
62368	Analyze spine infusion pump
95990	Pump refilling, maintenance
95991	Pump refilling, maintenance, administered by a physician
A4220	Pump Refill Kit
J-Codes	Drug charge

Charges for supplies are likely to be consistent from one setting to another.

The per diem charge is unique to the home health care setting, and the codes billed are specific to the home setting. Per diem codes are identifiable as S-codes.

The following is a list of payers, including the number of covered lives in Tennessee, that have recognized the value of services provided by Pentec by agreeing to pay Pentec's rates:

MCO Name	Covered Lives: TN	Contract Status
BlueCross BlueShield of Tennessee	2,006,613	OON
Cigna Corporation	921,379	CCX contract
UnitedHealthcare	669,646	OON
Aetna	258,693	HIT Contract
Humana, Inc.	237,000	HIT Contract
Anthem, Inc.	211,795	In Process
Blue Cross and Blue Shield of Alabama	46,199	OON
Centene Corporation	21,200	In Process
Independence Blue Cross (IBC)	10,295	HIT Contract

11. Provide comprehensive state regulations for each state in which you operate this type program.

A list and summary of the principal state statutes and administrative regulations applicable to the in-home provision of Specialty Infusion services by Pentec's primary care nurses is attached to this Response at Appendix: State Regulations.

How are these agencies regulated by each state, as home health agencies or pharmacies or as some other type entity?

The type of state regulation that applies to Pentec's Specialty Infusion division reflects the services provided and how those services are classified under applicable state law. Of the services typically associated with home health care, Pentec's Specialty Infusion division provides just one: skilled nursing. Pentec does not provide physical, occupational or speech therapy; home health aide services; or medical social services. In a number of states in which Pentec operates, provision of skilled nursing alone, without any of the ancillary services, triggers the requirement for home health licensure. In each case, the appropriate regulatory agency is the state Department of Health. States in which Pentec is licensed as a home health agency are:

1. Colorado
2. District of Columbia
3. Indiana
4. Kansas (2 HHA licenses; offices in Overland Park and McPherson)
5. Minnesota
6. Nebraska
7. New Hampshire
8. New Mexico
9. Texas
10. Virginia

In other states in which Pentec operates, the provision of skilled nursing services, without ancillary home health services, triggers a licensure requirement, but for a licensure category other than home health agency. In each of these states except New Jersey, the appropriate regulatory agency is the state Department of Health; in New Jersey, regulation is provided by the Office of Attorney General, Division of Consumer Affairs. These states, and the categories of license held by Pentec, are as follows:

1.	Illinois	Home Nursing Agency
2.	Kentucky	Mobile Health Service
3.	Maryland	Residential Service Agency
4.	New Jersey	Health Care Service Firm
5.	North Carolina	Home Care Agency

In the remaining states in which Pentec provides services through its Specialty Infusion division, Pentec has determined, after discussion with and confirmation by the appropriate Department of Health staff, that licensure at the entity or agency level is not required. In each of these states, skilled nursing services may be performed in the patient's place of residence by a registered nurse licensed to practice in that state (or in a Nurse Licensure Compact state, if applicable). These states are listed below, together with the reason that home health agency licensure is not required:

1.	Alabama	No licensure unless nursing + other services provided
2.	Arizona	No licensure unless nursing + other services provided
3.	Connecticut	No licensure unless nursing + other services provided
4.	Delaware	No licensure unless nursing + 1 other service provided
5.	Florida	No licensure unless nursing + 1 other service provided
6.	Georgia	No licensure unless nursing + 1 other service provided
7.	Iowa	No state licensure of HHAs
8.	Louisiana	No licensure unless nursing + 1 other service provided
9.	Massachusetts	No state licensure of HHAs
10.	Michigan	No state licensure of HHAs
11.	Mississippi	No licensure unless nursing + 1 other service provided
12.	Missouri	No licensure unless 2 or more services provided
13.	Ohio	No state licensure of HHAs
14.	Oregon	No licensure unless nursing + 1 other service provided
15.	Pennsylvania	No licensure unless nursing + 1 other service provided
16.	South Dakota	No state licensure of HHAs
17.	Vermont	No licensure unless nursing + 1 other service provided
18.	West Virginia	No licensure unless 2 or more services provided
19.	Wisconsin	No licensure unless nursing + 1 other service provided

None of the 34 jurisdictions in which Pentec's Specialty Infusion division is active has specific statutes or regulations pertaining to provision of intrathecal pump services in the home health setting. However, several states address intrathecal administration of medication in their home health care or nursing statutes or regulations, and these are discussed in the Appendix: State Regulations attached to this Response. Other state statutes and regulations that address intrathecal drug administration are not applicable to Pentec, e.g., those addressing (i) restrictions or prohibitions on intrathecal administration by licensed practical nurses and medical assistants (see, e.g., Tenn. Code Ann. 63-7-127(k)(3)), because Pentec uses only registered nurses, (ii) reimbursement under state Medicaid programs, and (iii) allowable therapies under state workers' compensation insurance programs.

Pentec is already licensed as a pharmacy in Tennessee (license number 4108), as well as the 49 other states and the District of Columbia; and it is registered with the federal DEA (registration number BP9684627). Pentec also has a Tennessee-licensed pharmacist-in-charge (Mr. Cliff Slavin; license number 0000028463). Because Pentec is seeking a CON for a home health agency, the attached Appendix: State Regulations does not address state pharmacy statutes or pharmacy board regulations. However, Pentec's pharmacy is compliant with all regulations of the Tennessee Board of Pharmacy (Tenn. Comp. R. & Regs. § 1140-01-.01 et seq.) that apply to its present operations in Tennessee; and Pentec would be able to comply with any additional applicable provisions of the Board of Pharmacy regulations if it were licensed as a home health agency.

Pentec notes in particular the comments of Commissioner Dreyzehner in his letter to Ms. Melanie Hill, Executive Director of the HSDA, dated March 17, 2015. First, Commissioner Dreyzehner noted that a dispenser is required under federal law to deliver a controlled substance to an ultimate user. Pentec's pharmacy handles controlled substances in accordance with the "closed system of distribution" contemplated by the federal Controlled Substances Act, 21 U.S.C. 801 et seq. and its implementing regulations, 21 C.F.R. Part 1301. When the Pentec pharmacy ships a container of

intrathecal medication to a Pentec primary care nurse, it is shipping to an employee of the DEA registrant, i.e., Pentec Health, Inc., who in turn delivers the medication directly to the ultimate user. This is consistent with the Tennessee Board of Pharmacy regulations on storage, sale and delivery of prescription drugs and controlled substances, which state that "[n]othing in this section prohibits delivery of a prescription to a patient's home or business by an agent of the pharmacy practice site." Tenn. Comp. R. & Regs. § 1140-03-.12(5).

Second, Commissioner Dreyzehner noted that the Board of Pharmacy regulations require face-to-face patient or caregiver counseling by a pharmacist when dispensing drugs. These regulations also provide that "[i]f the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means." Tenn. Comp. R. & Regs. § 1140-03-.01(1)(a). Pentec makes an offer to counsel patients or caregivers at the time of admission (or change in medication) through the primary care nurse, who is an employee of the DEA registrant; and, if desired by the patient or caregiver, Pentec has a pharmacist on call 24/7 from whom the patient or caregiver can also receive counseling.

Commissioner Dreyzehner also noted that the applicant must have written policies addressing personnel training and oversight related to drug diversion and drug screening. As noted elsewhere in this Response, Pentec maintains and continually updates a comprehensive manual of administrative, nursing and pharmacy policies and procedures, and several of the relevant policies are discussed in and attached to this Response, e.g., Administration Policy and Procedure – *Nurse Training Program*; Pharmacy Policy and Procedure – *Prescription Requirements and Review*; Pharmacy Policy and Procedure – *Controlled Drug Substance*; and General Policy and Procedure – *Narcotic Waste Disposal*.

Disclose and discuss any sanctions of existing licenses in other states in which you operate this type program and provide evidence that your company is in good standing.

As discussed in its CON Application at Section C, Contribution to the Orderly Development of Health Care, Item 8, Pentec received a Notice of Citation from the Indiana State Department of Health in August 2011 alleging a breach of licensure requirements, paid a civil fine of $10,000, and submitted a Plan of Correction that was accepted by the Department. Since then Pentec has been, and remains, in good standing in Indiana. A copy of its current HHA license, and the related cover letter from the Indiana State Department of Health, is attached to this Response as Attachment to Question 11.

Other than the August 2011 citation by the Indiana State Department of Health, Pentec has not been cited by any state in connection with the services offered by its Specialty Infusion division.

Have you ever been denied a certificate of need or a license (home health or pharmacy) in any state? If so, please provide documentation such as staff reports, minutes, denial letters, and/or transcripts.

Pentec has never been denied a certificate of need, home health agency license (or other appropriate license), or pharmacy license in any jurisdiction.

12. Did either applicant consider contracting with existing home health agencies to provide this service? If not, please explain why. In a contractual situation, the services could be provided under an existing agency's license utilizing IPM or Pentec nurses to provide the service.

Pentec has explored the possibility of partnering with other licensed agencies in a small number of other jurisdictions (e.g., in response to a statewide moratorium on issuance of new home health care licenses) to provide services to intrathecal pump patients. After evaluating the advantages and disadvantages of the partnership model, Pentec decided not to pursue these arrangements. Some of the specific factors that Pentec considered in those cases are discussed in the "pros and cons" below.

Pentec did not consider entering into such a relationship with an existing Tennessee home health agency licensee.

Discuss the pros and cons of this scenario and how reimbursement would differ.

In the hypothetical scenario described above, Pentec's role would be analogous to that of a nurse registry or nursing agency, i.e., it would furnish appropriately-licensed and trained registered nurses on a contract basis to provide services to patients of the licensed home health agency (pursuant to Tennessee Department of Health Regulations § 1200-08-26-.06(1)). Because Pentec would not have a home health agency license itself, under applicable Tennessee law it could not: (1) hold itself out as a provider of home health services; (2) provide services to patients in its own name; (3) accept patient referrals; (4) solicit patient referrals from physicians; (5) bill payers for services (including supplies, medications and per diem charges); (6) supervise its nurse-employees while they serve patients of the licensee; (7) enforce its policies regarding patient care, patient safety or delivery and storage of intrathecal medications; (8) permit use of its electronic medical records system; or (9) permit use of its 24-hour on-call system.

The pros and cons of such an arrangement are as follows:

Pros:

- Tennessee residents with intrathecal pumps who must travel to a physician's office or other health care facility for treatment would be able to receive treatment in their homes by registered nurses who are specialized providers of such care.

- Tennessee physicians who treat residents with intrathecal pumps would have the option of referring patients for specialized in-home treatment in cases where it is medically appropriate.

Cons:

- Pentec has a long history of providing the highest possible quality care of intrathecal pump patients in the residential setting. The only way to ensure that this high level of quality is maintained is to have complete control over every aspect of the patient care process.

- Pentec has developed, over a period of many years, comprehensive policies governing provision of nursing care, patient safety, and the handling of controlled

substances and other intrathecal medications (amongst others), and has developed management systems around these policies. Because Pentec would be a contract service provider, its nurses would be under the control and supervision of a third party, rather than Pentec, and would be required to follow the policies and procedures of that third party.

- Pentec's service delivery model involves close coordination between Pentec, patients and caregivers, and patients' referring physicians, including access by patients and their physicians to medical records through Pentec's proprietary Physician Portal and Patient Portal. As a contract service provider, Pentec would not have direct relationships with either patients or physicians, and, consequently, these systems could not be employed.

- Through its proprietary communications system, Pentec nurses are available to handle patient calls on a 24/7 basis. As a contract service provider, Pentec would not have patients and could not offer this essential service to patients directly.

- The largest component of Pentec's charge per patient visit is the "per diem" – a charge that covers the allocated costs of items such as the aforementioned electronic medical records and communications systems, related information technology systems and support, 24/7 on-call registered nurse and pharmacist, billing, etc. Although the other components of the charge – nursing services, supplies, and medications – could be passed through to the contracting licensee, the per diem charge relates to services and functions which, under Tennessee Department of Health Regulations § 1200-08-26-.04(5), discussed below, cannot be delegated by a licensed agency to a contractor. If the contracting licensee were required to provide these functions, but could not recover their cost through the per diem charge, the proposed arrangement likely would be economically unattractive to the contracting agency. Moreover, the capital investment required to develop and maintain all of the systems covered by the per diem charge would be so large that a contracting agency would most likely be discouraged from providing them in the first place.

- It is questionable whether any existing licensee would have, or have the resources or incentive to develop, the necessary relationships with physicians and practices who are specialists in the areas of interventional pain management and spasticity and who presently treat patients with intrathecal pumps.

- Pentec maintains comprehensive liability insurance coverage, including professional liability. Although it would run the risk of being named a defendant in an action arising from the contracting licensee's acts or omissions, it is questionable whether Pentec's coverage would extend to such situations.

- The Tennessee Department of Health Regulations, at § 1200-08-26-.04(5), state that "[a]dministrative and supervisory functions shall not be delegated to another agency." These non-delegable administrative and supervisory functions include (but are not limited to) provision of continuing education (§ 1200-08-26-.04(13)); development of appropriate policies and procedures (§ 1200-08-26-.04(15)); maintenance of medical records (§§ 1200-08-26-.05(9) and 1200-08-26-.06(11)); completion of a discharge plan (§ 1200-08-26-.05(9)); development of a plan of care (§ 1200-08-26-.06(3)); performance improvement planning (§ 1200-08-26-.06(9)); and development of

infection control procedures (§1200-08-26-.06(10)). Pentec has already developed, implemented and refined all of the foregoing as they relate specifically to the care of patients with intrathecal pumps, and questions how effectively these (and other) functions could be carried out by another licensed agency if Pentec's role were limited to that of contract service provider.

If an existing contracting licensee were able to provide the many services and functions covered by the per diem charge, then reimbursement may be substantially the same whether Pentec's services were provided directly or under contract with the licensee. However, for the reasons noted above, a contractual arrangement does not appear to be feasible from an operational perspective, and would probably be unattractive financially to any prospective Pentec partner.

13. Should the Agency determine there is a need for this type specialty home health agency, would the applicants be willing to consider approval for only half of the service area requested so that two agencies would cover the state instead of just one?

Approval to serve a portion of the state may be problematic from a physician referral perspective. Pentec has learned through experience that (1) because there are relatively few physicians who practice in the area of intrathecal medicine, these practices tend to draw patients from a wider geographical area than would ordinarily be the case, and (2) patients who must travel long distances for treatment at the physician's office are often good candidates for referral to Pentec for in-home treatment. If a strict geographic service area limitation is imposed, physicians may be less willing to consider an in-home option if Pentec is able to treat some, but not all, of the physicians' intrathecal pump patients.

A geographic restriction would also be detrimental to some Tennessee residents who have intrathecal pumps as they would be simply unable to obtain the high-quality care that Pentec offers in the home for the benefit of both patients and their family members or caregivers.

Would the project still be financially feasible if only a portion of the service area were approved?

The financial feasibility of Pentec's Specialty Infusion services is a function of patient census rather than geographic service area. Restriction to a portion of the state would be less financially attractive for Pentec, although in some jurisdictions in which Pentec has implemented Specialty Infusion services, it has been able to achieve break-even with 5-10 patients. However, such a restriction would not be in the best interest of Tennessee patients, because their ability to receive the high-quality, specialized in-home care offered by Pentec would be determined by their place of residence and not by more appropriate factors. And, as noted above, a geographic restriction would similarly limit physicians' ability to make referrals to Pentec.

ATTACHMENT TO QUESTION 1

The attached letter is provided by Stanley P. Fisher, M.D., Co-Director of St. Luke's Marion Bloch Neuroscience Institute, Kansas City, Missouri.

A biographical sketch for Dr. Fisher follows:

Dr. Stanley Fisher is currently serving as a Co-Director of Saint-Luke's Marion Bloch Neuroscience Institute (SLMBNI) in Kansas City, Missouri. He joined the SLMBNI in March of 2015 with the task of helping to create nationally recognized state-of-the-art Comprehensive Neuroscience Institute in the Kansas City area, in order to advance clinical practice and research in the field of neurosciences in close collaboration with University of Missouri-Kansas City School of Medicine.

Prior to that Dr. Fisher was with Houston Methodist Neurological Institute (HMNI) for more than nine years. He was a Founder and Co-Director of the Movement Disorders and Neurorehabilitation Center at HMNI, Elected Deputy Vice Chair of Neurology at the Houston Methodist Hospital as well as Associate Professor of Clinical Neurology at Weill Cornell Medical College and a Fellow of American Neurological Association. He also was appointed an Associate Member of Houston Methodist Research Institute in recognition of his achievement in clinical and translational research.

Under his leadership, the Houston Methodist Neurological Institute Movement Disorders and Neurorehabilitation Center has become one of the centers of excellence for deep brain stimulation, intrathecal baclofen and botulinum toxin therapy with frequent on-site training for neurologist and physiatrists from all over the country. Dr. Fisher was actively involved in training of students, residents and fellows during his tenure and for 8 years served as a Co-Chair of the HMNI Annual Advances in Neurology seminar, that attracted neuroscientists from every state of the union.

Dr. Fisher was a robotic engineer before returning to Temple University in Philadelphia, Pennsylvania, where he graduated Summa Cum Laude with a BA in Biology and Cognitive Neuroscience. During his college years Dr. Fisher was a well-known Personal and Fitness trainer in Philadelphia.

Dr. Fisher graduated from the MCP-Hahnemann School of Medicine in Philadelphia and completed his internship before moving to Texas. After he completed his residency in Neurology and Fellowship in Movement Disorders at The University of Texas-Houston, Dr. Fisher combined his skills as a robotic engineer, fitness trainer and neurologist to do research in the use of robotically-assisted technology for neurological rehabilitation. He became a nationally-recognized expert in the field of Neuromodulation, utilizing implantable devices for the treatment of Parkinson's disease, tremor, dystonia as well as spasticity due to stroke, multiple sclerosis, traumatic brain and spinal cord injury. For eight years he has served as a Founder and Program Director for Neurological Rehabilitation at the HealthSouth Center for Neurological Research and Recovery in Houston, TX which included four Acute Rehabilitation Hospitals in Houston Area.

For the last 2 years he has served as a Program Director for Neurological Rehabilitation for Reliant Hospitals in Houston area.

Dr. Fisher was involved in clinical research related to psychosis and emotional lability in patients with neurodegenerative disorders. For the last three years he was serving as a Medical Director for four Silverado Memory Care communities in Houston.

During his tenure in Houston, Dr. Fisher conducted sponsored and investigator-initiated trials in the field of Parkinson's Disease, stroke, spinal cord injury and Alzheimer's Disease.

Saint Luke's
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Stanley P. Fisher, M.D.,
Co-Director
Saint Luke's Marion Bloch neuroscience Institute

Inherent Risk of the Intrathecal Pump

There is inherent risk in any surgical procedure and any use of an implanted medical device, including the intrathecal pump. Nevertheless, there are at present an estimated 80,000 intrathecal pumps in use in the United States (including an estimated 1,976 in Tennessee), reflecting physicians' belief that the benefits of the intrathecal pump to their patients outweighed the inherent risk in the surgical implantation and subsequent use and maintenance of the pump. Moreover, use of the intrathecal pump has been approved by the U.S. Food and Drug Administration (FDA). The FDA approved the first intrathecal pump in 1999, and has approved additional pump models since then.

Pentec has no involvement the physician's recommendation or the patient's decision to undergo pump implantation surgery. All patients referred to Pentec for in-home care already have an intrathecal pump, and the initial pump fill has already been performed by a physician in a hospital or other setting outside the home. These decisions will be made, and pump implantation surgeries will occur, whether or not Pentec is involved in the patients' ultimate care.

Routine Pump Maintenance

The protocols for maintaining patient safety when an intrathecal pump is refilled are substantially the same whether the refill done in a physician's office or the patient's home. There are guidelines and standards set forth by the medical community, and, specifically, by the Polyanalgesic Consensus Conference (PACC). The PACC is a group of experienced and well-published health care practitioners who, based on current knowledge in the literature and clinical experience, meet periodically to update the standards of care for intrathecal pump therapies.

However, there are also inherent risks in the use and maintenance of the intrathecal pump once it has been implanted in the body of the patient. Chief among these are the risk of introducing an infection, the risk of subcutaneous administration of medication, and the risk of a pump programming error. In addition, intrathecal pumps, like other medical devices, have malfunctioned on rare occasions. A greater risk may be that of the pump simply running dry, which can lead to serious bodily harm or death, due to the patient's inability to travel to the physician's office for a scheduled refill and maintenance appointment. However, by offering safer, more efficient care to intrathecal pump patients at their place of residence, Pentec is able to reduce some of these inherent risks.

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Pentec Care and Safety Protocol

The difference between performance of the pump refill and maintenance in the physician's office versus in the patient's home by Pentec has to do with the level of training, experience and skill of Pentec's nursing staff and Pentec's comprehensive policies and procedures for patient care and safety. Pentec's primary care nurses treat intrathecal pump patients as a full-time occupation. Their employment begins with the most rigorous training in the industry. Although intrathecal pump manufacturers offer training courses of several weeks' duration, Pentec's training program is the only American Nurses Credentialing Center (ANCC) accredited program of its kind. Pentec nurses attend an intense, 90-day training program that assures patient safety in accessing, refilling, and managing intrathecal pumps. Included in the nurses' training is the successful completion of a 10-page competency tool confirming the highly-specialized knowledge and skills taught in the training program. This training is reinforced with continuing education and periodic competency testing.

Pentec's "high touch" model provides for frequent contact and interaction between refills to continually assess and monitor the status of the patient's intrathecal therapy. Every patient is provided with his or her assigned nurse's direct telephone number and can contact the nurse whenever there is a need. All patients can also use Pentec's 24-hour on-call service to reach the on-call nurse or pharmacist. Most significantly, Pentec employs a primary care delivery model. This creates consistency, promotes a therapeutic relationship with patients, and encourages early intervention which helps prevent hospitalizations.

Over a period of many years, Pentec has developed and implemented stringent policies and procedures to ensure consistently high-quality patient care, prevent the occurrence of infection, and respond appropriately if an emergency arises. As a result, Pentec's primary care nurses are more likely to recognize a problem, such as a pump malfunction, and to respond appropriately, than would a health care professional who has less frequent contact with intrathecal pump patients. By providing care in the patient's home, on a scheduled basis well before the "alarm date" (the date on which the pump must be refilled) Pentec eliminates the drug withdrawal risks that can occur due to a missed appointment and pump running dry.

In short, while the inherent risks involved with the intrathecal pump can never be eliminated entirely, providing pump refills and maintenance to patients on a regular basis in the home by specially-trained professionals represents the safest mode of ongoing care and treatment for this patient population.

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ATTACHMENT TO QUESTION 2

1. Administration Policy and Procedure – *Nurse Training Program*.

2. Accreditation letter from the American Nurses Credentialing Center (ANCC) dated September 24, 2013.

PENTEC HEALTH AND AFFILIATED COMPANIES

ADMINISTRATION

POLICY AND PROCEDURE

1.8 NURSE TRAINING PROGRAM (An ANCC-Accredited Nursing Skills Competency Program. Expiration date is September 2016)

PURPOSE:

To ensure proper training for each nurse hired to maintain consistent, high quality care in the provision of services to high tech patients served by Pentec Health, Inc.. To provide each newly trained nurse with a mentor to support them through their orientation, training and professional development.

POLICY:

1. Primary Care Nurses are interviewed and selected by a Regional Nurse Manager, a member of the Training Team, and/or the Vice President, Nursing Services.

2. All Primary Care Nurses are oriented to Pentec policies and procedures by a member of the Training Team and a Regional Nurse Manager as part of their orientation. This is provided during a two week intensive classroom presentation. The first week of classroom is presented by the Regional Nurse Manager and includes general orientation to the company (see New Associate Orientation Checklist Specialty Infusion-Nursing) as well as beginning introduction to the EMR, Programmer, Refills, etc.

3. The second week of classroom presentation is given by a member of the training team. The new Primary Care Nurse is given hands on practice with the N'Vision Programmer and practice with accessing Synchromed pumps as well as practice with the EMR system. The new PCN is introduced to the clientele serviced by Pentec Health along with the theory behind administration of intrathecal medications via an implanted pump. All trainers have completed a preceptor training program focused on adult learning.

4. Following completion of the classroom session, the new Primary Care Nurse will either spend two weeks in a high volume area (Pennsylvania or other high volume area) to do intensive access training or will return to his/her home area to start training with a Preceptor. Preceptors are experienced Primary Care Nurses who have completed the one day Preceptor Workshop. If there has been training in the high volume area, an Orientation Progress Report will be initiated via conference call prior to the new hire returning to their home area.

5. The training in the home area will encompass all aspects of care including but not limited to new admissions, pump refills, pump adjustments, patient assessments, physician contact and documentation. This training will be guided by a Preceptor (if in an existing area with an established patient base) or a Trainer (in an expansion area without established patients). At the end of each week, a report will be given to the Regional Nurse Manager and the Director of Education outlining the weekly progress and goals for the coming week.

6. At the completion of three months, the nurse will take a knowledge exam proctored by the Trainer or Regional Nurse Manager. The nurse must obtain a passing grade of 80%. (See Measurements of Success policy.) Remedial instruction will be given for all incorrect answers.

7. Orientation is not completed until the Preceptor/Trainer, the Director of Nursing Education and the Regional Nurse Manager are in agreement that the new Primary Care Nurse has successfully completed all areas of the "Initial Competency Tool for Nurses." Another conference call will be done at this time and an Orientation Progress Final Report will be completed. At this time a mentor will be assigned to the new PCN.

8. In the event that the Primary Care Nurse is unable to complete all aspects of the initial competency tool due to lack of exposure to those patients with the specified competency (Synchromed EL refill/programming, advanced flex programming, medication change with bridge bolus, reservoir rinse) the skill can be demonstrated in demo mode/simulation and can be marked as a demonstrated competency from that. When the nurse then encounters the actual situation she will notify the Regional Nurse Manager and discuss the procedure prior to seeing the patient.

9. The Nurse Training program has an expiration date of 3 years from the initial certification/recertification.

10. Primary Care Nurses shall follow the job description for the Primary Care Nurse as outlined by Pentec Health.

11. The Regional Nurse Manager will attempt to visit onsite a minimum of once yearly for the purpose of performance evaluations. The Regional Nurse Manager will arrange for yearly peer reviews on all staff. The "Annual Competency Tool for Nurses, Intrathecal Pump" will be filled out at that time, showing that they are competent to perform the necessary procedures and will be kept in their employee files.

Effective: 10/09
Revised: 4/10
Reviewed: 7/10
Revised: 6/11
Revised: 9/11
Revised: 4/12
Revised: 8/12
Revised: 10/13
Revised: 07/2014

NSCP0017

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September 24, 2013

Karen McHenry, MSN, RN
Vice President, Nursing Services
Pentec Health
4 Creek Parkway
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Karen,

The Commission on Accreditation is pleased to inform you that the Nursing Skills Competency Course "Intrathecal Nurse Training Program" has been accredited for three years. The period of accreditation is from September 23, 2013 – September 30, 2016.

Of note, please revise the program certificate to include the full accreditation statement (see below), remove the phrase "ANCC Credentialed" and remove "3 Years" under the expiration date. Additionally, a summary of findings from the review team is attached.

Programs accredited under the Nursing Skills Competency Program are required to use the following accreditation statement on all documents of completion and other materials referencing the accredited program:

"Intrathecal Nurse Training Program" is an ANCC-accredited Nursing Skills Competency Program. Expiration date is September 2016.

The Commission acknowledges your commitment to life-long learning and commends you in achieving accreditation.

Pamela S. Dickerson, PhD, RN-BC

Pamela S. Dickerson, PhD, RN-BC
Chairperson, Commission on Accreditation

NSCP0017

Summary of findings:

- Competency is re-evaluated annually. Peer reviewers complimented the applicant on this requirement given the high-risk involved with this skill set.

- Content about pump operation and medication administration was reviewed as "excellent and commendable" by the peer reviewers.

- Standards were not identified in the reference list and peer reviewers noted that content may have been more robust if they had been used to develop the content, particularly the content about different complex patients. This should be a consideration for future applications by this organization.

- Peer reviewers noted that members of the planning team have adequate expertise in management of intrathecal pumps, however there is no one named on the planning committee who has expertise in the administration of medications typically delivered by these pumps (pain medications, medications for spasticity). Additional evidence submitted revealed that the Medical Director for the Pain Management division "has reviewed, commented, and expressed support of the training program content" and additionally that the Pharmacy Manager and Pharmacist provide all pharmaceutical information for the course. The peer reviewers recommended that in the future, these personnel be formally named to the planning committee in all course/application documents.

ATTACHMENT TO QUESTION 3

1. Infusion Policy and Procedure – *Medication Safety*.
2. Specialty Infusion Policy and Procedure – *Synchromed Infusion System Refill*.
3. Specialty Infusion Policy and Procedure – *Patient Safety Checklist*.
4. *Infection Control Policies and Procedures*.

PENTEC HEALTH AND AFFILIATED COMPANIES

MEDICATION

INFUSION POLICY AND PROCEDURE

7.0 Medication Safety

Purpose: To promote patient safety in medication administration.

Procedure:

1. Upon receipt of medication delivery, check medication label, script, and most recent telemetry, if available, for programmable pumps, and last refill note, if available, for non-programmable pumps. . Complete Medication Check-In section of Safety Checklist.

2. Review medication label with the patient/caregiver per the five rights :
    a. right patient- confirm name and dob
    b. right medication
    c. right concentration/dose
    d. right route
    e. right time

3. Interrogate pump prior to refill if pump is programmable. The data on interrogation will match the medication label and the physicians order unless a change is ordered. For non-programmable pump, the data on the last refill note, medication label, and script will match. Any variance will prevent the RN from performing the refill until a clarification has been obtained. Complete Before Pump Access section of Safety Checklist.

4. After update and refill, if appropriate, review complete telemetry with patient or caregiver for programmable pump. For non-programmable pump, review medication and expectation for next visit. Complete After Pump Refill section of Safety Checklist.

5. Labels with patient identifiers found on the syringes and plastic bag should be treated as private patient information. Labels may be wiped

down with alcohol to remove the ink, torn off , or blacked out with permanent marker prior to disposal.

Original: 10/2012
Revised: 10/2013
Revised: 06/2014

5.9 Synchromed Infusion System Refill

Policy:

Refill implantable pump for pain management, spasticity management, or chemotherapy administration using a specific set of tasks to help ensure patient safety. Clinicians performing this refill must be registered nurses who are trained on the correct procedure and have met the Pentec competency guidelines.

Procedure:

1. Gather appropriate supplies. Use the supplied refill kit for the appropriate therapy.

   Note: Nurses are to use a protective barrier for the programmer, if necessary, when taken into the patient's home.

2. Locate the implanted pump in the patient. Palpate the pump through the skin to identify the necessary landmarks before establishing the sterile field.

3. Determine the location of the center reservoir refill port by palpating the margins of the pump and locating the catheter access port (CAP) as a reference point.

4. Interrogate the pump.

   a. Select the check box for " Logs ", enabling Logs to be recorded.

   b. Confirm the patient's name and date of birth, if not already programmed please add.

5. Follow medication safety policy checks before moving forward.

   Note: Below steps may vary in sequence based on nurses preference but sterility and patient safety must always be maintained. Use of hand sanitizer is needed between each glove change and as needed

6. Program any appropriate new parameters and perform update to the pump. Review the new pump settings screen for accuracy. Wipe the telemetry head of the programmer with alcohol and allow it to air dry after use.

   Note: Always program a bridge bolus when changing the primary drug concentration. The bridge bolus may be bypassed when making changes to medications other than the primary medication, based on nursing judgment. If the bridge bolus is bypassed, a comment is required in the notes section of the Patient Information tab to reflect the content of the catheter and either the duration of the bridge bolus or the approximate time the bridge bolus would be complete. Thoroughly educate the patient as to the expected time the new medication will begin to infuse. If the patient has a PTM, the PA doses will shorten the duration of the bridge bolus. For example: CAUTION: Bridge bolus bypassed, Hydromorphone 10 mcg/mL and Bupivacaine 30 mg/mL will infuse through 06/04/14 at 1251.

7. Open the dressing kit and refill kit. Place mask over mouth and nose. Don sterile latex-free gloves.

8. Cleanse entire pump area with povidone-iodine using sterile technique. Alternate skin preparation products may be used based on physician preference and policy for povidone iodine allergy.

9. Place the fenestrated sterile drape over the patient exposing the pump site.

10. Using sterile technique, assemble the 22-gauge Huber-type needle (1.5" or 2") and the empty 20 ml syringe to the extension tubing set with clamp. Use only the 22-guage needles included in the refill kit; use the 1.5" needle whenever possible. Ensure all connections are snug to maintain a closed system. Close the clamp on the extension tubing.

11. Select and place template over pump, aligning appropriate edges of template with edges of pump.

12. Maintaining sterile technique, insert needle through template center hole and into pump septum until the needle touches the needle stop. Avoid using excessive force with insertion as it will damage the needle tip area and possibly the septum when removed.

    Note: When inserting the needle you should feel the needle pass through the patients skin and subcutaneous tissue, hit the silicone septum, pass through the septum and hit the metal bottom of the refill port.

13. While ensuring that the needle stays securely in the septum, open the tubing clamp and

slowly withdraw fluid from the reservoir using gentle negative pressure. Empty the reservoir completely, until air bubbles are present in the extension tubing.
Accessing the center fill port should create negative pressure upon complete aspiration of the reservoir contents.

> ***Note:*** Failure to withdraw all residual medication from the reservoir and then subsequently attempting to overfill the reservoir may lead to reservoir over pressurization or activation of the reservoir valve.
> ***Note:*** If decreasing concentration or changing medications, perform a reservoir rinse, refer to Nursing Policy and Procedure on Reservoir Rinses for complete step by step instructions.
> ***Note:*** If drug concentration is of concern because there is a risk of under-dose or withdrawal symptoms, consider rinsing the pump with a portion of the new drug after performing the saline rinse. See step by step instructions in Nursing Policy and Procedure Reservoir Rinses.

14. Close the clamp. Ensure that the tubing system remains closed and that the needle with extension tubing attached remains in the reservoir septum. Rest the extension tubing carefully within the sterile field.

    ***Note*:** Failure to close the clamp completely could result in pump contamination, reservoir valve activation, over-pressurization of the pump reservoir. If reservoir valve is activated refer to Nursing Policy and Procedure on Reservoir Valve Deactivation.

15. Record the amount of medication withdrawn from the pump. The expected and actual amount of medication withdrawn should be compared and documented. A discrepancy of greater than 14.5% (+/- 10%) may be reported to the physician depending on nursing judgment. Calculation is based on the following formula provided by Medtronic:

16. Flow Rate % Error = $\frac{\text{(Expected Residual Volume in mL - Actual Residual Volume in mL)}}{\text{(Previous Refill Volume in mL - Expected Residual Volume in mL)}} \times 100$

17. Prepare the medication filled syringe by removing the air bubbles, attaching the filter, and priming the filter

18. Confirm the clamp is closed and disconnect the 20 mL syringe from extension tubing. Ensure that the tubing system remains closed and the needle with extension tubing attached remains in the reservoir septum. Attach syringe with filter to the extension tubing, ensure the connection is snug, but do not over tighten. Check that the needle is secure in the reservoir fill port.

19. As the clamp is opened, observe the following to indicate the needle continues to be

properly positioned: the bubbles in the extension set will immediately be drawn into the pump and the plunger may move slightly as drug is drawn into the pump. Apply gentle pressure to the plunger on the syringe at a maximum of one (1) mL per three seconds. Withdraw and observe a portion of the drug as it is being injected to confirm it has the expected appearance at least every ten (10) mL. If a second medication syringe is needed to complete the refill, clamp tubing before changing syringes, remove air from the medication syringe and repeat this step (17)

***Caution*:** If you encounter unusual resistance before the maximum reservoir volume is injected or you are unable to inject fluid, the reservoir valve may have been activated. Activation of the pump reservoir valve seals the pump reservoir valve closed. If the valve closes, a portion of the reservoir contents must be delivered or removed before filling can be completed, and procedural delays can occur.

20. To prevent activation of the pump reservoir valve while emptying or filling a pump:
    a. Completely aspirate all contents of the pump reservoir before filling;
    b. Do not allow air into the pump reservoir through open needle in the septum or an unclamped extension tubing; and
    c. Do not exceed the maximum reservoir volume indicated in the pump labeling.

21. If valve activation has occurred refer to Nursing Policy and Procedure on Reservoir Valve Deactivation Procedure

22. When filling is complete, close the clamp. Stabilize the pump surface with one hand and remove the needle with the opposite hand. Discard both needles in a sharps container. Apply pressure for one minute to the site after removing the needle using a gauze pad.

23. Remove the cleansing agent from the patient's skin using an alcohol pad or swab. Apply an adhesive bandage, if desired.

24. Discard all components of the kit. Refer to Nursing Policy and Procedure on Narcotic Waste Disposal for proper disposal of the withdrawn narcotic.

25. Print updated telemetry. Review the telemetry strip with the patient. Verbalize the medication, dose, rate, and new alarm date, bringing the patient's and your attention to the details. A copy is left with the patient, and may be the short form without logs.

26. Review the telemetry event logs for any unanticipated motor stalls. If noted:

    a. Notify the patients physician of the events

b. Submit a HOT form with detailed findings

27. Full telemetries with pre and post update and logs are to be uploaded into the patient care record the day of the visit.

28. Two nurses may be present for a pump refill if warranted.

TECHNICAL SUPPORT

A toll-free technical support service is available 24 hours a day for clinicians managing patients with Medtronic implantable infusion pumps. Telephone Technical Support at: **1-800-707-0933.**

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PENTEC HEALTH POLICY/PROCEDURE

DOCUMENTATION

S.I. POLICY AND PROCEDURE

9.12 Patient Safety Checklist

Policy:

To promote patient safety in refill of intrathecal pumps by implementing check points to confirm the accuracy of medication delivered to the nurse for administration to the patient, confirming the accuracy of medication prior to pump access, and reviewing all changes with the patient or caregiver.

Procedure:

1. Upon receipt of medication delivery (Medication Check In):
   a) Check all applicable boxes
   b) If no DOB on script, contact pharmacy to confirm and document accordingly

2. Before Pump Access (for refills and/or adjustments):
   a) Check all applicable boxes, reviewing out loud with the patient
   b) Confirm the label of syringe while you read the order
   c) If data on interrogation is not expected: STOP, CLARIFY, TAKE APPROPRIATE ACTION AND DOCUMENT IN EMR

3. After Pump refill and/or Adjustment:
   a) Review telemetry with the patient/caregiver or Pentec nurse as appropriate
   b) Record volume of medication in mLs and alarm date per current telemetry. Alarm date may vary based on medication stability, or physician/patient preferences
   c) Record volume of medication wasted in mLs.

4. Pentec nurse sign form acknowledging accuracy of above information

5. Patient/Caregiver to sign form acknowledging above information reviewed with them by the Pentec nurse and witness of medication wasted.

6. Scan form and attach in message center with the title "SAFETY CHECKLIST"

Effective: 12/2013 Revised: 07/2014 Revised: 04/2015

pentec health

Medication Safety Checklist

Patient Name:_____ DOB: _____

1. Medication check-in:

- ☐ N/A-adjustment only
- ☐ Patient's name and DOB verified
- ☐ No change in medication and/or concentration
- ☐ Change noted in medication and/or concentration
- ☐ Current pump settings reviewed
- ☐ Medication discard after date:_____
- ☐ Bridge bolus/demand bolus is needed
- ☐ Dose/program will be changed
- ☐ Dose/program will remain the same
- ☐ Non-programmable pump

Medication(s), concentration(s) and syringe volume(s)_____ _____

_____

2. To be reviewed with patient/caregiver prior to performing a refill and/or adjustment:

- ☐ Patient's name and DOB verified
- ☐ Data upon interrogation is expected
- ☐ Non-programmable pump
- ☐ Verbal confirmation: changes ARE NOT ordered
- ☐ Allergies reviewed
- ☐ Verbal confirmation: changes ARE ordered
- ☐ Medication verified
- ☐ Data upon interrogation is unexpected: STOP, CLARIFY, VERIFY

3. After pump refill and/or adjustment:

- ☐ Pump program reviewed with patient/caregiver/ facility
- ☐ Pump program reviewed with Pentec RN
- ☐ Non-programmable pump-refill information reviewed with patient/caregiver/facility
- ☐ Medication waste from the pump =_____ml. Witnessed per signature below.

Total volume is: _____mLs Alarm date is: _____

I have ensured the above information is accurate:

_____ **Date:** _____

The Pentec nurse has reviewed the above information with me:

_____ **Date:**_____

PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.0 INFECTION CONTROL PROGRAM OVERVIEW

PURPOSE:

A major safety goal of Pentec is the prevention of health care associated infections (HAI's). The goal of the Infection Control Program is to improve health outcomes by identifying and reducing the risks of infection in patients and staff through surveillance, prevention, reporting, and control of infection activities.

POLICY:

1. Company leaders collaborate with all services and disciplines to manage infection prevention and control activities.
2. All staff shall receive infection control training upon hire and annually.
3. The infection control program is ongoing and implemented by all staff. All staff is responsible for preventing and controlling infection.
4. The infection control program will consist of the following components: surveillance, identification, prevention, control and reporting.
5. The infection control program is a major component of Performance Improvement. Infection control reporting is done routinely via the Performance Improvement Committee and the total program is evaluated annually and whenever risks change. The evaluation includes a review of the following:
    - The infection prevention and control prioritized risks.
    - The infection prevention and control goals.
    - Implementation of the infection prevention and control activities.
    - The approach to preventing and controlling infections.
6. Pentec integrates its efforts with other health care and community leaders to the extent feasible and practical with the understanding that infection prevention and control is a community wide effort.
7. In the event of an increased number of infectious patients, Pentec will continue to provide care to its current patients, but will not accept new patients.
8. Pentec provides the necessary equipment and supplies to support infection prevention and control activities (i.e. gloves, masks, alcohol wipes, hand sanitizer, etc.).
9. Outbreaks of infections among our patients or staff are investigated through Performance Improvement when a trend has been noted.
10. In the event that a patient is transferred to another agency that has an infection requiring monitoring, treatment, and/or isolation, Pentec informs the receiving agency.
11. If Pentec receives a patient from another agency that has an infection requiring action that was not communicated, it informs the referring agency.

Surveillance is used to collect data about infections to detect any changes in infection trends. The State Health Departments are contacted periodically to determine community risk

assessments. The surveillance data is used to identify any problems or trends. Pentec prioritizes the identified risks for acquiring and spreading infections. These risks are documents as part of Performance Improvement. Current targeted surveillance criteria are pump site, catheter site and wound infections, sepsis and pneumonia.
Related policy: 8.6

Prevention is how the transmission of infection is stopped. This is done through policies and procedure and education of staff and patients. Staff members participate in yearly in-services and patients receive handouts on hand washing and avoiding infections.
Related policies: 8.2, 8.8, 8.9, 8.10,8.11, 8.12, 8.13, 8.14

Control is demonstrated by the implementation of policies and procedures to control the transmission of an infectious disease once it has occurred and has been identified.
Related policies: 8.1, 8.3, 8.4, 8.5, Emergency Management Plan 6.19

Reporting is done as mandated by law on all reportable diseases or infections. Appropriate staff members are notified as well.
Related policy: 8.7

GOALS OF INFECTION PREVENTION AND CONTROL:

- Addressing the prioritized risks identified.
- Limiting unprotected exposure to pathogens.
- Limiting the spread of infections associated with procedures.
- Limiting the spread of infections associated with the use of medical equipment, devices, and supplies.
- Improving compliance with hand hygiene guidelines.

Goals For Improving Influenza Vaccination Rates

- Influenza vaccination will be offered to all clinical staff
- Education is provided on the vaccine, non-vaccine control and prevention measures and the diagnosis, transmission and impact of influenza.
- The goal of the vaccination program is to have 90% of the clinical staff immunized for influenza by the year 2020. The goal for Pentec Health in 2012 is for 70% of the clinical staff to be immunized improving to 80% by 2015 and 90% by 2018.
- Pentec will collect and review the reasons given by clinical staff for declining the vaccine. This collection and review will be done annually. The results of this data will be provided to company Leaders and clinical staff yearly.
- In order to better protect our patients, any staff member that does not receive immunization will wear a mask from the time they enter the home until they leave the home form October 1 through March 31st each year.

Addendum: Minnesota:
The Minnesota Facility Tuberculosis Risk Assessment Worksheet for Health Care Settings shall be completed annually by infection control personnel in consultation with Minnesota staff.

Addendum Oklahoma:

The requirements to complete vaccinations or declination statements for each employee and/or worker may be suspended by the agency's medical director in the event of a shortage of vaccine as recognized by the Commissioner of Health.

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PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.1 EXPOSURE TO BLOOD BORNE PATHOGEN CONTROL PLAN

PURPOSE:

1. Identify employees who are at risk to occupational exposure to blood borne pathogens while performing specific tasks and procedures related to their job.

2. To describe a procedure for evaluating circumstances surrounding exposure incidences.

POLICY:

1. An exposure control plan shall be evaluated at least annually and whenever necessary to reflect changes in the workplace affecting occupational exposure.

2. The Performance Improvement Committee shall be responsible for reviewing and revising the exposure control plan.

EXPOSURE DETERMINATION:

JOB CLASSIFICATIONS

Nurses - Perform venipuncture, vascular access. Participation in invasive procedures, which involve blood and/or body substances. Touching mucous membranes, non-intact skin or handling items or surfaces soiled with blood, body fluids, secretions or excretions

METHODS OF IMPLEMENTATION:

1. In-service records will be maintained for three years. (See In-service Records and Standard Precautions Policies.)

2. All new employees shall receive instruction on infection control policies during orientation.

3. All employees shall receive an annual in-service on infection control policies.

4. Hand washing facilities are not always feasible or available in the field, therefore,

appropriate alcohol based hand sanitizer is provided to drivers and nurses (See Policy Hazardous Waste Disposal, Pharmacy Manual).

5. Contaminated needles and sharps are only handled in approved Sharps containers and shall not be capped or cut.

6. Hepatitis B vaccine shall be offered to targeted employees within 10 working days of assignment with Pentec Health. (See Policy Hepatitis B Vaccination).

7. Post Exposure Evaluation and Follow-Up Plan has been developed (See Policy Post Evaluation and Follow Up.)

8. The Infection Control Plan shall be evaluated annually by the Performance Improvement Committee.

9. All records will be made available upon request of employee or OSHA and will be maintained for 30 years past employment of employee. Upon cessation of Pentec Health to conduct business, Pentec will notify OSHA three months prior to disposal of records and transmit them to OSHA, if required.

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Reviewed: 11/13

PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.2 HEPATITIS B VACCINATION

TARGETED PERSONNEL:

Health Care Personnel: Nurses and anyone with possible patient contact.

ADMINISTRATION:

1. IM use only, into deltoid muscle in adults, anterolateral thigh is the recommended site for infants and young children. May be given SC route to persons at risk for hemorrhage.

2. Hepatitis B vaccine should be administered as follows:

   a. Initially 1 ml IM 20 mcg

   b. 1 month 1 ml IM 20 mcg

   c. 6 months 1 ml IM 20 mcg

3. The Nursing Director or RN designee at Pentec Health will administer the vaccine.

4. The vaccine must be made available to the employee that is at risk within 10 working days of assignment with Pentec Health. Those who decline to accept the vaccination must sign a declination form. If, however, after some period of time, the employee decides to accept the vaccination, Pentec Health will provide it.

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PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.3 POST EXPOSURE EVALUATION AND FOLLOW-UP

1. For immediate exposure/needle stick care see Policy 8.10 Standard Precautions.

2. If an incident of exposure occurs, Pentec Health will make available to the exposed employee at no cost a confidential medical evaluation and follow-up.

   Follow-up must include:

   A. Documentation of the routes and circumstances of exposure

   B. Identification and testing of the source individual. The testing will be performed at no charge to the source individual, and test results shall remain confidential. The Regional Nurse Manager or designee will contact the patient's physician and report the needle stick/exposure and assist with arrangements for testing the patient's blood (HIV, Hep B surface antigen, Hep C antibody, AST, ALT, Alk Phos).

   C. Testing of the exposed employee's blood within 48 hours of exposure upon consent. If source is known HIV positive, employee needs to seek treatment within the hour for preventative antiviral treatment.

   D. Post-exposure prophylaxis

   E. Counseling and evaluation of reported illness through First Calls nationwide 24 hour EAP service line: 800-382-2377.

Initial treatment will be provided through the closest ER or the employee's personal physician as they desire.

3. Pentec shall provide the employee with the following:

   A. Any results of the exposed employee's evaluation that comes through Pentec..

   B. Instructions given to exposed employee about any medical conditions resulting from the exposure, which requires further evaluation and treatment.

C. Any other findings or diagnosis, including the exposed employee's HIV status, which will remain confidential.

4. Pentec Health will maintain medical records for each employee with occupational exposure for the duration of employment plus 30 years. The records will be kept confidential and include name, social security number, Hepatitis B vaccination status (with dates), results of examinations, medical testing and follow-up procedures, healthcare professional's opinions and a copy of information provided to healthcare professionals. These records will be made available to anyone with written consent of the employee or OSHA.

5. The employee who is exposed must complete an Incident/Report (refer to Policy Incident Report, Safety Section).

6. Human Resources will coordinate follow-up with medical payments and processing with Pentec Health's workman's compensation carrier as needed.

7. All exposures are monitored by the Performance Improvement Committee

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PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.4 EMPLOYEES WITH SKIN INFECTIONS/OPEN LESIONS/BROKEN SKIN AREAS

POLICY:

1. All employees with skin infections, open lesions, or broken skin areas shall wear gloves during compounding procedures, home visits and patient contact.

2. It is the responsibility of the employee to report any possible exposure to his/her department head and to complete an Occurence Report (refer to Occurence Report, Safety Section).

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PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.5 EMPLOYEES WITH UPPER RESPIRATORY INFECTIONS

PURPOSE:

Prevents spread of airborne infection.

POLICY:

1. It is the responsibility of employees to report that they have an upper respiratory infection to their department head.

2. Employees with upper respiratory infections may not have contact with immunocompromised patients.

3. Employees shall wear masks if a patient/caregiver has an URI and shall dispose of the mask in the home and use good hand washing technique.

4. The following procedure will be followed in compounding admixtures or patient contact by employees with an upper respiratory infection.

PROCEDURE:

1. Pharmacists and Pharmacy technicians with upper respiratory infections shall wear a breathing mask when compounding and gathering supplies for use in the home.
2. RNs with upper respiratory infections will wear a breathing mask during visits to a patient's home.

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PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.6 PUMP SITE, CATHETER SITE, AND OTHER INFECTIONS

PURPOSE:
Pentec Health identifies healthcare associated infections (HAI's) as a component of the infection control program. Given the patient population of services provided, prioritized risks shall be to monitor pump site, catheter site, and other infections to promote quality patient care.

POLICY:

1. RN's shall notify the patient's physician to report any pump site, catheter site infections, or ther suspected infections.

2. All infections shall be reported to the Vice President of Nursing or designee. The RN shall record infections relating to the pump/catheter on an incident report.

3. Presence of the pump site, catheter site infection, and other infections shall be documented in the patient care record and on the HOT form Tool monitored by the Director of Nursing Education.

4. The Director of Nursing Education or designee shall collect and analyze data on all pump site, catheter site, and other infections as part of Pentec's Performance Improvement Program. If a trend is noted, a root cause analysis will be done to determine the source of infection and reeducation/process change will be initiated based on findings.

5. The Vice President of Nursing or designee shall collaborate with Pentec RN's regarding pump site, catheter line, and wound care policies and procedures and standards of care and make recommendations.

6. Pump site, catheter site and other infections shall be reported to the Performance Improvement Committee for further review and action.

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PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.7 PATIENT INFECTION REPORTING GUIDELINES

POLICY:

1. Infections present on admission and being treated in conjunction with the patient's plan of treatment (medical orders) shall be excluded from infection reporting guidelines. All reportable disease and conditions will be communicated via guidelines of the local state department of health and CDC (See guidelines).

2. Any diagnosed infection or the presence of signs and symptoms associated with infection which occur within three days (72 hours) after admission to agency services are considered agency-acquired infections.

3. All suspected or confirmed agency-acquired infections shall be reported to the Vice President of Nursing or designee. An incident report must be completed. This will also be documented on the HOT form monitored by the Director of Nursing Education to track patient infections. The Vice President of Nursing monitors the course of agency-acquired infection.

4. Signs and symptoms indicative of a reportable infection include the following:

   Pain
   Erythema
   Edema
   Heat associated with site
   Purulent drainage
   Fever

5. Patients diagnosed with sepsis or if infection is suspected, presence of infection will be confirmed by appropriate diagnostic testing ordered by the patient's physician.

6. Aggregate information regarding agency-acquired infections is reported to the Performance Improvement Committee.

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Reviewed: 6/91	Reviewed: 1/01	Reviewed: 7/10
Reviewed: 3/92	Reviewed: 4/01	Reviewed: 1/12
Revised: 2/93	Revised: 2/02	Revised: 8/12
Reviewed: 10/94	Reviewed: 6/03	Revised: 11/13
Revised: 11/95	Reviewed: 5/04	
Reviewed: 3/96	Reviewed: 4/05	
Reviewed: 3/97	Reviewed: 4/06	
Reviewed: 3/98	Revised: 4/07	
Reviewed: 3/99	Reviewed: 4/08	

7. Any employee or patient that requests testing for human immunodeficiency virus (HIV) and any other causative agent of acquired immune deficiency syndrome (AIDS) shall be assisted with doing so. This includes referral to their health care provider and community resources.

Effective: 6/90	Reviewed: 9/00	Reviewed: 8/09
Reviewed: 6/91	Reviewed: 1/01	Reviewed: 7/10
Reviewed: 3/92	Reviewed: 4/01	Reviewed: 1/12
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Reviewed: 10/94	Reviewed: 6/03	Revised: 11/13
Revised: 11/95	Reviewed: 5/04	
Reviewed: 3/96	Reviewed: 4/05	
Reviewed: 3/97	Reviewed: 4/06	
Reviewed: 3/98	Revised: 4/07	
Reviewed: 3/99	Reviewed: 4/08	

PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.8 TUBERCULIN TESTING

PURPOSE:

To determine if the health care provider has been exposed to tuberculosis (TB) and has active disease.

TARGETED PERSONNEL:

Nurses and anyone with patient contact
POLICY:

1. Designated personnel shall be required to have tuberculin testing via a Mantoux test (PPD) within 10 working days of employment with Pentec. Unless the employee is able to document skin testing within the last year, 2 step testing will be utilized with the second skin test being done within one month. If unable to obtain PPD at time of hire, a TB Screening Tool will be completed and a PPD administered as soon as possible.

2. Designated personnel shall be tested on an annual basis for TB exposure, and as needed if exposure is suspected.

3. Employees who know they test positive shall not have the Mantoux administered, rather they must submit physician documentation of TB status to Pentec for employee's record upon hire. Chest x-ray need only be repeated if exposure to TB or symptomatic.

4. Positive reactors must complete the TB screening tool on an annual basis – see 8.8a Screening Tool.

5. Employees who test positive, after receiving a PPD shall be referred to the State Department of Health and their physician shall be contacted.

6. All reports or copies of Mantoux, Chest X-Rays, medical evaluations must be maintained in the employee's confidential medical file.

7. Any company RN may administer the PPD.

PROCEDURE:

1. Obtain Purified Protein Derivative (PPD) from Pharmacy.

2. Obtain history of allergies and reaction to skin tests. If negative history, prepare skin with alcohol.

3. Administer 0.1ml intradermally into flexor surface of the forearm. Use tuberculin syringe with 26g or 27g ½" needle. PPD is CONTRAINDICATED in known TB positive reactors as severe reactions may occur.

4. Record site of PPD and date on Tuberculin Testing Form.

5. Read test within 48 to 72 hours. An induration of 10 mm or greater indicates a significant reaction (formerly called positive reaction). The amount of induration at the site - not erythema - determines the significance of the reaction. If the site is significant, refer individual to his/her physician and the State Department of Health.

6. Record results of PPD and date on Tuberculin Testing Form.

7. If employee has significant reaction, report to appropriate department head to ensure follow-up.

8. If employee has not had documented skin testing within the last year, a second skin test will be administered within one month following the same procedure.

Procedure: Positive Reactor

1. The symptom screening tool is to be completed on an annual basis, or as needed if exposure is suspected.

Procedure: Suspected Exposure

1. If any staff feels they may have been exposed to TB they must contact their manager and advise of possible exposure.

2. Administer a symptom screen and the Mantoux test to employees who previously had negative results.

3. If the initial result is negative, the test and symptom screen will be repeated in 8 to 10 weeks after the end of the exposure.

4. If the symptom screen, the first test result, or the 8 to 10 week follow up test result is positive, the presumed exposed employee will be promptly be evaluated for TB disease, including the use of a chest x-ray.

5. The employee must follow up with their primary physician and /or the State Department of Health.

6. Any employee exhibiting signs or symptoms consistent with TB must be evaluated by a physician within 72 hours. The employee must not return to work until determined by their physician to be non-infectious.

ADDENDUM: Minnesota

All designated personnel will complete a symptom screening tool in addition to the Mantoux upon hire and prior to having any contact with Minnesota patients.
If an employee has ever had a positive reaction to a Mantoux test, the employee must provide:

1. Documentation of a negative chest x-ray administered within the three months before working in a position involving direct client contact; **or**
2. Documentation of a negative chest x-ray administered each 12 months, for two years after the positive reaction to a Mantoux test; **or**
3. Documentation of completing or currently taking a course of tuberculosis preventative therapy.

ADDENDUM: Kansas:

All designated personnel will have evidence of good general health and a negative tuberculin skin test or chest X-ray upon employment and will be completed prior to any patient contact.

ADDENDUM: Indiana:

1. The second step of a two-step tuberculin skin test using the Mantoux method must be administered one (1) to three (3) weeks after the first tuberculin skin test was administered.

Resources: http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf

Effective: 3/93	Reviewed: 5/04	Revised: 02/2015
Reviewed: 10/94	Reviewed: 4/05	Revised: 03/2015
Reviewed: 12/95	Reviewed: 4/06	
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Reviewed: 3/97	Reviewed: 4/08	
Reviewed: 3/98	Reviewed: 8/09	
Revised: 4/99	Revised: 8/10	
Reviewed: 9/00	Reviewed: 1/12	

Reviewed: 4/01
Revised: 3/02
Reviewed: 6/03
Reviewed: 8/12
Revised: 8/13
Revised: 11/13

PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.8a TUBERCULIN SYMPTOM SCREENING TOOL

If you have had a previous positive PPD result, or you suspect you have been exposed to tuberculosis, please complete and sign the following screening tool and return to your manager.

Have you had:

1	Previous Positive PPD	Yes	No
2	Unexplained Weight Loss	Yes	No
3	Chronic Cough, Expectoration, Blood Streaked Sputum	Yes	No
4	Unexplained Night Sweats	Yes	No
5	Fever, Pain, Swollen Glands	Yes	No

Printed Employee Name:_____

Employee Signature:_____

Date Completed:_____

Addendum Minnesota: All employees who have patient contact must complete this form in addition to the Mantoux requirement

PENTEC HEALTH INC. AND AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.9 TUBERCULIN TESTING FORM

Name of Employee_____

Date of PPD_____ Time: _____

Site: Right forearm ❍ Left forearm ❍ Given By: _____

Lot Number _____ Expiration Date _____

Date of results: _____ Time: _____ Read by: _____

Results: _____MM _____ Non-reactive _____Signficant

Results given to:

Employee ❍ Yes ❍ No
Dept. Head ❍ Yes ❍ No Name:
_____
Health Dept ❍ Yes ❍ No
Physician ❍ Yes ❍ No Physician:
_____

Follow up:

Physician documentation received: ❍ Yes ❍ No

Dept. Head Signature: _____

Date: _____

ADDENDUM: Minnesota

All designated personnel will complete a symptom screening tool in addition to the Mantoux upon hire or prior to having contact with Minnesota patients.

Refer to Policy 8.8a in the Administrative Manual

PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

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8.10 STANDARD PRECAUTIONS

DEFINITION

"Standard Precautions" is the name for the Centers for Disease Control's recommended policy for healthcare workers regarding blood and body fluids of all the patients, as potential sources of blood borne pathogens. The primary focus is on Hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

PURPOSE

To comply with OSHA standard on Blood borne Pathogens, as published in Federal Register, December 6, 1991. Blood and body fluid precautions shall be *consistently* utilized in the care of *all* patients, not just those infected with the HIV virus or other blood borne pathogens. Universal Precautions provide protection for health care workers without compromising patient care or confidentiality.

POLICY

1. Pregnant health care workers should not do home visits or provide direct care to patients' known to have HIV, cytomegalovirus, or Hepatitis B.

2. *ALL* employees who have direct patient contact shall utilize Standard Precautions.

3. Any moist substance from a patient's body, e.g., blood, urine, stool, sputum, saliva, semen, spinal fluid, peritoneal fluid, amniotic fluid or any body fluid shall be considered a blood and body fluid substance.

4. THE FOLLOWING WORK PRACTICE CONTROLS MUST BE FOLLOWED WHEN DEALING WITH A PATIENT'S BLOOD AND BODY FLUID SUBSTANCES.

   a. Gloves shall be worn when:

      1. Handling any blood and body substances
      2. Touching any mucous membranes
      3. Non-intact skin exits
      4. Touching items or surfaces soiled with blood or body substances
      5. Performing venipuncture and other vascular access procedures

b. Hands and other skin surfaces must be washed with soap and water immediately and thoroughly if contaminated with blood or other body fluids, then wipe affected areas with alcohol.

c. Hands must be washed between all patient contacts.

d. Hands must be washed immediately after removing gloves.

e. If hand-washing facilities are not feasible, employee shall use hand gel.

f. Personnel are to wear masks, gowns, and protective eyewear (goggles) during procedures, which are likely to generate splashes or droplets containing blood or other body fluids.

g. Employees must remove all personal protective equipment that is overtly contaminated with blood or other potentially infectious materials immediately or as soon as possible prior to leaving the work area. The contaminated equipment must be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

h. Contaminated needles must not be sheared or broken.

i. Contaminated needles and other contaminated sharps must not be bent, recapped or removed unless there is no other feasible alternative or such action is required by a specific medical procedure. Recapping or removing a needle must be done through the use of a mechanical device or a one-handed technique.

j. Contaminated reusable sharps must be placed in appropriately labeled leak proof containers immediately or as soon as feasible after use.

5. Non-skin surfaces contaminated with the patient's blood or body substance shall be cleaned with a 1:10 solution of bleach and water (1 part bleach: 10 parts water).

6. Equipment shall be routinely checked to determine if blood or other potentially infectious materials must be decontaminated as necessary. Equipment should be checked, and, if necessary, decontaminated prior to servicing or shipping.

7. Employees are prohibited from eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in work areas when there is a reasonable likelihood of occupational exposure.

8. Food and drink must not be kept in refrigerators, freezers, shelves, cabinets or countertops where blood or other potentially infectious materials are present.

9. Employees are required to perform all procedures involving blood or other potentially

infectious materials in such a way as to minimize splashing, spraying, spattering and generation of droplets of blood or other potentially infectious material.

10. Employees are forbidden from performing mouth-pipetting or suctioning of blood or other potentially infectious materials.

11. Specimens of blood or other potentially infectious materials should be placed in a leak proof container that is labeled according to the OSHA standard. Use of a secondary container is required if the primary container may be punctured or becomes contaminated on the outside.

12. The Department Head in collaboration with the Director of Performance Improvement will arrange to educate employees regarding the requirements for dealing with Blood and Body Substances. Attendance must be documented. This information will be provided to all new employees during orientation. Nurses must complete this educational requirement prior to patient contact. All registered nurses will receive their bloodborne pathogen training during the orientation period from their trainer. Ongoing training is yearly as part of the mandatory inservices conducted during December each year.

13. All Pentec employees will be given universal precautions by the AMA to read and review.

PROCEDURE

1) Wear gloves when:

   a. Handling blood

      i. Performing of venipuncture (e.g., starting IV's, lab draws).

      ii. Performing any other vascular access procedures.

      iii. Participating in any invasive procedure.

   b. Touching mucous membranes, e.g., oral, nasal, vaginal, anorectal.

   c. Touching non-intact skin.

   d. Handling items or surfaces soiled with blood, bloody fluids, secretions or excretions.

      i. Trash

      ii. Instruments and other equipment and supplies.

      iii. Furniture, floors

iv. Laboratory specimens

2) Wash hands with soap and water:

a. Immediately after each patient contact or contact with a body substance, whether or not you have been wearing gloves.

b. Immediately after removing gloves.

c. Immediately and thoroughly if contaminated with any patient's blood or body fluids.

i. When unanticipated exposure occurs while not wearing gloves.

ii. When a glove is torn.

iii. When a needle stick or other injury occurs.

3) Wash other skin surfaces:

a. Immediately and thoroughly if contaminated with blood or body fluids.

4) Wear masks/gowns

a. During procedures that are likely to generate droplets or splashes of blood or other body fluids.

5) Wear protective eyewear or goggles:

a. During procedures that are likely to generate droplets, splashing of blood or other body fluids.

6) Wipe contaminated non-skin surfaces with solution of one part bleach to ten parts water.

7) Should an exposure occur, provide immediate care to the exposed area. Wash/rinse/flush the effected area involved as soon as possible for a minimum of 3-5 minutes. Notify your Lead Regional Nurse or immediate supervisor and see policy 8.3 Post Exposure Evaluation and Follow Up.

Effective: 6/87	Reviewed: 3/98	Reviewed:8/10
Reviewed: 6/88	Reviewed: 3/99	Revised: 5/11
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Revised: 5/90	Reviewed: 4/01	Reviewed: 1/12
Reviewed: 5/91	Revised: 2/02	Reviewed: 8/12
Revised: 3/92	Reviewed: 6/03	Reviewed: 11/13

Revised: 2/93	Reviewed: 5/04
Revised: 4/94	Reviewed: 4/05
Reviewed: 10/94	Reviewed: 4/06
Revised: 12/95	Revised: 4/07
Reviewed: 3/96	Reviewed: 4/08
Reviewed: 3/97	Reviewed: 8/09

PENTEC HEALTH INC.

INFECTION CONTROL

POLICY AND PROCEDURE

8.11 PERSONAL PROTECTIVE EQUIPMENT

PURPOSE

To ensure that employees use personal protective equipment where there is occupational exposure. The equipment cannot permit blood or other potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth or other mucous membrane under normal conditions of use.

POLICY

1. The personal protective equipment provided to employees at risk to occupational exposure includes, but is not limited to, gloves, gowns, lab coats, face shields or masks and eye protection, mouthpieces, resuscitation bags, pocket masks, or other ventilation devices.

2. Pentec shall provide and maintain personal protective equipment at no cost to the employee per OSHA standards.

3. Employees must wear personal protective equipment when at risk of occupational exposure per OSHA standards (refer to Universal Precautions Policy).

4. Employees must immediately remove defective or soiled equipment or garments.

5. All personal protective equipment must be removed before an employee leaves Pentec, a patient's home or any work area and should be placed in designated container or area for storage, washing, decontaminating or disposal.

6. Gloves must be worn when an employee has the potential to have hand contact with blood, other potentially infectious materials, mucous membranes and non-intact skin, and when handling contaminated items or surfaces. Gloves must be worn when performing vascular access procedures. Disposable (single use gloves) such as surgical or examination gloves must be replaced as soon as practical when contaminated or if torn, punctured, or when their ability to function as a barrier is compromised. Disposable gloves must not be washed or decontaminated for reuse. Utility gloves may be decontaminated for reuse so long as the integrity of the gloves is not compromised. If they are cracked, discolored, torn, punctured, or exhibit other signs or deterioration, utility gloves must be discarded.

7. An employee must wear masks in combination with eye protection devices, such as goggles or glasses with side shields or chin length face shields whenever splashes, spray, spatter, droppings, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or mouth contamination.

Effective: 01/90	Reviewed: 9/00	Reviewed: 8/10
Reviewed: 02/91	Reviewed: 4/01	Reviewed: 1/12
Reviewed: 02/92	Reviewed: 2/02	Reviewed: 8/12
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Revised: 12/95	Reviewed: 4/05	
Reviewed: 3/96	Reviewed: 4/06	
Reviewed: 3/97	Revised: 4/07	
Reviewed: 3/98	Reviewed: 4/08	
Reviewed: 3/99	Reviewed: 8/09	

PENTEC HEALTH, INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.12 REQUIREMENTS FOR CLEANING/DECONTAMINATING AND DISPOSAL OF HAZARDOUS WASTES.

PURPOSE:

To comply with OSHA standard on blood borne pathogens which requires each employer to assure that the workplace is maintained in a clear and sanitary condition.

POLICY:

1. Refer to the Pharmacy Manual for detailed protocols on cleaning/decontaminating equipment and disposal of hazardous wastes.

Effective: 1/90
Reviewed: 2/91
Reviewed: 2/92
Reviewed: 2/93
Reviewed: 10/94
Revised: 11/95
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Reviewed: 3/97
Reviewed: 3/98
Reviewed: 3/99
Reviewed: 9/00
Reviewed: 4/01
Reviewed: 2/02
Reviewed: 6/03
Reviewed: 5/04
Reviewed: 4/05
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Reviewed: 4/08
Reviewed: 8/09
Reviewed: 8/10
Reviewed: 1/12
Reviewed: 8/12
Reviewed: 11/13

PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.13 USE OF BIOHAZARD LABELS

PURPOSE:

To comply with OSHA standards blood borne pathogens which require that biohazard labels be affixed to containers used to store or transport blood or other potentially infectious materials.

POLICY:

1. Prior to storing or transporting specimens of blood or other potentially infectious materials, specimens must be placed in closeable, leak-proof container labeled according to OSHA standard. The leak-proof container used at Pentec shall be a cooler.

Effective: 3/96
Reviewed: 3/97
Reviewed: 3/98
Reviewed: 3/99
Reviewed: 9/00
Reviewed: 4/01
Reviewed: 2/02
Reviewed: 6/03
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Revised: 4/07
Reviewed: 4/08
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Reviewed: 8/10
Reviewed: 1/12
Reviewed: 8/12
Reviewed: 11/13

PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.14 HANDWASHING

PURPOSE:

To ensure that employees use proper technique when washing hands prior to handling equipment or doing any patient care to comply with current CDC hand hygiene guidelines.

POLICY:

The following are indications for hand washing and hand antisepsis:

1. When hands are visibly dirty or contaminated with proteinaceous material or are visibly soiled with blood or other bodily fluids, wash hands with soap and water.
2. If hands aren't visibly soiled, use an alcohol based hand rub for routinely decontaminating hands.
3. Decontaminate hands before having direct contact with patients.
4. Decontaminate hands before donning sterile gloves and after removing gloves.
5. Decontaminate hands after contact with a patient's intact skin.
6. Decontaminate hands between patients.
7. Before eating and after using a restroom, wash hands with soap and water.
8. All nurses and warehouse delivery drivers are regularly supplied with alcohol-based hand sanitizer. Alcohol-based hand sanitizer is also available throughout the office as well as in the pharmacy.
9. All nurses will maintain their natural nail tips at ¼ inch in length and will refrain from wearing artificial nails.

Goals for improving compliance with hand hygiene guidelines:

- Provide alcohol-based hand sanitizer to all nurses and warehouse delivery drivers for them to use when hand washing facilities are not available.
- Educate staff on the hand washing policy.

*Compliance with hand hygiene guidelines will be evidenced by no patient infections caused by poor hand hygiene.

PROCEDURE:

1. Turn on water and leave it running.

2. Wet hands with water.

3. Apply soap to hands and scrub vigorously for at least 20 seconds, covering all surfaces of the hands and fingers.

4. Rinse hands with water while holding hands in a downward direction.

5. Thoroughly dry your hands with a disposable towel.

6. Use a paper towel or other available barrier to turn off the water. Discard in trash.

7. In the event hand-washing facilities are not available, appropriate alcohol-based hand sanitizer will be used; and hands should be washed as above as soon as possible. When using an alcohol-based hand rub, apply product to palm of one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.

Effective: 12/95	Reviewed: 5/04	Revised: 1/13
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Revised: 3/98	Revised: 4/07	
Revised: 4/99	Reviewed: 4/08	
Reviewed: 9/00	Revised: 8/09	
Reviewed: 4/01	Revised: 7/10	
Reviewed: 2/02	Review: 1/12	
Reviewed: 6/03	Reviewed: 8/12	

PENTEC HEALTH INC. & AFFILIATED COMPANIES

INFECTION CONTROL

POLICY AND PROCEDURE

8.15 TB PATIENT CARE

PURPOSE:

To ensure that staff are properly protected against TB transmission.

POLICY:

1. Should a patient be diagnosed with active TB or a referral be made with the diagnosis of active TB, steps will be taken to prepare the staff so they can provide care.

2. Preparations will assure that the company remains in compliance with federal regulations.

3. Preparation includes, but is not limited to a physical examination by a physician and fit testing with a NIOSH approved respirator.

4. If referral is made and adequately trained staff are not available or available staff can not be prepared in an acceptable time frame, the physician and the referral source will be notified.

5. If a patient on service is diagnosed with active TB, and adequately trained staff are not available, the physician will be notified and the patient will be transferred to a provider equipped to care for the patient.

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PENTEC HEALTH, & AFFILIATES

INFECTION CONTROL

POLICY AND PROCEDURE

8.16 VACCINATION FOR INFLUENZA AND PNEUMOCOCCAL PNEUMONIA

PURPOSE;

To ensure that all patients have made arrangements for a vaccination against influenza and that all patients over 65 have made arrangements for a vaccination against pneumococcal pneumonia.

POLICY;

1. Beginning October 1 each year, every patient will be asked if they have received a flu shot and every patient over age 65 will be asked if they have received a pneumococcal pneumonia shot.
2. Every patient who has not received such will be referred to their primary care physician, the local health department or another community location.
3. When a referral is made, the nurse will assist the patient in developing a plan for getting to the referral.
4. Documentation will be made on the Vaccination for Influenza and Pneumococcal Pneumonia form (see policy 8.17).
5. The vaccines will also be offered to Pentec Health staff.

Effective: 1/11
Reviewed: 1/12
Reviewed: 8/12
Reviewed: 11/13

PENTEC HEALTH, & AFFILIATES

INFECTION CONTROL

POLICY AND PROCEDURE

8.17 VACCINATION FOR INFLUENZA AND PNEUMOCOCCAL PNEUMONIA FORM

NAME OF PATIENT_____**DATE**_____

INFLUENZA VACCINATION

Administered prior to this time. _____yes _____no

Referral for administration made. _____yes _____no

Vaccine contraindicated for patient. _____no _____yes

Reason _____

Vaccination refused _____yes

PNEUMOCOCCAL PNEUMONIA VACCINATION (Over 65 only)

Administered prior to this time. _____yes _____no

Referral for administration made. _____yes _____no

Vaccine contraindicated for patient. _____no _____yes

Reason _____

Vaccination refused. _____yes

Pentec Health, Inc. & Affiliated Companies

Infection Control

8.18 Surveillance – Employee and Patient Infection

Purpose:
To provide a framework for determining rates of infection and to decrease potential for infections related to service provided.

Policy:

1. The Infection Control Officer or his/her designee is responsible for tracking occurrences of patient infections acquired while on service. This will be monitored and data aggregated quarterly. These will include but not be limited to: pump infections, urinary tract infections, and respiratory infections. Occurrences shall be tracked using the HOT form.
2. Employee health and communicable infections will be monitored, evaluated and the employee counseled in the event of but not limited to:
   a. Contagious diseases (e.g., chicken pox, hepatitis, measles, mumps)
   b. Needle-stick injury (refer to Post Exposure Evaluation and Follow-up)
3. Counseling will be provided by the supervisor and recommendations for appropriate procedure and follow-up will be provided (e.g., physician follow-up, mental health referral, county or local health department testing) based on the type of disease. Occurrences shall be tracked using the Unusual Occurrence/Incident Report
4. Communicable diseases shall be reported to the appropriate health authorities. Reportable diseases may vary from one region to another. The Infection Control Officer or his/her designee is responsible to check the state and community listings via the internet or the local Public Health Department. Diseases that are not directly transmissible or diseases of such epidemiological nature as to offer no special practical measures for control (e.g., common cold) are not reportable.
   Http://www.statepublichealth.org/index.php
5. The Performance Improvement Committee will evaluate rates of infection. Action plans will be developed based on analysis to decrease potential risk for further infections related to the service provided.

ADDENDUM: Kentucky, Indiana, District of Columbia, Rhode Island
Each employee who will have direct patient contact will have a physical exam by a physician or nurse practitioner not more than

180 days prior to the date the employee has direct patient contact and then yearly after, The physical exam will be of sufficient scope to ensure that the employee will not spread infectious or communicable diseases to patients.

Addendum Nebraska: Each employee who will have direct patient contact will have a health screening performed by their physician. This will occur after accepting employment and prior to assuming job responsibilities in Nebraska. The employee will provide a note from their physician that they are fit for duty and free from communicable diseases.

Addendum Colorado: Work restrictions will be placed on direct care staff who are known to be affected with any illness in a communicable stage or to be a carrier of a communicable illness or disease; afflicted with boils, jaundice, infected wounds, vomiting, diarrhea or acute respiratory infections.

Original: 1/11
Reviewed:1/12
Reviewed: 8/12
Revised: 11/12
Revised: 1/13
Revised: 10/13
Reviewed: 11/13
Revised: 3/14

ATTACHMENT TO QUESTION 4

1. Pharmacy Policy and Procedure – *Prescription Requirements and Review*.
2. Pharmacy Policy and Procedure – *Controlled Drug Substance*.
3. General Policy and Procedure – *Narcotic Waste Disposal*.

pentec health
Large Enough to Serve Small Enough to Care

PENTEC HEALTH INC. AND AFFILIATED COMPANIES

PHARMACY OPERATIONS

PHARMACY POLICY AND PROCEDURE

1.05 v 10 PRESCRIPTION REQUIREMENTS AND REVIEW

1.0 Purpose:

To insure that prescriptions are correctly received, documented, signed, tracked, and filed.

2.0 Policy:

Prescriptions will be processed as per procedure.

3.0 Definitions:

3.1 Nonproprietary drug – A drug containing any quantity of a controlled substance or A drug which is required by an applicable Federal or state law to be dispensed only by prescription.

3.2 Schedule VI (Massachusetts only) – Schedule VI shall consist of all prescription drugs, which are not included in any other schedule established by the Commissioner.

3.0 Procedure:

3.1 General

3.1.1 A prescription must be obtained for all legend drugs prior to being dispensed by the pharmacy according to State and/or Federal laws.

3.1.2 Prescriptions must be issued by a practitioner acting within the scope of his/her practice who is licensed to administer and prescribe drugs.

3.1.3 If allowed by State law, a prescription may be accepted if it was written by an out-of-state physician provided the prescription was valid where written. Applicable to the Massachusetts division only: CII prescriptions are only valid if written by a physician from a state contiguous to the commonwealth of Massachusetts or Maine, and only if written within the preceding 5 days.

3.1.4 New prescriptions will be generated (a) as required by DEA regulations; and (b) whenever there is a change in the drug or components, dose,

frequency, or route of administration, or if the prescribing physician authorizes additional refills beyond those authorized on the initial prescription.

3.1.5 All prescriptions written, telephoned, or faxed will be reviewed by a pharmacist for completeness and appropriateness prior to dispensing.

3.1.6 Prescriptions that do not appear appropriate in the pharmacist's experience will be confirmed directly with the physician who signed the prescription order.

3.1.7 If the prescription is telephoned in, a pharmacist must confirm the prescription with the physician or designee.

3.1.7.1 Immediately reduce it to writing or enter into patient's electronic record.

3.1.7.2 Indicate the name and title of who telephoned the prescription.

3.1.7.3 Indicate the name and/or initials of the pharmacist receiving the prescription

3.1.7.4 Must be verified by reading the order back to the person communicating the order, AFTER entering it into the electronic patient record or writing it down on paper.

3.1.7.5 Pharmacist will document the read back on the physician order form or patient electronic record.

3.1.7.6 For Specialty Infusion patients, a copy of a medication order change will be sent with the delivery.

3.2 Prescription Requirements

3.2.1 Prescriptions kept on file in the pharmacy must meet the following requirements:

3.2.1.1 The name and address of the patient

3.2.1.2 The name and address of the prescriber

3.2.1.3 Name of the supervising physician for nurse practitioners and physician assistants.

3.2.1.4 The date the prescription was issued

3.2.1.5 The name, dosage, strength per dosage unit, and quantity dosage units of the drug prescribed

3.2.1.6 Directions for its use

3.2.1.7 Statement indicating the number of times to be refilled

3.2.1.8 Cautions communicated to the ultimate consumer by means of auxiliary labels

3.2.1.9 The date the prescription was compounded, dispensed, and the quantity dispensed

3.2.1.10 The name or initials of the dispensing pharmacist

3.2.2 Prescriptions for controlled substances must show the DEA number of the prescriber.

3.2.3 If a prescription for a nonproprietary drug is refilled, a record of the refill must show the date of the refill, the name or initials of the dispensing pharmacist, and the quantity dispensed.

3.2.3.1 Prescriptions for nonproprietary or schedule VI drugs may be refilled for 1 year from the date of the prescription if refills have been authorized by the prescriber

3.2.4 A pharmacist may decline to fill or refill a prescription if the pharmacist knows or has reason to know that it is false, fraudulent, or unlawful.

3.2.4.1 A pharmacist may not knowingly fill or refill a prescription for a controlled substance or nonproprietary drug or device if the pharmacist knows or has reason to know it is for use by a person other than the one for whom the prescription was written, or will be otherwise diverted, abused, or misused.

3.2.5 No prescription may be knowingly filled or refilled for a patient which prescription was written for prior use by a prescriber who is deceased or no longer in practice.

3.2.6 Indications for use are required for a prescription unless otherwise specified by physician.

3.2.7 In the case of titration or tapering protocols, the order will include the amount of change, the interval, duration and any other parameters specific

to the prescribed therapy.

3.2.8 Orders based on a dose "range" are accepted based on the conditions being treated. In the event of a "Range" order not related to a patient's diagnosis or therapy, the prescribing physician will be contacted for clarification.

3.2.9 The prescribing physician will be contacted 3 to 7 days prior to the anticipated completion of therapy to verify intent to discontinue and obtain follow up instructions as appropriate.

3.3 Prescription Review

3.3.1 In the event any prescription order is incomplete, illegible or unclear, the pharmacist will clarify the order with the physician.

3.3.2 All new prescriptions are reviewed by a pharmacist against the patient's medication profile for patient allergies; potential drug-drug interactions, drug-food interactions and the appropriateness of the medication, dose, frequency, and route of administration, current or potential impact as indicated by lab values if applicable, therapeutic duplication, other contraindications, and variations from approved indications for use.

3.3.3 Refill prescriptions are not permitted for Schedule II controlled drug substances. All refill prescriptions for Schedule III, IV, and V controlled drug substances shall be reviewed by the pharmacist to confirm compliance with DEA's restrictions on refills.

3.3.4 All controlled drug substance prescriptions for implanted pump patients are reviewed by a pharmacist for appropriateness by matching the quantity prescribed against the pump telemetry read out and the patient's treatment plan to confirm the appropriate amount of medication to be dispensed.

3.3.5 After completion of the review, all concerns, issues, or questions are directly clarified with the physician. Such communication and outcome will be documented in the patient's clinical record.

3.3.6 Prescriptions for non-commercially available combinations or concentrations will be evaluated via current literature for appropriateness on a case by case basis.

3.4 Offer to Counsel

3.4.1 An offer to counsel shall be made to each patient or caregiver when the pharmacist fills, delivers, or sends a new retail or outpatient prescription

3.4.1.1 If neither the patient nor caregiver comes to the pharmacy, the pharmacist must send a written offer to counsel together with the filled prescription which is delivered to the patient.

3.4.1.2 The written offer must include a toll-free telephone number of the pharmacy which a patient or caregiver may use to obtain counseling.

3.4.2 Only a pharmacist may counsel

3.4.3 The following are examples of matters which a pharmacist might deem significant and discuss with the patient or caregiver:

3.4.3.1 The name and description of the medication

3.4.3.2 The route of administration, dosage form, dosage, and duration of drug therapy

3.4.3.3 Special directions and precautions for preparation, administration and use by the patient.

3.4.3.4 Common side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered with legend and non-lend medications

3.4.3.5 Prescription refill information

3.4.3.6 Proper storage

3.4.3.7 Action to be taken in the event of a missed dose or adverse reaction

3.4.3.8 Techniques for self-monitoring drug therapy

3.4.4 Information gained by a pharmacist about a patient during counseling shall be regarded as confidential.

3.5 Prescription Record Keeping

3.5.1 Prescriptions will be filed according to State and/or Federal laws.

3.5.1.1 A manual and/or electronic recordkeeping system will be used as allowed by State law.

3.5.2 Signed, original prescriptions for scheduled II drugs will be maintained in a separate narcotic file in the pharmacy with a copy placed in the patient's

clinical record.

3.5.3 When required by law, signed, original prescriptions for schedules III, IV, or V drugs will contain a red "C" in the bottom right hand corner of the prescription and will be filed separately with copies maintained in the patient's clinical record.

3.5.4 Signed, original prescriptions for all other drugs will be maintained in the patient's clinical record.

3.5.5 Pharmacy will maintain records of prescription refills as required by State laws and regulations which may include the use of mixing reports and packing slips maintained in the patient's clinical record, automated records, or other manual documentation systems.

3.5.6 Original prescriptions or readily retrievable images of the original prescriptions shall be kept for 2 years from the date of the most recent filling.

4.0 Version Change Summary

4.1 Formatting throughout policy
4.2 Definitions added
4.3 Changed "registered practitioner" to "physician" and added "Maine" as a contiguous state for writing CII prescriptions in step 3.13
4.4 Modified entire section 3.2 Prescription Requirements
4.5 Removed "and refill" from step 3.3.2 regarding prescriptions that are reviewed by a pharmacist against the patient's medication profile
4.6 Added entire section 3.4 Offer to Counsel
4.7 Added step 3.5.6 indicating that prescriptions shall be kept for 2 years

5.0 Effective/ Revision Dates

5.1	Effective:	01/1993
5.2	Reviewed:	01/1994
5.3	Reviewed:	11/1995
5.4	Revised:	03/1996
5.5	Reviewed:	05/1996
5.6	Reviewed:	02/1997
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5.11	Reviewed:	03/2002

5.12	Reviewed:	03/2003
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5.14	Reviewed:	04/2005
5.15	Revised:	06/2009
5.16	Revised:	11/2009
5.17	Revised:	12/2009
5.18	Revised:	11/2012
5.19	Revised:	07/2013
5.20	Revised:	01/2014
5.21	Revised:	11/2014
5.22	Revised:	11Dec2014

6.0 Approval

	Printed Name	Signature	Date
Initiator	Michael Cardosi		15 Dec 14
Management	Barbara Knightly		15 Dec 14
QA	Andrew Waggoner		15 Dec 14

END OF PROCEDURE

pentec health

Large Enough to Serve Small Enough to Care

PENTEC HEALTH INC. & AFFILIATED COMPANIES

PHARMACY OPERATIONS

PHARMACY POLICY AND PROCEDURE

1.06 v 07 CONTROLLED DRUG SUBSTANCE

1.0 Purpose:

To outline how controlled drug substances are ordered, received, tracked and distributed at Pentec Health.

2.0 Policy:

The Pharmacist-in-charge will be responsible for staff compliance with laws or regulations regarding the ordering, dispensing, receiving, and recordkeeping of controlled drug substances. Acquisition, inventory recordkeeping, and adequate security measures for the storage of controlled substances, shall be in accordance with Federal and State pharmacy laws.

3.0 Attachments:

3.1 Form - 1.06.1 Controlled Substance Record

4.0 Procedure:

4.1 General

4.1.1 Controlled drug substances include those drugs known as Schedule II, III, IV, and V. (in Massachusetts, all medications not included in Schedule II-V are considered Schedule VI.)

4.2 DEA Registration

4.2.1 Obtain and maintain registration with the Drug Enforcement Agency (DEA) and, where applicable, with the State, to purchase and dispense controlled drug substances which are listed in schedules II through V.

4.2.2 DEA applications, both initial and renewals will be signed by the CEO. State applications must be signed by the designated pharmacist-in-charge.

4.2.2.1 When the pharmacist-in-charge changes, a new DEA Power of Attorney form and notification to the local State Board of Pharmacy must be completed.

4.2.2.2 When the pharmacist-in-charge changes, a complete inventory of controlled drugs must be taken. Both the old and new pharmacist-in-charge must sign the inventory record, which must be filed with the biennial inventory records.

4.3 Storage and Security of Controlled Drug Substances

4.3.1 Schedule II drugs will be stored in a locked cabinet inside the pharmacy. The cabinet must be firmly affixed to a solid interior wall. The cabinet will be locked at all times when not in immediate use.

4.3.2 Although State and Federal Law may allow Schedule III, IV and V drugs to be dispersed throughout the pharmacy inventory, at Pentec Health they will be stored in a locked cabinet inside the pharmacy.

4.3.2.1 Exception: Schedule III, IV and V controlled drugs that require storage conditions other than controlled room temperature should be stored under the appropriate conditions. For example, lorazepam is stored in the refrigerator.

4.3.2.2 A locked box is not required in the refrigerator unless Schedule II drugs are to be stored there

4.3.3 Only the pharmacists will have the key or combination to access the controlled drug substance cabinet.

4.4 Inventory of Controlled Drug Substances

4.4.1 A perpetual inventory will be maintained by the pharmacist for controlled drug substances, in schedules II, III, IV, and V using the Pentec Health Controlled Substance Record form CSR1.6 (attached)

4.4.1.1 The Pentec Health Controlled Substance Record will be used to record the inventory of controlled substances.

4.4.1.2 A separate Pentec Health Controlled Substance Record will be maintained for each controlled drug substance.

4.4.1.3 The perpetual inventory will be reconciled each time the pharmacist dispenses or receives a controlled drug substance.

4.4.1.4 Any discrepancies in the controlled drug substance perpetual inventory will be immediately reported to the manager or the next higher level of management if the manager is not available. If the discrepancy cannot be rectified, a variance report will be completed using the occurrence report form.

4.4.1.5 Inventory records will be kept a minimum of 3 years.

4.4.2 On at least a monthly basis, a pharmacist will inventory all controlled drug substances and record the actual amounts of the perpetual inventory sheets as well as their signature on each. For the Massachusetts location, perpetual inventory will be performed by a pharmacist at a minimum of every 10 days in accordance with state law.

4.4.3 When the pharmacist-in-charge changes, a complete inventory of all scheduled drugs must be taken. This inventory will be documented on the perpetual inventory records.

4.4.4 Every two years, according to DEA regulations and/or State Law, an actual count of all controlled drug substances (schedule 2-5) will be performed. This count can take place anytime within 2 years of the last inventory date to meet DEA requirements.

4.4.4.1 Pentec Health will do this physical inventory count at the end of every calendar year.

4.4.4.2 The count will be documented on inventory count sheets and must include:

4.4.4.2.1 Name, address and DEA registration number of pharmacy

4.4.4.2.2 Signature of the pharmacist-in-charge or person responsible for taking the inventory

4.4.4.2.3 Date and time (open or close of business day) the inventory was taken

4.4.4.2.4 Name, strength and dosage form of the controlled substance

4.4.4.2.5 Volume of number of units or volume in each container

4.4.4.2.6 Total quantity of the item

4.5 Ordering Controlled Drug Substances

4.5.1 Schedule II drugs are ordered on the DEA 222 form. These forms are obtained from the DEA, using DEA Form-222a, by calling the nearest DEA Registration Field office or by contacting the DEA Headquarters Registration Unit at 800-882-9539. The forms are usually mailed within 10 days.

4.5.2 Who May Order

4.5.2.1 The ordering of federal controlled drug substance order forms and all scheduled II drugs will be limited to the pharmacist who signed the most recent application for DEA registration, or to persons who have been granted a power of attorney for this purpose.

4.5.2.2 A power of attorney will be issued as appropriate when approved by the pharmacist-in-charge and the manager. Only the pharmacist-in-charge may sign the power of attorney, and this individual may revoke a power of attorney at any time.

4.5.2.3 There should be no more than two powers of attorney granted within an individual pharmacy location.

4.5.2.4 A power of attorney form is available at www.dea.gov. Click on "Diversion Control and Prescription Drugs" and then select "Publications", then "Manuals". Choose the "Pharmacist's Manual", go to "Ordering Controlled Substances" then "Power of Attorney to Sign an Official Order form", and print or download the form.

4.5.3 Use of DEA 222 Controlled Drug Substance Order Form

4.5.3.1 Scheduled II drugs may only be obtained by ordering them in writing on DEA form 222.

4.5.3.2 Under no circumstances will the DEA form 222 be signed unless an order is being placed at that time. Pre-signed blank forms are not permitted.

4.5.3.3 DEA 222 forms must be executed sequentially by the serial number on the form.

4.5.3.3.1 Missing or lost order forms must be immediately reported to the pharmacist-in-charge, manager, the DEA, and the State Board of Pharmacy.

4.5.3.4 Only one supplier may be listed on each DEA 222 form.

4.5.3.5 Each item ordered must be on a separate line, i.e., each different NDC number goes on a separate line, and all boxes should be completed on each line.

4.5.3.6 If a mistake is made anywhere on the form, the entire form must be voided and a new form started. A voided form must be retained. Do not tear it up or discard it. Keep the voided form with the file with executed 222 forms in sequential order. Every DEA form must be accounted for.

4.5.3.7 Only scheduled II drugs are to be ordered on the DEA form; other controlled drugs are ordered through the usual mechanisms.

4.5.3.8 Once the DEA 222 form is complete, the pharmacist keeps and files copy 3 and sends copies 1 and 2 to the wholesaler or manufacturer.

4.6 Receiving Controlled Drug Substances

4.6.1 When receiving a schedule II controlled drug substance wholesale or manufacturer order, a pharmacist will verify the contents of the delivery

and receive it into inventory.

4.6.2 If discrepancies are noted, the discrepancies must be immediately reported to the manufacturer/distributor and documented on the invoice and DEA form.

4.6.3 The following information will be recorded by the pharmacist on Pentec Health Controlled Substance Record:

4.6.3.1.1 date of receipt

4.6.3.1.2 222 Form number

4.6.3.1.3 Quantity received

4.6.3.1.4 Signature or initials of pharmacist receiving medication

4.6.3.1.5 Balance amount in inventory

4.6.4 In addition, the pharmacist will acknowledge receipt by completing the appropriate section of the DEA form 222 indicating the number of packages received and the date, as well as signing and dating the corresponding invoice; the original invoice will be attached to the DEA order form for filing.

4.6.5 If a partial order is sent by the drug wholesaler, the pharmacist will acknowledge receipt by completing the appropriate section of the DEA form 222 indicating the number of packages received and the date, as well as signing and dating the corresponding invoice; the original invoice will be attached to the DEA order form for filing. When the remaining balance of CDS is delivered by the drug wholesaler the pharmacist will record the number of packages received and the date, as well as signing and dating the corresponding invoice and attach the additional invoice to the original DEA 222 form to complete the original order.

4.6.6 All CII invoices will be filed separately from all CIII – CVI invoices.

4.6.7 For scheduled III through VI drugs, the pharmacist will acknowledge receipt by checking each received item and by signing and dating the original invoice.

4.6.8 All invoices will be filed in the pharmacy and will be retained for a minimum of two years or according to state law.

4.7 Dispensing Controlled Drug Substances

4.7.1 Controlled drug substances must be dispensed pursuant to a valid prescription issued by a practitioner acting within the scope of his/her practice who is licensed to administer and prescribe drugs.

4.7.2 A facsimile (fax) copy of a prescription may serve as the "original" prescription when allowed by law for drugs in schedule II through VI.

4.7.3 Telephone prescriptions for schedule II substances will not be accepted unless:

4.7.3.1 It is an EMERGENCY PRESCRIPTION where:

4.7.3.1.1 An immediate administration of a schedule II drug is necessary for the patient's care

4.7.3.1.2 No other proper alternative treatment is available.

4.7.3.1.3 It is not reasonably possible for the physician to present a written prescription prior to dispensing.

4.7.3.1.4 Such dispensing is allowable by law and regulation

4.7.3.2 The quantity dispensed must be limited to an emergency supply and a written prescription must be obtained within 72 hours.

4.7.4 Upon dispensing any scheduled II prescriptions, the dispensing pharmacist will indicate in the electronic prescription record:

4.7.4.1 Name of the product used (including manufacturer or vendor in the case of generics) if it is not specified in the prescription

4.7.4.2 The exact amount of product used to prepare the prescription

4.7.4.3 Dispensing pharmacist's initials or signature according to state law

4.7.4.4 Date dispensed

4.7.5 If the pharmacist is unable to completely fill a prescription for a schedule II drug, the prescription may be partially filled provided that:

4.7.5.1 It is noted in the electronic prescription record that the prescription was partially filled with the date and quantity supplied

4.7.5.2 The remainder is provided within 72 hours

4.7.6 If the pharmacist is unable to complete the prescription within 72 hours, the physician must be notified and a new prescription obtained.

4.7.7 A schedule II prescription may also be partially filled only when allowed by applicable law and regulation.

4.7.8 Prescriptions for schedule III through V drugs may not be refilled more than 5 times in 6 months after the date of issue.

4.7.9 Refill authorizations may not exceed the amount initially prescribed.

4.7.10 When a controlled drug substance is dispensed, the following information will be recorded on the Pentec Health Controlled Substance Record:

4.7.10.1 Date dispensed

4.7.10.2 Prescription number

4.7.10.3 Patient name

4.7.10.4 Quantity dispensed

4.7.10.5 Signature or initials of pharmacist dispensing medication according to state law

4.7.10.6 Balance amount in inventory

4.8 Returning Scheduled II Drugs to a Wholesaler

4.8.1 When schedule II drugs are to be returned to a wholesaler, the pharmacist must request the wholesaler to initiate a DEA order form.

4.8.2 The pharmacy is then obligated to act as a supplier and to complete the section designated as "To Be Filled In By The Supplier" and to file one copy of the form with the DEA.

4.8.3 The supplier's copy of the DEA form will be maintained as the primary record of dispersal.

4.8.4 The DEA forms will be maintained with all other schedule II forms and invoices.

4.9 Distribution to another Registered Dispenser

4.9.1 Pursuant to the pharmacy's limited right to distribute schedule II drugs to another dispenser, i.e. a physician or another pharmacy, the other dispenser must complete a DEA form 222 and forward it to the pharmacy.

4.9.2 The pharmacy is then obligated to act as a supplier and to complete the section designated as "To Be Filled in by the Supplier" and to file one copy of the form with the DEA.

4.9.3 The supplier's copy of the DEA form will be maintained as the primary record of dispersal.

4.9.4 The DEA forms will be maintained with all other schedule II forms and invoices.

4.9.5 Distribution must not exceed 5% of the annual gross sales of all controlled drug substances distributed and dispensed.

4.9.6 Prescriptions labeled as "FOR OFFICE USE ONLY" are not acceptable for distribution of CII drugs.

4.10 Accidental Destruction and Loss of Controlled Drug Substances

4.10.1 When there is breakage, damage, spillage or other forms of accidental destruction or loss, the following procedures must be followed.

4.10.1.1 If the spillage is not recoverable, the pharmacist must document the circumstances of the spillage in their inventory records.

4.10.1.2 Two individuals who witnessed the breakage or other accidental destruction or loss must sign the inventory records, indicating what they witnessed.

4.10.1.3 Call the DEA Diversion Field Office for help if there are any questions about breakage or spillage of controlled substances, and it is not clear how to handle the situation.

4.10.1.4 DEA Form 41 must be completed. This form may be completed on-line at http://www.deadiversion.usdoj.gov/21cfr reports/surrend/index.html , or a blank form can be printed from the same website.

4.10.1.5 The DEA website is also a useful source of information.

4.11 Planned Disposal of Controlled Drug Substances

4.11.1 A controlled drug substance may be removed from inventory for disposal and/or destruction, because it is spilled, damaged, outdated, or recalled.

4.11.2 The disposal of any controlled drug substances must be done according to current DEA regulations and any applicable State Laws.

4.11.3 DEA Form 41 must be completed and submitted to DEA before the destruction or disposal of controlled drug substances.

4.11.3.1 This form may be completed on-line at http://www.deadiversion.usdoj.gov/21cfr reports/surrend/index.html, or a blank form can be printed from the same website.

4.11.3.2 After submission, wait for instructions from DEA on how to proceed before destroying or disposing of the controlled drug substances.

4.11.3.3 Call the DEA Diversion Field Office for help if there are any

questions about submitting this form.

4.11.3.4 The DEA website is also a useful source of information.

4.11.4 Prior to disposal/destruction, the following information will be recorded on the appropriate inventory record:

4.11.4.1 date removed

4.11.4.2 quantity removed

4.11.4.3 reason for removal

4.11.4.4 pharmacist removing

4.11.4.5 balance amount in inventory

4.11.5 All destructions and disposals of controlled drug substances must be witnessed and documented by two pharmacists.

4.12 Unused Controlled Drug Substance Returns

4.12.1 Patients may not return any controlled drug substance to the pharmacy for disposal. There is no provision in state or federal laws for this.

4.12.1.1 The only instances when patients may return a controlled drug to the pharmacy for disposal are in the case of a drug recall or a pharmacy dispensing error.

4.12.2 Patients with unwanted controlled drug substances are responsible for disposing of them, and do not need approval from the DEA to do so.

4.12.2.1 Patients who call about disposing of controlled drug substances should be advised on how to dispose of these dangerous drugs so that they cannot be easily retrieved.

4.12.3 A Pentec employed nurse may return a controlled drug substance to the pharmacy for disposal when it has been continuously in the control of the nurse and not delivered to the patient. The chain of custody remains with the company as long as the delivery to the patient home is not made.

4.12.3.1 The nurse must contact a pharmacist with the patient name, medication, and reason for return of the medication (i.e. patient in hospital, patient deceased, no show visit, etc.).

4.12.3.2 The nurse will repackage the medication for return by placing the medication inside a bubble envelope then the bubble envelope inside a pre-addressed Fed Ex envelope.

4.12.3.3 The nurse will call Fed Ex (1-800-463-3339) to arrange a pick up

of the medication.

4.12.3.4 The nurse will then contact a pharmacist with the expected pick up date.

4.12.3.5 The pharmacist will then notify the warehouse staff of the expected medication return.

4.12.3.6 Once the medication return arrives at Pentec:

4.12.3.6.1 The warehouse personnel will notify a pharmacist.

4.12.3.6.2 Two pharmacists will log the medication name and quantity on the Pentec Health Controlled Substance record log with their initials as witness of the disposal

4.12.3.6.3 The two pharmacists will empty the syringe(s) containing the medication down the ante room sink.

4.12.3.6.4 DEA Form 41 shall be completed as applicable.

4.13 Report of Theft or Loss of Controlled Drug Substances

4.13.1 If a theft or loss of controlled drug substances occurs, it must be reported on DEA form 106.

4.13.1.1 Report immediately any theft or loss to the pharmacist-in-charge, the pharmacy manager, and the DEA. The DEA may assist the pharmacist in completing DEA form 106.

4.13.2 This form is not used to record damage, spillage, breakage, or other forms of destruction.

4.14 Recordkeeping of Controlled Drug Substances

4.14.1 Prescriptions will be filed according to State and/or Federal laws.

4.14.2 Signed, original prescriptions for scheduled II drugs will be maintained in a separate narcotic file in the pharmacy with a copy placed in the patient's clinical record.

4.14.3 All records will be filed in the pharmacy and will be retained for a minimum of two years or according to state law.

5.0 Version Change Summary

5.1 Formatting throughout policy.
5.2 Added Purpose section to policy
5.3 Updated instructions to obtain power of attorney form in step 4.5.2.4

PENTEC HEALTH INC. AND AFFILIATED COMPANIES
1.06 v 07 CONTROLLED DRUG SUBSTANCE

6.0 Effective/ Revision Dates

6.1	Revised:	11/2012
6.2	Revised:	07/2013
6.3	Revised:	01/2014
6.4	Revised:	04/2014
6.5	Revised:	05/2014
6.6	Revised:	11/2014
6.7	Revised:	11Dec2014

7.0 Approval

	Printed Name	Signature	Date
Initiator	Michael Cardosi		15 Dec 14
Management	Barbara Knightly		15 Dec 14
QA	Andrew Waggoner		15 Dec 14

END OF PROCEDURE

PENTEC HEALTH AND AFFILIATED COMPANIES

ADMINISTRATION

S.I. POLICY AND PROCEDURE

1.16 Evaluation of Staffing

PURPOSE: To guide regional managers in establishing and maintaining adequate nursing staff in each region

POLICY:

1. The levels of staffing are determined by the Regional Nurse Manager and ultimately the Vice President of Nursing. Managers monthly, if not more often, evaluate the amount of patients each nurse has in their region. Adequate staffing takes in to consideration multiple factors that include, but are not limited to: acuity, travel time, PCN experience, completion of orientation, potential new referrals, and staff personal activity.

2. The average nurse patient ratio is 40:1. Some nurses are able to care for 50 patients. New nurses often assume care for 30 patients the first months off orientation. This is determined by the factors described above.

3. Minimum requirements of the Primary Care Nurse:

    - Current licensure as a Registered Nurse and the ability to become licensed in another state if needed.
    - 3 years clinical nursing experience required.
    - Home care experience preferred.
    - Current CPR certification.

4. Patients will be assigned and triaged by the Regional Nurse Manager in the event of employee illness, unexpected voluntary or involuntary termination of employment.

5. The Primary Care Nurse will be expected to schedule patients around Paid Time Off as able. In the event this is not feasible, the Primary Care Nurse will discuss coverage needs with the Regional Nurse Manager prior to taking Paid Time Off.

6. The back-up plan for missed scheduled visits shall not include calling for an ambulance or other emergency services unless the presence of the scheduled staff in the home would still have warranted the summons of emergency services.

See policy 1.8 Nurse Training program for information concerning orientation.

Reviewed: 12/2013 Revised 6/2014 Revised: 07/2014

PENTEC HEALTH, INC AND AFFILIATED COMPANIES

GENERAL POLICIES

POLICY AND PROCEDURE

2.15 Narcotic Waste Disposal

PURPOSE:

The nurse will document and ensure safe disposal of narcotic waste.

POLICY:

All SI Nursing personnel will adhere to this policy and procedure at all times.

PROCEDURE:

1. Narcotic removed from pump during refill procedure will be mixed with iodine into absorbent material prior to or after absorbent material is disposed of into provided waste bag. Waste bag will then be disposed of per policy.

2. The nurse will document the amount withdrawn from the pump on the refill note.
3. If the new narcotic is not used in entirety during the refill procedure, it will be considered waste and disposed as directed by step 1.

4. Narcotic waste must be witnessed by either the second nurse present or the patient/caregiver and noted by placing a check mark on the designated spot on the refill note.

5. The nurse will document the amount wasted on the Medication Safety Checklist and have the witness sign the form as the Checklist is revieved.

6. An **unused** controlled drug substance must be returned to the pharmacy for disposal only when it has been continuously in the control of the nurse and not delivered to the patient. The chain of custody remains with the company as long as the delivery to the patient is not made.
    a. The nurse must contact a pharmacist with the patient name, medication, and reason for return of the medication (i.e. patient in hospital, patient deceased, no show visit, etc.).
    b. The nurse will repackage the medication for return by placing the medication inside a bubble envelope and requesting a Fed Ex return label from the clinical liaison.
    c. The nurse will return the drug via Fed Ex, either at a drop off location or by scheduling a pickup (1-800-463-3339)
    d. The nurse will contact a pharmacist with the expected return date.

e. The medication should arrive in pharmacy with 7 days of the determination that the drug will not be administered (see Pharmacy policy 1.06).

7. The nurse will contact pharmacy for guidance regarding the determination of a narcotic waste vs unused medication in unusual circumstances.

Effective: 9/23/09	Revised: 1/2010	Revised 5/2013	Revised: 07/2014
Revised: 11/2014	Revised: 01/2015	Revised 4/2015	

ATTACHMENT TO QUESTION 5

1. Specialty Infusion Policy and Procedure – *Management of an Inadvertent Subcutaneous Administration of Medication (Pocket Fill) During an Intrathecal Pump Refill Procedure*.

2. Specialty Infusion Policy and Procedure – *Emergency Administration of Naloxone for Opiate Overdose*.

7.4 Management of an Inadvertent Subcutaneous Administration of Medication (Pocket Fill) During the Intrathecal Pump Refill Procedure

Purpose:

To support immediate detection, dose determination, and emergency intervention in the event of an inadvertent subcutaneous administration of medication during an intrathecal pump refill procedure.

SYMPTOMS INCLUDE:

- Complaint of burning or discomfort at injection site
- Injection site edema
- Fluid leakage at injection site
- Altered mental status, sedation or confusion
- Altered vital signs, hypo/hypertension
- Respiratory depression
- Loss of consciousness

Procedure:

1. If full or partial pocket fill is suspected activate Emergency Medical System immediately

2. Initiate rescue breathing/CPR immediately upon determining necessity

3. If patient has not experienced a loss of consciousness
   A. Obtain baseline vital signs
   B. Continue monitoring until either EMS takes over or rescue breathing/CPR are required

4. Re-access pump to determine subcutaneous dose administered
   A. Re-instill remaining medication
   B. Instill 20ml preservative free saline if no medication can be recovered from pump
   C. Program update for actual pump volume

5. Notify patient's physician regarding
   A. Medication and subcutaneous dose administered
   B. Provide medication toxicity information

C. Program update for flow rate per physician's order

6. Notify Regional Nurse Manager, Regional Nurse Manager to notify Vice President, Nursing

PENTEC HEALTH AND AFFILIATED COMPANIES

MEDICATION

S. I. POLICY AND PROCEDURE

7.4a Emergency administration of Naloxone for opiate overdose

PURPOSE:

To establish a protocol to administer emergency opiate reversal in the event of opiate overdose

POLICY:

All Personnel administering opiate medications shall be trained to administer Naloxone in the event of an opiate overdose.

BACKGROUND:
Pentec Health administers medications containing opiates, ie. Morphine, Hydromorphone, Sufentanil, and Fentanyl to patients via intrathecal drug delivery devices. This policy is intended to reverse opiate overdose in the event of an unintentional subcutaneous administration of medication that could occur.

MATERIALS REQUIRED:

- Pentec Health Naloxone Kit:
  - #3 Naloxone 0.4mg/ml 1 ml vials
  - #3 3 ml syringe with 22g 1# needle
  - #10 alcohol swabs
  - Oral CPR barrier

Signs and symptoms of opiate overdose

- Respiratory depression: cyanosis, agonal respirations and progression to respiratory arrest
- CNS depression: altered metal status, dizziness, severe drowsiness, progression to loss of consciousness
- Bradycardia and chest pain progressing to cardiac arrest

PROCEDURE:

1. Once an opiate overdose is confirmed call 911
2. Initiate Policy 7.4 in the event of an inadvertent subcutaneous administration of an opiate
3. Proceed with naloxone administration if the patient progresses to cardiac or respiratory arrest;
   a) Access the Pentec Health Naloxone kit
   b) Remove cap of the naloxone vial
   c) Draw up 1cc of naloxone 0.4mg/ml into a 3ml syringe with a 22g 1" needle
   d) Cleanse the injection area with an alcohol swab
   e) Administer an intramuscular injection into the upper arm, thigh, or buttock
4. Provide Continuous Monitoring until EMS arrives

a. Naloxone re-administration may be required after 5minutes of the initial dose, if the patient fails to rouse
b. Naloxone serum half -life ranges from 30-81 minutes. The half-life of Naloxone is shorter than many opioids. Therefore it is important to continue to monitor for return of sedation or respiratory depression at which time the patient can lapse back into overdose.
c. If re-overdose dose occur, repeat administration procedure.

5. When the patient revives, prepare to educate them on the temporary effects of narcotic reversal, while keeping patient calm until EMS can transport them to a medical facility for inpatient monitoring and care.

Caution: Naloxone administration to a patient physically dependent on opioids will cause the abrupt awakening, return of pain and can precipitate withdrawal symptoms: anxiety, irritability and muscle aches, nausea and vomiting, diarrhea, sweating and agitation.

References

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http://www.drugs.com/pro/narcan.html

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Rx List, The Internet Drug Index (2009). Narcan. Retrieved on March, 2015, from

http://www.rxlist.com/narcan-drug.htm

ATTACHMENT TO QUESTION 6

Specialty Infusion Policy and Procedure – *Evaluation of Staffing*.

PENTEC HEALTH AND AFFILIATED COMPANIES

ADMINISTRATION

S.I. POLICY AND PROCEDURE

1.16 Evaluation of Staffing

PURPOSE: To guide regional managers in establishing and maintaining adequate nursing staff in each region

POLICY:

1. The levels of staffing are determined by the Regional Nurse Manager and ultimately the Vice President of Nursing. Managers monthly, if not more often, evaluate the amount of patients each nurse has in their region. Adequate staffing takes in to consideration multiple factors that include, but are not limited to: acuity, travel time, PCN experience, completion of orientation, potential new referrals, and staff personal activity.

2. The average nurse patient ratio is 40:1. Some nurses are able to care for 50 patients. New nurses often assume care for 30 patients the first months off orientation. This is determined by the factors described above.

3. Minimum requirements of the Primary Care Nurse:

    - Current licensure as a Registered Nurse and the ability to become licensed in another state if needed.
    - 3 years clinical nursing experience required.
    - Home care experience preferred.
    - Current CPR certification.

4. Patients will be assigned and triaged by the Regional Nurse Manager in the event of employee illness, unexpected voluntary or involuntary termination of employment.

5. The Primary Care Nurse will be expected to schedule patients around Paid Time Off as able. In the event this is not feasible, the Primary Care Nurse will discuss coverage needs with the Regional Nurse Manager prior to taking Paid Time Off.

6. The back-up plan for missed scheduled visits shall not include calling for an ambulance or other emergency services unless the presence of the scheduled staff in the home would still have warranted the summons of emergency services.

See policy 1.8 Nurse Training program for information concerning orientation.

Reviewed: 12/2013 Revised 6/2014 Revised: 07/2014

ATTACHMENT TO QUESTION 8

1. Physician Letters.
2. Patient Letter.

Consultants in Pain Management
2000 Stein Drive
Chattanooga, TN 37421
(423)648-8480 Fax (423)648-8481

April 28, 2015

Dear CON board,

I am writing in support of Pentec Health, Inc. being granted their certificate of need by the state of Tennessee to become licensed as a home health agency so that patients with intrathecal pumps can be efficiently serviced in their homes.

Intrathecal pumps allow highly concentrated medications for pain and spasticity to be administered through the intrathecal space surrounding the spinal cord. This form of drug administration is very different from the delivery of medication intravenously or subcutaneously and requires highly specialized nursing and pharmaceutical services. Several of my patients have an intrathecal pump because they have not been able to obtain proper relief from traditional treatments for conditions such as chronic pain and/or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer.

Currently, these patients must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of few providers in Tennessee that treat patients with intrathecal pumps. We have over 115 patients coming from all areas of the state for intrathecal pump maintenance.

Sincerely,

Gregory Ball, MD

131 SAUNDERSVILLE ROAD SUITE 160, HENDERSONVILLE, TN 37075 | WWW.CPSPAIN.COM

December 1, 2014

Dear ,

I am writing in support of Pentec Health, Inc. being granted their certificate of need by the state of Tennessee to become licensed as a home health agency so that patients with intrathecal pumps can be efficiently serviced in their homes.

Intrathecal pumps allow highly concentrated medications for pain and spasticity to be administered through the intrathecal space surrounding the spinal cord. This form of drug administration is very different from the delivery of medication intravenously or subcutaneously and requires highly specialized nursing and pharmaceutical services. Several of my patients have an intrathecal pump because they have not been able to obtain proper relief from traditional treatments for conditions such as chronic pain and/or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer.

Currently, these patients must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of few providers in Tennessee that treat patients with intrathecal pumps. We have patients coming from all areas of the state.

Sincerely,

Physician

April 10, 2015

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

To Whom It May Concern:

I am writing to you as a consumer of health care in Tennessee to show my support of Pentec Health, Inc. obtaining a Certificate of Need for a Home Care Organization in Tennessee. I am a current patient of Pentec and have been since August 2014. Although I live in Kentucky and my primary physician is located in Kentucky, I also receive some health care services in Tennessee.

In October 2014, I was hospitalized at St. Thomas Hospital in Nashville, Tennessee. During my time in Tennessee my intrathecal pump, which I use for management of chronic pain, was about to go dry. My Pentec nurse was unable to fill my pump because Pentec is not licensed in Tennessee. Despite great efforts on my and Pentec's part, which included coordinating with the hospital; contacting Medtronic, the manufacturer of my pump; and contacting Ann Rutherford Reed, RN, Director of Licensure in the Division of Health Licensure and Regulations to request special permission, Pentec was unable to get permission to fill my pump on an emergency basis in Tennessee. Unfortunately, no one was able to fill my pump during my time in Tennessee.

Rather than allowing my pump to actually run dry, which likely would damage the pump and prevent it from functioning correctly ever again, it was decided that someone would turn my pump down to "minimal rate" (the minimum required to keep it running). I am not sure who did this while I was in St. Thomas Hospital, but it was done during my hospitalization. I believe it may have been a Medtronic representative.

Since this time, I have remained on minimal rate. The plan is to slowly increase the rate of my pump back to where it was prior to my October 2014 hospitalization. Unfortunately, with the medication concentration that I am on, the next dose my physician has ordered cannot be administered with the pump. My understanding is the difference between minimal rate and the lowest rate the pump can run in regular mode would be too big of a jump in my dosing. I now need to have the medication concentration decreased, which will include removing the contents of my catheter. Unfortunately, this procedure must be done at my physician's office, and due to my health status, I have not been able to get to the office.

If Pentec had been allowed into St. Thomas Hospital to fill my pump, I would not be in the situation I am currently in and my therapy would not have been interrupted. For this reason I support Pentec's application for a Certificate of Need for a Home Care Organization in Tennessee.

Sincerely,

Paula Pennington

ATTACHMENT TO QUESTION 10

List of Pentec Services Covered by the Per Diem Charge.

pentec health

SERVICES COVERED BY THE PER DIEM

A. Pharmacy Professional and Cognitive Services. Including:

1. Initial and ongoing patient assessment and clinical monitoring.
2. Development and implementation of pharmaceutical care plans.
3. Coordination of care with physicians, nurses, patients, patient's family, other providers, and other caregivers.
4. Sterile procedures, including intravenous admixtures, clean room upkeep, vertical and horizontal laminar flow hood certification, and all other biomedical procedures necessary for a safe environment.
5. Compounding of medications.
6. Pharmacokinetic dosing.
7. Medication profile set-up.
8. Drug utilization review.
9. Comprehensive knowledge of vascular access systems.
10. Patient educational activities.
11. Monitoring of potential drug interactions.
12. Review and interpretation of patient test results.
13. Recommendation of dosage or medication changes based on clinical findings.
14. Patient discharge services, including communication with other medical professionals and closing of the medical record. Other applicable professional and cognitive services.

B. Overhead and operational expenses. Including:

1. Wages, salaries, benefits, payroll taxes, FICA, unemployment insurance, and workers compensation premiums.
2. Office supplies.
3. Sales, advertising, and marketing.
4. Physical plant expenses.
5. Utilities and telephone.
6. Cell phones and pagers.
7. Postage and shipping.
8. Patient education materials.
9. Continuing education expenses.
10. Legal and accounting expenses.
11. Licensing fees.
12. Infectious waste storage and removal.
13. Medical records storage and retrieval.
14. Community commitment and charitable donations.
15. Property Taxes.
16. New product research and development.
17. Other applicable overhead and operational expenses.

C. Infusion therapy related supplies. Including:

1. Durable, reusable infusion pumps.
2. Elastomeric, disposable infusion pumps.
3. All other infusion therapy administration devices.
4. Short peripheral vascular access devices.
5. Needles, gauze, sterile tubing, catheters, dressing kits, and other supplies necessary for the safe and effective administration of infusion therapy.
6. Other applicable supply expenses.

D. Comprehensive 24 hour per day, seven days per week delivery and pick-up services. Includes mileage and the constant availability of a dedicated infusion team consisting of pharmacist(s), nurse(s), delivery team, and all other medical professionals responsible for clinical response, problem solving, trouble shooting, question answering, and other professional duties during evenings, weekends, holidays, and all other times.

E. Clinical Coordination. Including:

1. Development and monitoring of nursing care plans.
2. Coordination of benefits, care and services.
3. Development of Patient Assessment and Patient Education materials.
4. Coordination of non-Infusion related services.
5. Case Management services.
6. Measurement of Field Nursing competency with subsequent education and training.
7. Coordination, education, training and management of Field Nursing staff (or sub-contracted agencies).

F. Inventories and accounts receivable. Including:

1. Interest and opportunity costs associated with the carrying of large accounts receivable balances.
2. Depreciation expenses.
3. Equipment maintenance and repair.
4. Other applicable inventory and accounts receivable expenses.

G. Costs associated with substantial insurance requirements.

Includes costs associated with remaining in compliance with all state and federal regulatins related to minimal insurance coverage.

H. Costs associated with accreditation requirements. Including:

1. Outcomes assessments and analysis.
2. Ongoing staff development and competency assessment.
3. Continuous quality assessment and performance improvement programs.
4. All other policies and procedures necessary to remain in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Community Health Accreditation Program (CHAP), Accreditation Commission for HealthCare (ACHC), and other professional accreditation standards.
5. Certification fees and expenses.
6. Other applicable accreditation expenses.

I. Costs associated with administrative requirements. Including:

1. Insurance verification processes.
2. Prior authorization requirements.
3. Billing functions.
4. Account Posting functions.
5. Account collection activities.
6. Bad debt expense.
7. Certificate of medical necessity and other medical necessity documentation.
8. Internal and external auditing and other regulatory compliance activities.
9. Quality assessment and improvement activities.
10. Professional association and subsequent fees.
11. Other applicable administrative costs.

ATTACHMENT TO QUESTION 11

1. Indiana State Department of Health letter dated April 22, 2015, re: HHA license renewal.
2. Indiana Home Health Agency License No. 15-012608-1.

Indiana State
Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

April 22, 2015

Facility 012608

KAREN MCHENRY
ADMINISTRATOR
PENTEC HEALTH INC
48 NORTH EMERSON AVENUE SUITE 300
GREENWOOD, IN 46143

Dear KAREN MCHENRY:

We are pleased to inform you that you meet the licensure requirements for home health agencies in Indiana.

Your license covering the period from June 1, 2015 through May 31, 2016 is enclosed. You should report any changes in staffing, service, or organization, which might affect your licensure status, to the State Department of Health.

We appreciate your cooperation and look forward to your continued participation in the licensing program.

Sincerely,

Kelly Hemmelgarn

KELLY HEMMELGARN, BSN, RN
PHNSS - PROGRAM DIRECTOR
ACUTE CARE DIVISION
317/233-7541

Enclosure

Indiana State Department of Health

Home Health Agency License

This is to certify that:

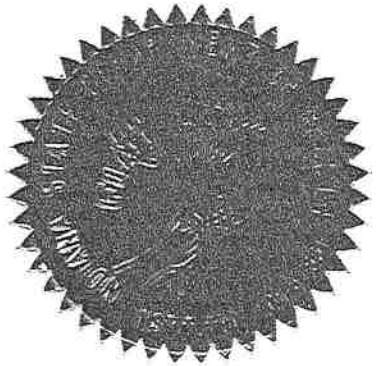
Pentec Health Inc d/b/a

PENTEC HEALTH INC
48 NORTH EMERSON AVENUE SUITE 300
GREENWOOD, IN

a Home Health Agency, along with all off premise locations listed on the supplemental license, has fulfilled the requirements for licensure and is subject to provisions of IC 16-27, 410 IAC 17 and the rules of the Indiana State Department of Health issued thereunder.

This license shall not be assignable or transferable, and shall be subject to revocation at any time by the Indiana State Department of Health for failure to comply with the laws of the State of Indiana or the rules of the Indiana State Department of Health issued thereunder.

License number 15-012608-1 is effective June 1, 2015 and expires May 31, 2016.



Randall Snyder

RANDALL SNYDER PT, MBA
DIRECTOR, ACUTE CARE DIVISION

State Form 44840 (R6/5-05)

APPENDIX: STATE REGULATIONS

The following is a list and summary of the principal state statutes and regulations governing Pentec's provision of Specialty Infusion services in the residential setting, whether Pentec (i) is licensed as a home health agency, (ii) is licensed under a category other than home health agency, or (iii) operates without an entity-level license, but with state-licensed registered nurses. The corresponding Tennessee statutes and regulations are listed, for information only, at the end of the table below.

As part of each state licensure process, Pentec prepares a cross-reference of applicable regulatory requirements to its standard Policies and Procedures Manual, and prepares state-specific policies and procedures to the extent necessary.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
1.	Alabama	None	Nursing Statute: Ala. Code § 34-21-1 et seq. Board of Nursing Regulations: Ala. Admin. Code r. 610-X-1-.01 et seq.	Specific nursing regulatory requirements re: intrathecal drug administration include: • Standardized procedures required. • RN prohibited from administering initial dose. See Ala. Admin. Code r. 610-X-1-.07(5) and (6) (attached). *No state licensure of HHAs, but CON is required if agency provides skilled nursing and other enumerated services.* Ala. Admin. Code r. 410-2-4-.07.
2.	Arizona	None	Nursing Statute: Ariz. Rev. Stat. Ann. § 32-1601 et seq. Board of Nursing Regulations: Ariz. Admin. Code R4-19-101 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other enumerated service.* Ariz. Rev. Stat. Ann. § 36-151; Ariz. Admin. Code R9-10-101 et seq.; Ariz. Admin. Code R9-10-1201 et seq.
3.	Colorado	HHA (Class A)	HHA Licensure Statute: Colo. Rev. Stat. Ann. § 25-27.5-101 et seq. HHA Administrative Regulations: 6 Colo. Code Regs. § 1011:XXVI-1 et seq. Nursing Statute: Colo. Rev. Stat. Ann. § 12-38-103 et seq. Board of Nursing Regulations: 3 Colo. Code Regs. § 716-1:1-1 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and periodic inspection at DOH discretion. In-state office required; limited office hours permitted. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.

[1] The term "home health agency" or "HHA" is used for convenience; some states use other names for home health care providers.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
4.	Connecticut	None	Nursing Statute: Conn. Gen. Stat. Ann. § 20-87a et seq. Board of Nursing Regulations: Conn. Agencies Regs. § 20-90-45 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and other enumerated services.* Conn. Agencies Regs. § 19-13-D66 et seq.
5.	Delaware	None	Nursing Statute: 24 Del. Code Ann. § 1902 et seq. Board of Nursing Regulations: 24 Del. Admin. Code § 1900-1.0 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other service.* 16 Del Admin. Code § 4410-1.0 et seq.
6.	District of Columbia	HHA	CON Regulations: 22 D.C. Mun. Regs. § 4000 et seq. HHA Licensure Statute and Regulations: D.C. Code Ann. § 44-501 et seq. 22-B D.C. Mun. Regs. § 3100 et seq. HHA Administrative Regulations: 22-B D.C. Mun. Regs. § 3900 et seq. Nursing Statute: D.C. Code Ann. § 3-1205.01 et seq. Board of Nursing Regulations: 17 D.C. Mun. Regs. § 5400 et seq.	CON required as a condition to HHA licensure; no specific CON requirements re: intrathecal infusion. HHA licensure required if agency provides at least one service. Subject to initial survey and annual inspection. In-District office required. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
7.	Florida	None	Nursing Statute: Fla. Stat. Ann. § 464.003 et seq. Board of Nursing Regulations: Fla. Admin. Code r. 64B9-1.001 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if an entity provides more than one health care professional discipline (of which skilled nursing is one).* Fla. Stat. Ann. § 400.461 et seq.
8.	Georgia	None	Nursing Statute: Ga. Code Ann. § 43-26-3 et seq. Board of Nursing Regulations: Ga. Comp. R. & Regs. r. 410-1-.01 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other service.* Ga. Code Ann. § 31-7-150 et seq.; Ga. Comp. R. & Regs. r. 111-8-31-.01 et seq. *Private Home Care Provider licensure not required if agency provides skilled nursing as an integral part of home infusion therapy.* Ga. Code Ann. § 31-7-300 et seq.; Ga. Comp. R. & Regs. r. 111-8-65-.10 et seq.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
9.	Illinois	Home Nursing Agency ("HNA")	HHA and HNA Licensure Statute: 210 Ill. Comp. Stat. Ann. 55/1.01 et seq. HHA and HNA Administrative Regulations: 77 Ill. Admin. Code § 245.10 et seq. Nursing Statute: 225 Ill. Comp. Stat. Ann. 65/60-5 et seq. Board of Nursing Regulations: 68 Ill. Admin. Code § 1300.10 et seq.	HHA licensure required if agency provides *skilled nursing and at least one other service.* HNA licensure required if agency provides *skilled nursing only.* Subject to initial survey and periodic inspection at DOH discretion. In-state office required; limited office hours permitted. Service area may be restricted depending on staff levels. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
10.	Indiana	HHA	HHA Licensure Statute: Ind. Code Ann. § 16-27-0.5-0.5 et seq. HHA Administrative Regulations: 410 Ind. Admin. Code r. 17-9-1 et seq. Nursing Statute: Ind. Code Ann. § 25-23-1-1.1 et seq. Board of Nursing Regulations: 848 Ind. Admin. Code r. 1-1-2.1 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and periodic inspection at DOH discretion. In-state office required; limited office hours permitted. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
11.	Iowa	None	Nursing Statute: Iowa Code Ann. § 147.1 et seq. Board of Nursing Regulations: Iowa Admin. Code r. 655-11.1 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *Iowa does not license HHAs.*
12.	Kansas	HHA	HHA Licensure Statute: Kan. Stat. Ann. § 65-5101 et seq. HHA Administrative Regulations: Kan. Admin. Regs. § 28-51-100 et seq. Nursing Statute: Kan. Stat. Ann. § 65-1113 et seq. Board of Nursing Regulations: Kan. Admin. Regs. § 60-1-102 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and periodic inspection not less than every 3 years. In-state office required. Service area limited to 100-mile radius around office location. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
13.	Kentucky	Mobile Health Service ("MHS")	Health Care Facility Licensure Statute and Administrative Regulations: Ky. Rev. Stat. Ann. § 216B.010 et seq. 902 Ky. Admin. Regs. § 20:008 MHS Administrative Regulations: 902 Ky. Admin. Regs. § 20:275 Nursing Statute: Ky. Rev. Stat. Ann. § 314.011 et seq. Board of Nursing Regulations: 201 Ky. Admin. Regs. § 20:056 et seq.	CON required as a condition to MHS licensure. CON specifies that (i) service is not restricted to start-up of therapy; and (ii) service is limited to intrathecal pump services; no IV infusion permitted. Otherwise, no specific CON requirements re: intrathecal infusion. MHS licensure subject to initial survey and periodic inspection at DOH discretion. No in-state office required. Service area is limited to 116 of the 120 counties in Kentucky. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
14.	Louisiana	None	Nursing Statute: La. Rev. Stat. Ann. § 37:913 et seq. Board of Nursing Regulations: 46 La. Admin. Code § 3101 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other service.* La. Rev. Stat. Ann. § 40:2116.31 et seq.; 48 La. Admin. Code § 9101 et seq.
15.	Maryland	Residential Service Agency ("RSA")	RSA Licensure Statute: Md. Code, Health – Gen. § 19-4A-01 et seq. RSA Administrative Regulations: 10 Code Md. Regs. § 07.05.01 et seq. Nursing Statute: Md. Code, Health Occup. § 8-101 et seq. Board of Nursing Regulations: 10 Code Md. Regs. § 27.01.01 et seq.	HHA licensure required if agency provides *skilled nursing and at least one other service.* RSA licensure required if agency provides *skilled nursing only.* RSA licensure subject to periodic inspection at DOH discretion. No in-state office required. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. Specific nursing regulatory requirements re: intrathecal drug administration include: • Authorization of RN to refill, program and administer medication by intrathecal pump, after completion of a specialized educational program (including clinical practicum) with standards established by bodies approved by the Board and documented evidence of clinical competency. • RN prohibited from administering initial dose. See 10 Code Md. Regs. §§ 27.20.02(B)(30); 27.20.06(B)(4) and (C)(1) (attached)

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
16.	Massachusetts	None	Nursing Statute: Mass. Gen. Laws Ann. ch. 112 § 74 et seq. Board of Nursing Regulations: 244 Mass. Regs. Code § 3.00 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *Massachusetts does not license HHAs.*
17.	Michigan	None	Nursing Statute: Mich. Comp. Laws Ann. § 333.16174 et seq. Board of Nursing Regulations: Mich. Admin. Code r. 338.10101 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *Michigan does not license HHAs.*
18.	Minnesota	HHA (Class A)	HHA Licensure Statute: Minn. Stat. Ann. § 144A.43 et seq. HHA Administrative Regulations: Minn. R. 4668.0002 et seq. Nursing Statute: Minn. Stat. Ann. § 148.171 et seq. Board of Nursing Regulations: Minn. R. 6301.0100 et seq.; 6305.0100 et seq.; 6310.2600 et seq.; 6321.0100 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and periodic inspection not less than every 2 years. In-state office required; limited office hours permitted. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
19.	Mississippi	None	Nursing Statute: Miss. Code Ann. § 73-15-3 et seq. Board of Nursing Regulations: Miss. Admin. Code 30-18-2801:1.1 et seq.; 30-18-2810:1.1 et seq.; 30-18-2820:1.1 et seq.; 30-18-2830:1.1 et seq.; 30-18-2840:1.1 et seq.; 30-18-2850:1.1 et seq.; 30-18-2870:1.1 et seq.; 30-18-2880:1.1 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other service.* Miss. Code Ann. § 41-71-1 et seq.; Miss. Admin. Code 15-16-1:46.1 et seq.
20.	Missouri	None	Nursing Statute: Mo. Ann. Stat. § 335.016 et seq. Board of Nursing Regulations: 20 Mo. Code Regs. § 2200-1.010 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides two or more services.* Mo. Ann. Stat. § 197.400 et seq.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
21.	Nebraska	HHA	HHA Licensure Statute: Neb. Rev. Stat. Ann. § 71-401 et seq. HHA Administrative Regulations: 175 Neb. Admin. Code § 14-001.01 et seq. Nursing Statute: Neb. Rev. Stat. Ann. § 38-2201 et seq. Board of Nursing Regulations: 172 Neb. Admin. Code § 101-001 et seq.	HHA licensure required if agency provides skilled nursing or at least one other therapeutic service. Subject to initial survey and periodic inspection at DOH discretion. In-state office required; limited office hours permitted. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
22.	New Hampshire	HHA	HHA Licensure Statute: N.H. Rev. Stat. Ann. § 151.1 et seq. HHA Administrative Regulations: N.H. Code Admin. R. He-P 809.01 et seq. Nursing Statute: N.H. Rev. Stat. Ann. § 326-B:2 et seq. Board of Nursing Regulations: N.H. Code Admin. R. Nur. 101.01 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and annual inspection. In-state office required (waived per agreement with DOH). No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
23.	New Jersey	Health Care Service Firm ("HCSF")	HCSF Licensure Statute: N.J. Rev. Stat. Ann. § 34:8-43 – 8-46 HCSF Administrative Regulations: N.J. Admin. Code § 13:45B-13.1 et seq. Nursing Statute: N.J. Rev. Stat. Ann. §§ 45:11-23; 45:11-26 Board of Nursing Regulations: N.J. Admin. Code § 13:37-1.1 et seq.	HHA licensure required if agency provides *skilled nursing and other therapeutic, preventive and rehabilitative services*. N.J. Admin. Code § 8:42-1.1 et seq. HCSF licensure required if agency *employs individuals to provide health care services in the home*. No in-state office required. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
24.	New Mexico	HHA	Health Facilities Licensure Statute: N.M. Stat. Ann. § 24-1-5. HHA Administrative Regulations: N.M. Admin. Code § 7.28.2.1 et seq. Nursing Statute: N.M. Stat. Ann. § 61-3-3 et seq. Board of Nursing Regulations: N.M. Admin. Code § 16.12.1 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and annual inspection. In-state office required; limited office hours permitted. Service area limited to 100-mile radius around office location, but requirement is waivable on a patient-by-patient basis if alternative home care is unavailable. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
25.	North Carolina	Home Care Agency ("HCA")	HCA Licensure Statute: N.C. Gen. Stat. § 131E-135 et seq. HCA Administrative Regulations: 10A N.C. Admin. Code § 13J.0901 et seq. Nursing Statute: N.C. Gen. Stat. § 90-171.20 et seq. Board of Nursing Regulations: 21 N.C. Admin. Code § 36.0101 et seq.	HHA licensure required if a home health agency is *Medicare and Medicaid certified*. N.C. Gen. Stat. § 131E-136. HCA licensure required if a home health agency is *not Medicare and Medicaid certified*. Subject to initial survey and periodic inspection at DOH discretion. In-state office required; limited office hours permitted. Service area may be restricted depending on staff levels. Specific HCA regulatory requirements re: "infusion nursing" (including intrathecal drug administration): • Must be provided by or under supervision of a registered nurse with special training in the therapies provided by the agency, in accordance with agency policy, and in accordance with the N.C. Nursing Practice Act. • Services must be available 24/7. See 10A N.C. Admin. Code §§ 13J.0901(13); 13J.1108 (attached) No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
26.	Ohio	None	Nursing Statute: Ohio Rev. Code Ann. § 4723.01 et seq. Board of Nursing Regulations: Ohio Admin. Code § 4723-2-01 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *Ohio does not license HHAs.*
27.	Oregon	None	Nursing Statute: Or. Rev. Stat. § 678.010 et seq. Board of Nursing Regulations: Or. Admin. R. 851-001-0000 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other service.* Or. Rev. Stat. § 443.005 et seq.; Or. Admin. R. 333-097-0000 et seq.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
28.	Pennsylvania	None	Nursing Statute: Pa. Stat. Ann. § 212 et seq. Board of Nursing Regulations: 49 Pa. Code § 21.1 et seq.	Specific nursing r regulatory requirements re: intrathecal drug administration include: • Administration of intrathecal medications falls within the scope of "registered nursing practice." • The RN must have adequate knowledge, skills and training in the practice area. • Standards of practice developed by "appropriate nursing associations" are required for safe and effective practice. See 49 Pa. Code §§ 21.413(b)(3) and (4); 21.11(c) and (d) (attached) *HHA licensure required if agency provides skilled nursing and at least one other service.* 28 Pa. Code § 601.6.
29.	South Dakota	None	Nursing Statute: S.D. Codified Laws § 36-9-1 et seq. Board of Nursing Regulations: S.D. Admin. R. 20:48:01:01 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *South Dakota does not license HHAs.*
30.	Texas	HHA	HHA Licensure Statute: Tex. Health & Safety Code Ann. § 142.001 et seq. HHA Administrative Regulations: 40 Tex. Admin. Code § 97.1 et seq. Nursing Statute: Tex. Occ. Code Ann. § 301.002 et seq. Board of Nursing Regulations: 22 Tex. Admin. Code §§ 213.1 et seq.; 216.1 et seq.; 217.1 et seq.; 228.1 et seq.	HHA licensure required if agency provides at least one service. Subject to initial survey and periodic inspection not less than every 3 years. In-state office required; limited office hours permitted. No service area restrictions. No specific statutory or regulatory requirements re: intrathecal infusion. No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
31.	Vermont	None	Nursing Statute: 26 Vt. Stat. Ann. § 1572 et seq. Board of Nursing Regulations: Vt. Code R. 20-4-1100:1 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and at least one other service.* Vt. Code R. 12-4-205:1 et seq.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
32.	Virginia	HHA	HHA Licensure Statute: Va. Code Ann. § 32.1-162.7 et seq. HHA Administrative Regulations: 12 Va. Admin. Code § 5-381-10 et seq. Nursing Statute: Va. Code Ann. § 54.1-3000 et seq. Board of Nursing Regulations: 18 Va. Admin. Code § 90-20-10 et seq.	HHA licensure required if agency provides one or more services. Subject to initial survey and annual inspection. In-state office required; limited office hours permitted. No service area restrictions. Specific HHA regulatory requirements re: "infusion therapy" (which includes intrathecal drug administration): • Medications may be administered only by licensed nurses. • Agency must develop written policies and procedures. • Agency must employ a registered nurse who has completed training in infusion therapy and has the knowledge, skills and competencies to safely administer infusion therapy, who shall supervise administration of medications, ensure compliance with policies and applicable law, and assess staff competency. See 12 Va. Admin. Code §§ 5-381-10; 5-381-350(C) and (D) (attached) No specific nursing statutory or regulatory requirements re: intrathecal drug administration.
33.	West Virginia	None	Nursing Statute: W.Va. Code Ann. § 30-7-1 et seq. Board of Nursing Regulations: W.Va. Code St. R. §§ 19-3-1 et seq.; 19-10-1 et seq.; 19-11-1 et seq.; 19-14-1 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *No state licensure of HHAs, but CON is required if agency provides skilled nursing and at least one other service.* W.Va. Code Ann. § 16-2D-1 et seq.
34.	Wisconsin	None	Nursing Statute: Wis. Stat. Ann. § 441.001 et seq. Board of Nursing Regulations: Wis. Admin. Code § N 1.01 et seq.	No specific nursing statutory or regulatory requirements re: intrathecal drug administration. *HHA licensure required if agency provides skilled nursing and other services.* Wis. Stat. Ann. § 50.49 et seq.; Wis. Admin. Code § DHS 101.03 et seq.

	State	Licensure Category[1]	Principal Applicable Statutes and Regulations	Summary of Requirements
	Tennessee		*CON Statute and Regulations:* *Tenn. Code Ann. § 68-11-1601 et seq.* *Tenn. Comp. R. & Regs. § 0720-01 et seq.* *HHA Licensure Statute:* *Tenn. Code Ann. § 68-11-201 et seq.* *HHA Administrative Regulations:* *Tenn. Comp. R. & Regs. § 1200-08-26-.01 et seq.* *Nursing Statute:* *Tenn. Code Ann. § 63-7-103 et seq.* *Board of Nursing Regulations:* *Tenn. Comp. R. & Regs. § 1000-01-.01 et seq.*	*CON required as a condition to HHA licensure; no specific CON requirements re: intrathecal infusion.* *HHA licensure required if agency provides one or more of the services specified at Tenn. Comp. R. & Regs. § 1200-08-26-.01(29). Subject to initial survey and annual license renewal. In-state office required. No specific statutory or regulatory requirements re: intrathecal infusion.* *No specific nursing statutory or regulatory requirements re: intrathecal drug administration.*

Alabama Administrative Code Currentness
Alabama Board of Nursing
Chapter 610-X-6. Standards of Nursing Practice

Ala. Admin. Code r. 610-X-6-.07

610-X-6-.07. Medication Administration And Safety.

(1) The registered nurse or licensed practical nurse shall have applied knowledge of medication administration and safety, including but not limited to

(a) Drug action.

(b) Classifications.

(c) Expected therapeutic benefit of medication.

(d) Expected monitoring.

(e) Indications based on existing patient illness or injury processes.

(f) Contraindications based on presence of additional known patient illnesses, disease processes or pre-existing conditions.

(g) Possible side effects and interventions for same.

(h) Adverse reactions and interventions for same.

(i) Emergency interventions for anaphylactic reactions.

(j) Safety precautions including but not limited to:

(i) Right patient.

(ii) Right medication.

(iii) Right time.

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(iv) Right dose

(v) Right route.

(vi) Right reason.

(vii) Right documentation.

(k) Interactions with other drugs, foods or complementary therapies.

(l) Calculation of drug dosages.

(m) Federal and state legal requirements related to storage of controlled substances.

(n) Patient education specific to medication.

(2) The registered nurse or licensed practical nurse shall exercise decision-making skills when administering medications, to include but not limited to:

(a) If medications should be administered.

(b) Assessment of patient's health status and complaint prior to and after administering medications including as needed (PRN) medications.

(c) When to contact the prescriber.

(d) Education of patient, family and caregiver regarding prescribed medication.

(3) The registered nurse or licensed practical nurse shall exhibit skills when administering medications including but not limited to:

(a) Physical ability to open medication packaging and access delivery systems.

(b) Read, write, and comprehend English.

(c) Read, write, and comprehend scientific phrases relevant to administration of medication.

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(d) Measuring medication dosages.

(e) Math calculations.

(f) Routes of administration.

(g) Proper usage of technical equipment for medication administration.

(4) Documentation of medication administration shall comply with the principles of documentation and include safety precautions of medication administration, controlled drug records per federal and state law, and facility policy.

(5) Administration of medications by routes beyond basic educational preparation, including but not limited to intrathecal, intracavitary, intraosseus, require a standardized procedure.

(6) The registered nurse may not administer the initial dose of any medication by intrathecal, epidural, intrapleural or peripheral nerve catheter.

(7) The registered nurse is not authorized to administer bolus dosages via an epidural or brachial plexus catheter.

(8) The topical, intradermal, subcutaneous, or intramuscular administration of a local anesthetic agent in a specified amount designated by order of a licensed physician or dentist and in compliance with the Food and Drug Administration regulations may be performed by a registered nurse or licensed practical nurse when they meet the requirements of Rule 610-X-6-.04 or 610-X-6-.05 respectively.

(9) The monitoring and adjustment of local anesthetic agent(s) and analgesic agent(s) infusing via an epidural, brachial plexus, or femoral catheter placed by a qualified certified registered nurse anesthetist or qualified licensed physician may be performed by a registered nurse, with the use of an electronic pump or infusion reservoir, as ordered by a licensed prescriber.

(a) The registered nurse is authorized to replace and refill reservoirs with a solution prepared by a licensed registered pharmacist. The registered nurse is authorized to adjust infusion rates at the direction of a physician licensed to practice medicine or a certified registered nurse anesthetist.

(b) A standardized procedure is required for monitoring and adjustment of epidural, brachial plexus, and femoral catheter infusions of local anesthetics and analgesics.

(c) The organized program of study shall include:

(i) Advanced cardiac life support or other comparable certification.

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(ii) Review of pertinent anatomy, physiology, and pathophysiology.

(iii) Electronic pump/reservoir management.

(iv) Theory of epidural analgesia.

(v) Neurological assessment.

(vi) Recognition and management of complications.

(vii) Pharmacokinetiecs and pharmacodynamics

(viii) Annual review and competency evaluation.

(10) Intravenous chemotherapeutic agents may be administered by registered nurses following participation in:

(a) An organized program of study.

(b) Supervised clinical practice.

(c) Demonstrated clinical competence.

(d) Annual evaluation of competence.

AUTHOR:

Alabama Board of Nursing

STATUTORY AUTHORITY:

Code of Ala. 1975, §§ 34-21-2(c)(21).

HISTORY:

New Rule: Filed October 29, 2001; effective December 3, 2001. **Repealed and New Rule:** Filed November 23, 2009; effective December 28, 2009.

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Code of Maryland Regulations
Title 10. Department of Health and Mental Hygiene
Subtitle 27. Board of Nursing
Chapter 20. Management of Infusion Therapy by the Registered Nurse and the Licensed Practical Nurse (Refs & Annos)

COMAR 10.27.20.02

.02. Definitions.

Currentness

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Administer" means to hang or give subsequent fluids and medications.

(2) "Antineoplastic" means:

(a) Chemical or biologic agents that have a toxic effect on the disease-causing agent or modify the host environment; or

(b) Drugs that are capable of destroying invading organisms or malignant tumor cells.

(3) "Arterial catheter" means a catheter or needle inserted into an artery.

(4) "Assign" means to designate another licensee to be responsible and accountable to perform nursing acts that are within the licensee's scope of practice, knowledge, judgment, and skill.

(5) "Central venous catheter (CVC)" means a catheter whose tip is located in a central vessel.

(6) "Chronic dialysis client" means a client with end stage renal disease who is receiving routine dialysis treatments in an outpatient facility.

(7) "Clinical competence" means the demonstrated ability to perform the identified IV tasks consistent with the standards established by the INS, ONS, or other bodies approved by the Board.

(8) "Comprehensive assessment" means a nursing assessment that includes:

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(a) The specific individual patient's clinical status;

(b) Medical treatment regime; and

(c) Complexity of the infusion therapy treatment regime including:

(i) The purpose and effects of the specific infusate or medication,

(ii) Skills to access and de-access the infusion catheter access device, and

(iii) The potential harm to the patient should an error occur.

(9) Direct Supervision.

(a) "Direct supervision" means oversight exercised by a registered nurse who is present on the unit of care during the infusion therapy process.

(b) "Direct supervision" includes the actions of:

(i) Observation;

(ii) Assessment;

(iii) Evaluation; and

(iv) Direction.

(10) "First dose" has the meaning defined by the facility's policies and procedures.

(11) "Hypodermoclysis" means the infusion of fluids into subcutaneous tissue for hydration.

(12) Implanted Port.

(a) "Implanted port" means a reservoir surgically placed under the skin and attached to a catheter which is placed in a vessel, body cavity, or organ.

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(b) "Implanted port" is often referred to as a medi-port, port-a-cath, infuse-a-port, infusion port, or a subcutaneous port.

(13) "Implanted pump" means a catheter surgically placed into a vessel, body cavity, or body space, and attached to a reservoir placed under the skin, that contains a pumping mechanism for continuous medication administration.

(14) "Infusion therapy" means the initiation and administration of medication, fluids, and nutrients via an intravenous access device.

(15) "Initiate" means to hang and administer the first dose of medications or fluids.

(16) "INS" means Infusion Nurses Society.

(17) "Intraventricular reservoir" means a catheter threaded through the dura into a ventricle of the brain.

(18) "LPN" means a licensed practical nurse as defined in Health Occupations Article, §8-301, Annotated Code of Maryland.

(19) "Midclavicular catheter" means a peripherally inserted catheter with the distal tip located between the axilla and the vena cava.

(20) "Midline catheter" means a peripherally inserted catheter with the tip terminating below the axilla.

(21) "Multi-lumen catheter" means a venous access device that has more than one lumen.

(22) "Non-tunneled catheter" means a percutaneously placed catheter inserted into the vein.

(23) "ONS" means Oncology Nursing Society.

(24) "On-site supervision" means oversight exercised by a supervising registered nurse who is:

(a) Present in the facility; and

(b) Quickly and easily available to the patient and the assigned nurse during the course of infusion therapy.

(25) "Peripheral catheter" means a catheter or needle inserted into a superficial vein with the tip residing outside of the central venous system.

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(26) "Peripheral veins" means those veins in the superficial aspects of the body excluding the external jugular vein.

(27) "Peripherally inserted central catheter (PICC)" means a catheter, inserted with or without a guide wire, whose tip is located in the vena cava.

(28) "PPN" means partial parenteral nutrition.

(29) "RN" means a registered nurse as defined in Health Occupations Article, §8-301, Annotated Code of Maryland.

(30) "Specialized catheter" means an epidural, intrathecal, intrapleural, or peripheral nerve catheter.

(31) "Subcutaneous infusion of medication" means a continuous or intermittent infusion of medication by an indwelling needle or catheter inserted into subcutaneous tissue.

(32) "TPN" means total parenteral nutrition administered into the central venous system.

(33) "Tunneled catheter" means a CVC designed to have a portion of the catheter lie in a subcutaneous passage before exiting the body.

(34) "Nonsurgically placed" means a catheter placed percutaneously.

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COMAR 10.27.20.02, MD ADC 10.27.20.02

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Code of Maryland Regulations
Title 10. Department of Health and Mental Hygiene
Subtitle 27. Board of Nursing
Chapter 20. Management of Infusion Therapy by the Registered Nurse and the Licensed Practical Nurse (Refs & Annos)

COMAR 10.27.20.06

.06. Infusion Therapy Acts -RN.

Currentness

A. In addition to all previously identified procedures in Regulations .04 and .05A-C of this chapter, the RN may perform the following procedures:

(1) Administer medication via IV "push";

(2) Initiate subcutaneous infusion of medication; and

(3) Provide care and manage arterial catheters and arterial ports by:

(a) Changing IV administration set;

(b) Flushing or aspirating;

(c) Changing dressing;

(d) Obtaining blood specimens;

(e) Accessing and de-accessing; and

(f) Changing injection cap.

B. The RN, upon completion of a second specialized educational program in infusion therapy which includes didactic content and a clinical practicum consistent with the standards established by the ONS or other bodies approved by the Board and with documented evidence of clinical competency, may perform the following additional infusion therapy activities:

(1) Administer antineoplastic agents;

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(2) Aspirate fluid from an intraventricular reservoir;

(3) Administer fluids and medications via an intraventricular reservoir;

(4) Manage implantable pumps by programming and filling with fluids and medications;

(5) Insert, repair, and remove PICC and midclavicular catheters;

(6) Insert and remove midline catheters;

(7) Manage specialized catheters for analgesia;

(8) Remove nonsurgically placed central and arterial catheters;

(9) Administer pharmacological agents to de-clot or restore blood return; and

(10) Repair a catheter.

C. The RN may not perform the following acts:

(1) Administer the initial dose of any medication by intrathecal, epidural, intrapleural, or peripheral nerve catheter; or

(2) Remove any tunneled catheter.

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COMAR 10.27.20.06, MD ADC 10.27.20.06

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North Carolina Administrative Code
Title 10a. Department of Health and Human Services. (Refs & Annos)
Chapter 13. NC Medical Care Commission
Subchapter 13J. The Licensing of Home Care Agencies
Section .0900. General

10A NCAC 13J.0901

.0901 DEFINITIONS

Currentness

Terms used in this Subchapter have the meanings as defined in G.S. 131E-136 and as follows:

(1) "Activities of Daily Living" (ADL) means mobility, eating, bathing, dressing, toileting, and continence.

(2) "Agency" means a home care agency.

(3) "Agency director" means the person having administrative responsibility for the operation of the agency.

(4) "Allied health personnel" means licensed practical nurses, physical therapy assistants, occupational therapy assistants or other health professionals as defined in occupational licensure laws that are subject to supervision by a health professional.

(5) "Appropriate professional" means a licensed health care professional or a person with a baccalaureate degree in social work or an individual who meets the job specifications established for a social worker by the Office of State Personnel.

(6) "Client" means a home care client.

(7) "Clinical respiratory services" means the provision of respiratory equipment and services that involve the assessment of a client's pulmonary status, monitoring of a client's response to therapy and reporting to the client's physician. Procedures include: oximetry, blood gases, delivery of medication via aerosolization, management of ventilatory support equipment, pulmonary function testing and infant monitoring.

(8) "Department" means the North Carolina Department of Health and Human Services.

(9) "Extensive Assistance" means a client is totally dependent or requires weight-bearing support more than half the time while performing part of an activity, such as guiding or maneuvering of limbs, and meets one of the following criteria:

(a) Requires extensive assistance in more than two activities of daily living (ADLs), as defined in Item (1) of this Rule; or

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(b) Needs an in-home aide to perform at least one task at the nurse aide II level; or

(c) Requires extensive assistance in more than one ADL and has a medical or cognitive impairment as defined in Item (19) of this Rule.

(10) "Follow-up care" means services provided to a licensed hospital's discharged clients in their homes by a hospital's employees. No services except pulmonary care, pulmonary rehabilitation or ventilator services shall exceed three visits in any two month period and shall not extend beyond a 12 month period following discharge.

(11) "Governing body" means the person or group of persons having legal authority for the operation of the agency.

(12) "Hands-on care" means any home care service which involves touching the patient in order to implement the patient's plan of care.

(13) "Infusion nursing services" means those services related to the administration of pharmaceutical agents directly into a body organ or cavity. Routes of administration include but are not limited to sub-cutaneous intravenous, intraspinal, epidural or intrathecal infusion. Administration shall be by or under the supervision of a registered nurse in accordance with their legal scope of practice.

(14) "In-home aide" means an individual who provides hands-on care to home care clients.

(15) "In-home aide services" are hands-on paraprofessional services which assist individuals, their family or both with home management tasks, personal care tasks, or supervision of the client's activities, or all of the above, to enable the individual, their family or both, to remain and function effectively at home as long as possible.

(16) "In-home care provider" means any individual who provides home care services as enumerated in G.S. 131E-136.

(17) "Licensed practical nurse" means a person licensed as such, pursuant to G.S. 90-171.30.

(18) "Limited Assistance" means care to a client who requires hands-on care involving guided maneuvering of limbs with eating, toileting, bathing, dressing, personal hygiene, self monitoring of medications or other tasks assigned that require weight bearing assistance half the time or less during the activity and does not meet the definition of extensive assistance in Item (9) of this Rule.

(19) "Medical or cognitive impairment" means a diagnosis and client assessment that documents at least one of the following:

(a) Pain that is present more than half the time that interferes with an individual's activity or movement.

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(b) Dyspneic or noticeably short of breath with minimal exertion during the performance of ADLs and requires continuous use of oxygen.

(c) Individual is not alert and oriented or is unable to shift attention and recall directions more than half the time.

(20) "Medical social services" means those professional services provided to individuals in their homes by a medical social worker, or by a medical social worker assistant under the supervision of a medical social worker, when provided by an agency in conjunction with other nursing or therapy services provided by the same agency.

(21) "Medical social worker" means a person with a masters degree from a school of social work approved by the Council on Social Work Education who is eligible for certification by the North Carolina Social Work Certification Licensure Board as a Certified Master Social Worker.

(22) "Medical social worker assistant" means a person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least one year of social work experience.

(23) "Nursing registry" means a person or organization that maintains a list of nurses or in-home aides or both that is made available to persons seeking nursing care or in-home aide services but does not collect a placement fee from the worker or client, coordinate the delivery of services or supervise or control the provision of services.

(24) "Nursing services" means professional services provided by a registered nurse or a licensed practical nurse under the supervision of a registered nurse.

(25) "Occupational therapist" means a person licensed as such, pursuant to G.S. 90-270.70.

(26) "Occupational therapist assistant" means a person licensed as such, pursuant to G.S. 90-270.70.

(27) "Occupational therapy services" means professional services provided by a licensed occupational therapist or a licensed occupational therapist assistant under the supervision of a licensed occupational therapist.

(28) "Paraprofessional" means an in-home care provider who does not hold a professional license or professional certification and through the nature of their duties assists a professional.

(29) "On-call services" means unscheduled home care services made available to clients on a 24-hour basis.

(30) "Personal care" includes tasks that range from assistance to an individual with basic personal hygiene, grooming, feeding and ambulation to medical monitoring and other health care related tasks.

(31) "Physical therapist" means a person licensed as such, pursuant to G.S. 90-270.29.

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(32) "Physical therapist assistant" means a person licensed as such pursuant to G.S. 90-270.29.

(33) "Physical therapy services" means professional services provided by a licensed physical therapist or a licensed physical therapist assistant under the supervision of a licensed physical therapist.

(34) "Physician" means a person licensed as such, pursuant to G.S. 90-15.

(35) "Plan of care" means the written description of the authorized home care services and tasks to be provided to a client.

(36) "Premises" means the location or licensed site from which the agency provides home care services or maintains client service records or advertises itself as a home care agency.

(37) "Qualified" means suitable for employment as a consequence of having met the standards of education, experience, licensure or certification established in the applicable job description created and adopted by the agency.

(38) "Registered nurse" means a person licensed as such, pursuant to G.S. 90-171.30.

(39) "Respiratory therapist" means a person who is credentialed by the National Board for Respiratory Care.

(40) "Respiratory practitioner" means those persons licensed in the state of North Carolina who provide clinical respiratory services in a client's home.

(41) "Scope of services" means those specific services provided by a licensed agency as listed on their home care license.

(42) "Survey" means an inspection by the Division of Health Service Regulation in order to assess the compliance of agencies with the home care licensure rules.

(43) "Social worker" means a person who meets the qualifications of the North Carolina Office of State Personnel for social workers.

(44) "Speech and language pathologist" means a person licensed as such, pursuant to G.S. 90-294.

(45) "Speech therapy" means professional services provided by a licensed speech and language pathologist.

(46) "Skilled Services" means all home care services enumerated in G.S. 131E-136(3) with the exception of in-home aide services.

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Current with rules received through March 27, 2015.

10A NCAC 13J.0901, 10A NC ADC 13J.0901

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North Carolina Administrative Code
Title 10a. Department of Health and Human Services. (Refs & Annos)
Chapter 13. NC Medical Care Commission
Subchapter 13J. The Licensing of Home Care Agencies
Section .1100. Scope of Services

10A NCAC 13J.1108

.1108 INFUSION NURSING SERVICES

Currentness

(a) If an agency provides infusion nursing services, the services shall be provided by or under the supervision of a registered nurse with training in infusion services or special training in the drug and nutritional therapies the agency offers, as identified in agency policies, and in accordance with the North Carolina Nursing Practice Act, G.S. Chapter 90, Article 9A, and a plan of care signed by a physician.

(b) If an agency provides or arranges for infusion services, the agency shall provide on-call infusion nursing services on a 24 hour basis, seven days a week.

(c) If the agency provides or contracts for infusion pharmacy services there shall be policies and procedures governing the scope of pharmacy services provided. Pharmacy services shall be provided in accordance with the Pharmacy Laws of North Carolina and related rules and shall be provided on a 24-hour basis, seven days a week.

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10A NCAC 13J.1108, 10A NC ADC 13J.1108

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West's Pennsylvania Administrative Code
Title 49. Professional and Vocational Standards
Part I. Department of State
Subpart A. Professional and Occupational Affairs
Chapter 21. State Board of Nursing
Subchapter A. Registered Nurses
Responsibilities of the Registered Nurse

49 Pa. Code § 21.11

§ 21.11. General functions.

Currentness

(a) The registered nurse assesses human responses and plans, implements and evaluates nursing care for individuals or families for whom the nurse is responsible. In carrying out this responsibility, the nurse performs all of the following functions:

(1) Collects complete and ongoing data to determine nursing care needs.

(2) Analyzes the health status of the individuals and families and compares the data with the norm when possible in determining nursing care needs.

(3) Identifies goals and plans for nursing care.

(4) Carries out nursing care actions which promote, maintain and restore the well-being of individuals.

(5) Involves individuals and their families in their health promotion, maintenance and restoration.

(6) Evaluates the effectiveness of the quality of nursing care provided.

(b) The registered nurse is fully responsible for all actions as a licensed nurse and is accountable to clients for the quality of care delivered.

(c) The registered nurse may not engage in areas of highly specialized practice without adequate knowledge of and skills in the practice areas involved.

(d) The Board recognizes standards of practice and professional codes of behavior, as developed by appropriate nursing associations, as the criteria for assuring safe and effective practice.

Credits
Amended Oct. 23, 1976.

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Current through Pennsylvania Bulletin, Vol. 45, Num. 19, dated May 9, 2015.

49 Pa. Code § 21.11, 49 PA ADC § 21.11

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West's Pennsylvania Administrative Code
Title 49. Professional and Vocational Standards
Part I. Department of State
Subpart A. Professional and Occupational Affairs
Chapter 21. State Board of Nursing
Subchapter D. Interpretations
Statement of Policy

49 Pa. Code § 21.413

§ 21.413. Interpretations regarding the administration of drugs--statement of policy.

Currentness

(a) The following nursing practices fall within the scope of registered nursing practice under §§ 21.11, 21.12 and 21.14 (relating to general functions; venipuncture; intravenous fluids; and administration of drugs):

(1) Intravenous administration of Pavulon to a patient maintained on a mechanical ventillator.

(2) Use of lidocaine as an analgesic prior to venipuncture.

(3) Use of lidocaine or xylocaine for analgesia prior to use of a vascular access device of an implantable infusion pump.

(b) The following nursing practices fall within the scope of registered nursing practice under §§ 21.11 and 21.14:

(1) The addition of medications to peritoneal dialysate.

(2) The administration of chemotherapy.

(3) The refilling of implantable drug delivery systems following placement by a physician in the proper anatomical site.

(4) The administration of intrathecal medications by an externalized ventriculoperitoneal shunt.

(5) Monitoring and administering medications by epidural catheter or other pain relief devices to be used as analgesia for pain control. Administration of medications as used in this paragraph does not include initiation of the medication.

(6) When a physician writes a prescription order for a patient for a specific medication with a range of dosage, the registered nurse shall use professional judgment to determine the amount of medication within the range to be given to the patient.

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(c) The following nursing practices fall within the scope of registered nursing practice under § 21.11 and § 21.15 (relating to monitoring, defibrillating and resuscitating):

(1) Measurement of a cardiac output by thermodilution method.

(2) Inflation of a Swan-Ganz catheter balloon for the purpose of obtaining intermittent pulmonary capillary wedge pressure readings.

(3) Establishment of arterial lines with or without a cannula.

(4) Analysis of rhythm strips of patients with permanent programmable pacemakers.

(5) Endotrachael intubation and extubation.

(6) Endotracheal intubation in infant intensive care unit.

(7) Needle aspiration of pneumothorax in infant intensive care unit.

(8) Performance of cardioversion in the presence or absence of a physician.

(9) Umbilical vessel catheterization in infant intensive care units.

(10) Pulling back on Swan-Ganz catheter when it is wedged.

(d) As used in this subsection, "conscious sedation" is defined as a minimally depressed level of consciousness in which the patient retains the ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal commands. The registered nurse who is not a certified registered nurse anesthetist may administer intravenous conscious sedation medications, under § 21.14, during minor therapeutic and diagnostic procedures, when the following conditions exist:

(1) The specific amount of intravenous conscious sedation medications has been ordered in writing by a licensed physician and a licensed physician is physically present in the room during administration.

(2) Written guidelines specifying the intravenous medications that the registered nurse may administer in a particular setting are available to the registered nurse.

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(3) Electrocardiogram, blood pressure and oximetry equipment are used for both monitoring and emergency resuscitation purposes pursuant to written guidelines which are provided for minimum patient monitoring. Additional emergency resuscitation equipment is immediately available.

(4) The patient has a patent intravenous access.

(5) The registered nurse involved in direct patient care is certified in advanced cardiac life support (ACLS). Provisions shall be in place for back-up personnel who are experts in airway management, emergency intubation and advanced life support if complications arise.

(6) The registered nurse possesses the knowledge, skills and abilities related to the management of patients receiving intravenous conscious sedation with evaluation of competence on a periodic basis. This includes, but is not limited to, arrhythmia detection, airway management and pharmacologic action of drugs administered. This includes emergency drugs.

(7) The registered nurse managing the care of the patient receiving intravenous conscious sedation medication may not have other responsibilities during the procedure. The registered nurse may not leave the patient unattended or engage in tasks which would compromise continuous monitoring.

(8) The registered nurse monitors the patient until the patient is discharged by a qualified professional authorized to discharge the patient in accordance with established criteria of the facility.

Credits

Adopted Feb. 21, 1987; Amended June 22, 1991; Amended Jan. 18, 1992; Amended Nov. 13, 1993; Amended Oct. 24, 1998.

Current through Pennsylvania Bulletin, Vol. 45, Num. 19, dated May 9, 2015.

49 Pa. Code § 21.413, 49 PA ADC § 21.413

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Virginia Administrative Code
Title 12. Health
Vac Agency NO. 5. Department of Health (Refs & Annos)
Hospitals, Nursing Homes, and Related Institutions and Services
Chapter 381. Regulations for the Licensure of Home Care Organizations (Refs & Annos)
Part IV. Pharmaceutical Services

12 VAC 5-381-350

12 VAC 5-381-350. Pharmacy services.

Currentness

A. All prescription drugs shall be prescribed and properly dispensed to the client according to the provisions of the Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and the regulations of the Virginia Board of Pharmacy, except for prescription drugs authorized by § 54.1-3408 of the Drug Control Act, such as epinephrine for emergency administration, normal saline and heparin flushes for the maintenance of IV lines, and adult immunizations, which may be given by a nurse pursuant to established protocol.

B. Home attendants may administer normally self-administered drugs as allowed by § 54.1-3408 of the Virginia Drug Control Act (Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia). Any other drug shall be administered only by a licensed nurse or physician assistant.

C. The organization shall develop written policies and procedures for the administration of home infusion therapy medications that include, but are not limited to:

1. Developing a plan of care or service;

2. Initiation of medication administration based on a prescriber's order and monitoring of the client for response to the treatment and any adverse reactions or side effects;

3. Assessment of any factors related to the home environment that may affect the prescriber's decisions for initiating, modifying, or discontinuing medications;

4. Communication with the prescriber concerning assessment of the client's response to therapy, any other client specific needs, and any significant change in the client's condition;

5. Communication with the client's provider pharmacy concerning problems or needed changes in a client's medication;

6. Maintaining a complete and accurate record of medications prescribed, medication administration data, client assessments, any laboratory tests ordered to monitor response to drug therapy and results, and communications with the prescriber and pharmacy provider;

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7. Educating or instructing the client, family members, or other caregivers involved in the administration of infusion therapy in the proper storage of medication, in the proper handling of supplies and equipment, in any applicable safety precautions, in recognizing potential problems with the client, and actions to take in an emergency; and

8. Initial and retraining of all organization staff providing infusion therapy.

D. The organization shall employ a registered nurse, who has completed training in infusion therapy, and has the knowledge, skills, and competencies to safely administer infusion therapy, to supervise medication administration by staff. This person shall be responsible for ensuring compliance with applicable laws and regulations, adherence to the policies and procedures related to administration of medications, and conducting periodic assessments of staff competency in performing infusion therapy.

Official Virginia Administrative Code, current through 31:17 VA.R April 20, 2015, and fast-track regulations current through 31:11, January 26, 2015.

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12 5-381-350, 12 VA ADC 5-381-350

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Virginia Administrative Code
Title 12. Health
Vac Agency NO. 5. Department of Health (Refs & Annos)
Hospitals, Nursing Homes, and Related Institutions and Services
Chapter 381. Regulations for the Licensure of Home Care Organizations (Refs & Annos)
Part I. Definitions and General Information

12 VAC 5-381-10

12 VAC 5-381-10. Definitions.

Currentness

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Activities of daily living" or *"ADLs"* means bathing, dressing, toileting, transferring, bowel control, bladder control and eating/feeding. A person's degree of independence in performing these activities is part of determining the appropriate level of care and services. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform personal care tasks in order to live independently.

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion or any other means, to the body of a client by (i) a practitioner or by his authorized agent and under his direction or (ii) the client at the direction and in the presence of the practitioner as defined in § 54.1-3401 of the Code of Virginia.

"Administrator" means a person designated in writing by the governing body as having the necessary authority for the day-to-day management of the organization. The administrator must be an employee of the organization. The administrator, the director of nursing, or other clinical director may be the same individual if that individual is dually qualified.

"Available at all times during operating hours" means an individual is readily available on the premises or by telecommunications.

"Barrier crimes" means certain offenses, specified in § 32.1-162.9:1 of the Code of Virginia, that automatically bar an individual convicted of those offenses from employment with a home care organization.

"Blanket fidelity bond" means a bond that provides coverage that protects an organization's losses as a result of employee theft or fraud.

"Branch office" means a geographically separate office of the home care organization that performs all or part of the primary functions of the home care organization on a smaller scale.

"Chore services" means assistance with nonroutine, heavy home maintenance for persons unable to perform such tasks. Chore services include minor repair work on furniture and appliances; carrying coal, wood and water; chopping wood; removing snow; yard maintenance; and painting.

"Client record" means the centralized location for documenting information about the client and the care and services provided to the client by the organization. A client record is a continuous and accurate account of care or services, whether hard copy

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or electronic, provided to a client, including information that has been dated and signed by the individuals who prescribed or delivered the care or service.

"Client's residence" means the place where the individual or client makes his home such as his own apartment or house, a relative's home or an assisted living facility, but does not include a hospital, nursing facility or other extended care facility.

"Commissioner" means the State Health Commissioner.

"Companion services" means assisting persons unable to care for themselves without assistance. Companion services include transportation, meal preparation, shopping, light housekeeping, companionship, and household management.

"Contract services" means services provided through agreement with another agency, organization, or individual on behalf of the organization. The agreement specifies the services or personnel to be provided on behalf of the organization and the fees to provide these services or personnel.

"Criminal record report" means the statement issued by the Central Criminal Record Exchange, Virginia Department of State Police.

"Department" means the Virginia Department of Health.

"Discharge or termination summary" means a final written summary filed in a closed client record of the service delivered, goals achieved and final disposition at the time of client's discharge or termination from service.

"Dispense" means to deliver a drug to an ultimate user by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Drop site" means a location that HCO staff use in the performance of daily tasks such as obtaining supplies, using fax and copy machines, charting notes on care or services provided, and storing client records. These locations may also be called charting stations, workstations, or convenience sites.

"Employee" means an individual who has the status of an employee as defined by the U.S. Internal Revenue Service.

"Functional limitations" means the level of a client's need for assistance based on an assessment conducted by the supervising nurse. There are three criteria to assessing functional status: (i) the client's impairment level and need for personal assistance, (ii) the client's lack of capacity, and (iii) how the client usually performed the activity over a period of time. If a person is mentally and physically free of impairment, there is not a safety risk to the individual, or the person chooses not to complete an activity due to personal preference or choice, then that person does not need assistance.

"Governing body" means the individual, group or governmental agency that has legal responsibility and authority over the operation of the home care organization.

"Home attendant" means a nonlicensed individual performing skilled, pharmaceutical and personal care services, under the supervision of the appropriate health professional, to a client in the client's residence. Home attendants are also known as certified nurse aides or CNAs, home care aides, home health aides, or personal care aides.

"Home care organization" or *"HCO"* means a public or private entity providing an organized program of home health, pharmaceutical or personal care services, according to § 32.1-162.1 of the Code of Virginia in the residence of a client or individual to maintain the client's health and safety in his home. A home care organization does not include any family members, relatives or friends providing caregiving services to persons who need assistance to remain independent and in their own homes.

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"Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets the requirements for participation in Medicare under 42 CFR 440.70 (d), by providing skilled nursing services and at least one other therapeutic service, for example, physical, speech, or occupational therapy; medical social services; or home health aide services, and also meets the capitalization requirements under 42 CFR 489.28.

"Homemaker services" means assistance to persons with the inability to perform one or more instrumental activities of daily living. Homemaker services may also include assistance with bathing areas the client cannot reach, fastening client's clothing, combing hair, brushing dentures, shaving with an electric razor, and providing stabilization to a client while walking. Homemaker services do not include feeding, bed baths, transferring, lifting, putting on braces or other supports, cutting nails or shaving with a blade.

"Infusion therapy" means the procedures or processes that involve the administration of injectable medications to clients via the intravenous, subcutaneous, epidural, or intrathecal routes. Infusion therapy does not include oral, enteral, or topical medications.

"Instrumental activities of daily living" means meal preparation, housekeeping/light housework, shopping for personal items, laundry, or using the telephone. A client's degree of independence in performing these activities is part of determining the appropriate level of care and services.

"Licensed practical nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a licensed practical nurse.

"Licensee" means a licensed home care provider.

"Medical plan of care" means a written plan of services, and items needed to treat a client's medical condition, that is prescribed, signed and periodically reviewed by the client's primary care physician.

"Nursing services" means client care services, including, but not limited to, the curative, restorative, or preventive aspects of nursing that are performed or supervised by a registered nurse according to a medical plan of care.

"OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

"Operator" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that is responsible for the day-to-day administrative management and operation of the organization.

"Organization" means a home care organization.

"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a home care organization.

"Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently.

"Primary care physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the client as having the primary responsibility

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in determining the delivery of the client's medical care. The responsibility of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.

"Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.

"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client care and services, pursue opportunities to improve client care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients and others.

"Registered nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a registered nurse.

"Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons.

"Skilled services" means the provision of the home health services listed in 12 VAC 5-381-300.

"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction.

"Sworn disclosure statement" means a document disclosing an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state.

"Third-party crime insurance" means insurance coverage that protects an organization's losses as a result of employee theft or fraud.

Official Virginia Administrative Code, current through 31:17 VA.R April 20, 2015, and fast-track regulations current through 31:11, January 26, 2015.

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12 5-381-10, 12 VA ADC 5-381-10

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Virginia Administrative Code
Title 12. Health
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"OLC" means the Office of Licensure and Certification of the Virginia Department of Health.

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"Organization" means a home care organization.

"Person" means any individual, partnership, association, trust, corporation, municipality, county, local government agency or any other legal or commercial entity that operates a home care organization.

"Personal care services" means the provision of nonskilled services, including assistance in the activities of daily living, and may include instrumental activities of daily living, related to the needs of the client, who has or is at risk of an illness, injury or disabling condition. A need for assistance exists when the client is unable to complete an activity due to cognitive impairment, functional disability, physical health problems, or safety. The client's functional level is based on the client's need for assistance most or all of the time to perform the tasks of daily living in order to live independently.

"Primary care physician" means a physician licensed in Virginia, according to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia, or licensed in an adjacent state and identified by the client as having the primary responsibility

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in determining the delivery of the client's medical care. The responsibility of physicians contained in this chapter may be implemented by nurse practitioners or physician assistants as assigned by the supervising physician and within the parameters of professional licensing.

"Qualified" means meeting current legal requirements of licensure, registration or certification in Virginia or having appropriate training, including competency testing, and experience commensurate with assigned responsibilities.

"Quality improvement" means ongoing activities designed to objectively and systematically evaluate the quality of client care and services, pursue opportunities to improve client care and services, and resolve identified problems. Quality improvement is an approach to the ongoing study and improvement of the processes of providing health care services to meet the needs of clients and others.

"Registered nurse" means a person who holds a current license issued by the Virginia Board of Nursing or a current multistate licensure privilege to practice nursing in Virginia as a registered nurse.

"Service area" means a clearly delineated geographic area in which the organization arranges for the provision of home care services, personal care services, or pharmaceutical services to be available and readily accessible to persons.

"Skilled services" means the provision of the home health services listed in 12 VAC 5-381-300.

"Supervision" means the ongoing process of monitoring the skills, competencies and performance of the individual supervised and providing regular, documented, face-to-face guidance and instruction.

"Sworn disclosure statement" means a document disclosing an applicant's criminal convictions and pending criminal charges occurring in Virginia or any other state.

"Third-party crime insurance" means insurance coverage that protects an organization's losses as a result of employee theft or fraud.

Official Virginia Administrative Code, current through 31:17 VA.R April 20, 2015, and fast-track regulations current through 31:11, January 26, 2015.

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12 5-381-10, 12 VA ADC 5-381-10

End of Document

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AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 6 day of May, 2015, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

Christine Britton

NOTARY PUBLIC

My commission expires 11-4-2018

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Christine Britton, Notary Public
Upper Chichester Twp., Delaware County
My Commission Expires Nov. 4, 2018
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

Saul Ewing LLP

Richard D. Leigh
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rleigh@saul.com
www.saul.com

June 4, 2015

VIA FEDERAL EXPRESS (615-741-2364)

Ms. Melanie Hill – Executive Director
State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Pentec Health, Inc. / Certificate of Need Application CN1411-046 / Supplemental Response to Request for Additional Information

Dear Ms. Hill:

Pentec has reviewed the answers provided by Implanted Pump Management LLC ("IPM"), CN1407-027, in response to your request for additional information of April 2, 2015.

Pentec believes that IPM's answer to Question 13 contains factually incorrect and misleading information regarding a 2013 FDA inspection of Pentec's pharmacy facility. This Supplemental Response is intended as a response to the statements made by IPM in its answer to Question 13.

If you have any questions about this Supplemental Response, or require additional information, please feel free to contact me at 717-257-7501 or rleigh@saul.com. Again, we look forward to working with the Agency in connection with Pentec's Certificate of Need application.

Sincerely,

Richard D. Leigh

Enclosure
cc: Robert A. Provonche – Pentec Health, Inc.
Karen McHenry, RN – Pentec Health, Inc.
Steven Behrens – Pentec Health, Inc.
Kim Harvey Looney, Esquire – Waller Lansden Dortch & Davis, LLP

PENTEC HEALTH, INC.

SUPPLEMENTAL RESPONSE

TO

REQUEST FOR ADDITIONAL INFORMATION

IN CONNECTION WITH

CERTIFICATE OF NEED APPLICATION CN1411-046

JUNE 2015

Pentec Health, Inc. ("Pentec") submits this Supplemental Response in response to the answer provided by Intrathecal Pump Management LLC ("IPM") to Question 13 of the Health Services and Development Agency's letter to Pentec and IPM dated April 2, 2015. Question 13 asked:

Should the Agency determine there is a need for this type specialty home health agency, would the applicants be willing to consider approval for only half of the service area requested so that two agencies would cover the state instead of just one? Would the project still be financially feasible if only a portion of the service area were approved?

IPM's answer to Question 13, which ignores the second part of the question, states in pertinent part:

> "IPM would not concede to approval of only half of the state so that the half of the State could be served by Pentec. The reason that IPM considers this an un-safe option is that there is documented proof that Pentec still has an ongoing investigation with the FDA that illustrates unsafe pharmacy conditions. The findings on the FDA report of Pentec certainly show similarities to those of the NECC FDA findings."

Pentec addressed this matter during the March 25, 2015, HSDA meeting (see meeting transcript from page 48, line 2, to page 51, line 3, a copy of which is attached to this Supplemental Response). However, since IPM has raised it again, Pentec is compelled to respond to IPM's factually incorrect and misleading answer with further detail, as follows:

Pentec's "Form 483" and Response

Pentec was one of many compounding pharmacies that the FDA inspected following the outbreak of fungal meningitis that was associated with drugs compounded by a Massachusetts pharmacy, New England Compounding Center ("NECC") in the fall of 2012. From March 18 to April 1, 2013, two FDA investigators inspected Pentec's compounding pharmacy facility in Boothwyn, Pennsylvania as part of a nationwide program. The inspection was not done based upon any complaint or suspected issues. For part of the inspection the FDA inspectors were accompanied by representatives from the Pennsylvania State Board of Pharmacy and the Pennsylvania Department of State. Pentec passed the simultaneous Pennsylvania state inspection with **no** adverse observations.

Pentec is confident in the safety of its dispensed prescriptions based upon its Pennsylvania State Board of Pharmacy authorization and adherence to United States Pharmacopeia Chapter 797 ("USP <797> ") standards. As the Board is likely aware, the USP is an official compendium under the Federal Food, Drug, and Cosmetic Act, and USP <797> provides widely recognized standards – historically relied upon by industry, Federal, and state regulators – governing the compounding of sterile preparations. These standards are well understood to be the basis for sterile prescription compounding.

Pentec welcomed the FDA's review of its operations, providing full access to the pharmacy's facilities, operations, documents, and personnel. On April 1, 2013, the FDA investigators delivered to Pentec an FDA "Form 483" with nine observations that identified deviations from current good manufacturing practices ("CGMP") that are applicable to large-scale drug manufacturers, but not to Pentec. Pentec has been in the compounding pharmacy business for more than 30 years, and 100% of its business remains patient-specific. Because Pentec does

not mass produce medication, and fills patient-specific prescriptions from licensed physicians, Pentec's pharmacy is not regulated by the FDA's CGMP guidelines. Instead, it adheres to USP <797> standards developed specifically for the compounding pharmacy industry.

Although Pentec is a traditional compounding pharmacy that is not subject to CGMP, it is not satisfied with merely meeting minimum requirements. Instead, Pentec exceeds legally mandated requirements by adopting the best practices from CGMP that are appropriate for the traditional pharmacy compounding environment, and it continues to invest in enhancing its practices to exceed the level required by law.

Pentec responded in writing to the Form 483 on April 22, 2013, and committed to address the FDA's observations in an appropriate, comprehensive, and timely fashion, even though the observations applied standards from federal CGMP regulations from which Pentec is clearly exempt under federal law. Even though the FDA was overreaching by applying CGMP standards with respect to Pentec, Pentec chose to go beyond USP <797> standards by voluntarily adopting various practices from FDA's CGMP regulations for pharmaceutical manufacturers that could reasonably be incorporated into a patient-specific operation like Pentec.

Pentec's Limited, Voluntary Recall

On May 15, 2013, Pentec initiated a limited, voluntary recall of in-date nutritional therapies for renal patients that were compounded in one particular laminar flow hood on or before May 2, 2013. Pentec took this action after choosing to re-certify all of its laminar flow hoods two months sooner than required by USP <797>. Under USP <797>, compounding pharmacies are to re-certify their facilities and equipment at least every six months. Pentec had most recently conducted re-certification in January 2013, and thus its next re-certification was not due until July 2013. Nevertheless, Pentec chose to re-certify all of its hoods in May 2013 using a new re-certification vendor and advised the FDA of this early re-certification schedule.

Based on the results of the early re-certification testing, Pentec chose to decommission one of its hoods as a precautionary measure even though multiple sterility test results from the surface and air in the hood, as well as products compounded in the hood, all showed sterility. Although Pentec was confident in the quality of the prescriptions prepared in the hood, FDA personnel informed Pentec that they believed the frequency of Pentec's testing results was insufficient to assure sterility, unless viable sampling is performed in every hood on a daily basis. FDA personnel believed that that fact, together with the company's decision to decommission the hood, suggested that in-date prescriptions prepared in the hood should be recalled. Even though USP <797> neither requires nor recommends a recall in such circumstances, Pentec chose to undertake the voluntary recall out of an abundance of caution.

Pentec executed the recall between May 15 and 17, 2013, by telephoning all the recipients of the drugs covered by the recall (*i.e.*, in-date renal therapies compounded on one laminar flow hood). The recall was conducted with the full knowledge of the FDA, and the FDA reviewed in advance Pentec's telephone scripts for conducting the recall and Pentec's press release announcing the action, which was issued as a nationwide release on May 16, 2013.

The prescriptions that were recalled from 163 patients were IV bags containing (1) IDPN (intradialytic parenteral nutrition), composed of amino acids, dextrose, and sterile water in

varying amounts, (2) IDPN with lipids, and (3) IPN (intraperitoneal nutrition), a dialysate solution with added amino acids. The IDPN therapies were supplied to dialysis centers and the IPN therapies were supplied directly to patients. None of the medications involved in the recall were prescriptions involving intrathecal pump patients.

Pentec completed all of its recall-related activities in May 2013. To date, Pentec has received no reports of injury, illness, or other adverse reactions associated with any of the prescriptions subject to this recall. Pentec received a letter from the FDA on December 17, 2014, confirming that the recall was complete – approximately 1 1/2 years after the recall in May 2013.

Pentec's Warning Letter and Response

Even though Pentec had already responded to the FDA, Pentec received a warning letter from the FDA dated March 7, 2014, based on the FDA inspection that had been completed on April 1, 2013. Pentec responded on March 28, 2014, by addressing the two specific observations in the warning letter and again providing a comprehensive overview of the corrective and preventative actions that Pentec had voluntarily undertaken following receipt of the Form 483 on April 1, 2013.

In addition, Pentec committed to utilizing the services of a highly-regarded consulting firm with expertise in aseptic processing to assess its pharmacy operations, including the methods, facilities, processes, and controls used in the compounding, processing, packing, holding, and distribution of drugs, in an effort to become as close to CGMP-compliant as prescription based compounding can be. To date, Pentec has voluntarily conducted two separate CGMP audits (in July 2013 and again in July 2014). Pentec has kept the FDA updated as it continues to make improvements based on the CGMP recommendations. The last update occurred in November 2014 which informed the FDA that Pentec had completed all the action items from the audit.

Commitment to Quality

The FDA has neither returned to inspect Pentec since April 1, 2013, nor responded to the multiple updates that Pentec has provided. However, Pentec has received successful and compliant inspections from the following pharmacy regulatory organizations which speak to its ongoing commitment to quality:

- March 18, 2013 — Pennsylvania Board of Pharmacy inspection (same day as the FDA inspection)
- April 23, 2013 — National Association of Boards of Pharmacy ("NABP") inspection on behalf of Iowa (one day after Pentec's 483 response was sent to the FDA)
- May 2, 2014 — NABP inspection for Verified Pharmacy Program (VPP)
- June 6, 2014 — Survey by The Joint Commission
- April 21, 2015 — Pennsylvania Board of Pharmacy inspection
- May 6, 2015 — California Board of Pharmacy inspection for Sterile Compounding License

Pentec is confident in the safety and quality of the prescriptions it compounds and dispenses. The above-referenced recent inspections, which are specific to USP <797>, only reinforce its confidence.

For IPM to assert that Pentec is "subject to an ongoing FDA investigation" is simply a misrepresentation of the facts. Furthermore, for IPM to imply that Pentec's pharmacy operation is **anything** like that of NECC – which resulted in 64 deaths, the surrender of its pharmacy license in multiple jurisdictions including Tennessee, and numerous criminal indictments – is purely inflammatory and false.

1 Mr. Wynd, or a substitute.
2 MR. SLAVEN: Good afternoon. My
3 name is Cliff Slaven. I am the pharmacy
4 manager for Pentec Health in Boothwyn,
5 Pennsylvania. I'm also a licensed pharmacist
6 here, and I want to address the 483 findings
7 that we had a few years ago.
8 We were inspected by the FDA in
9 response to what happened with NECC. They
10 inspected us as though we were a
11 CGMP-compliant pharmacy -- or facility, as
12 though we were Merck or AstraZeneca or a
13 rather large manufacturer, which we are not.
14 We are not designed -- we were not set up to
15 do large repetitive compounding of
16 multiple-ingredient identical products.
17 So when they came in and
18 inspected us, they were sort of looking at
19 us -- it was an apples and oranges kind of
20 thing. Regardless, in all respect to their
21 findings, we did take them seriously and we
22 made serious progress in terms of what we've
23 done for corrective measures. The first thing
24 is being a -- establishing a quality unit. We
25 have our own microbiologist on staff; we have

1 our own in-process testing where we've done
2 initial qualifications, process
3 qualifications, ongoing qualifications of
4 everything that we do. So we did take it
5 seriously.
6 With regard to the product that
7 was recalled, when we went through, as part of
8 our routine maintenance annual -- I'm sorry --
9 biannual surveys of our hoods, we found that
10 we had a laminar flow hood that was leaking
11 outside of the cabinet. It was not in
12 anything that could have affected the
13 sterility of the product; however, the piece
14 of equipment was out of specifications by the
15 manufacturer. The responsible thing to do was
16 to recall the product that was just made in
17 that particular hood.
18 That's all I have to add to that
19 at this point.
20 MR. WYND: Thanks, Cliff. And
21 I'll add just one thing about the product that
22 was recalled. There was 163 units that were
23 recalled with the -- because we didn't know if
24 there was contamination in the product --
25 MS. HILL: Sir, can you state

1 your name, please.
2 MR. WYND: Oh, I'm sorry. Doug
3 Wynd again. So sorry.
4 Those products were recalled,
5 and we replaced the products on a different
6 side of our business, at the renal side; renal
7 division. Patients received replacement
8 product, and no patient lost a dose because of
9 this recall. The products that were recalled
10 were put on a shelf to see if we could grow
11 out a contamination, and no contamination was
12 drawn out from those products that we
13 recalled.
14 So we recalled it because we
15 weren't sure. And we sat it on a shelf, and
16 we did not grow out anything that would cause
17 patient harm, even if it was given to a
18 patient, and no patient was at risk for that
19 issue. And Cliff gave the explanation, as a
20 pharmacist, when the issue is brought up by
21 our competition in the marketplace, we explain
22 exactly what happened, and our customers
23 understand the lingo and they get the fact
24 that our pharmacy is above the standards and
25 they get the whole process and, in fact, will

1 deepen their relationship with Pentec because
2 of the issues being raised and being addressed
3 by us.
4 In terms of the concerns by NEC
5 -- or NHC, in terms of the need, when I did
6 say that the patients were referred to us and
7 we couldn't fill them and service them, they
8 were seen by another company, but it was Roy's
9 company with Basic Home Infusion. So Basic
10 Home Infusion is operating here in your state
11 without your agency's approval, without
12 licensure, and that's something that we
13 wouldn't do. We had the opportunity to and we
14 said we're not going to do it, and then those
15 patients found another home.
16 Other examples where patients
17 were on vacation seeing a daughter here in
18 East Tennessee, their pump was alarming and
19 needed to be refilled, we had to say we
20 couldn't fill that patient because we weren't
21 licensed in Tennessee. And there were other
22 patients who were cancer pain patients being
23 treated in Georgia that were residents of
24 Tennessee, asking us to take care of them when
25 they got home from -- after getting their pump

AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 2 day of June, 2015, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

Christine Britton
NOTARY PUBLIC

My commission expires 11-4-2018

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Christine Britton, Notary Public
Upper Chichester Twp., Delaware County
My Commission Expires Nov. 4, 2018
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

HF-0043
Revised 7/02

HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
MARCH 25, 2015
APPLICATION SUMMARY

NAME OF PROJECT: Pentec Health, Inc.

PROJECT NUMBER: CN1411-046

ADDRESS: 424 Church Street, Suite 2000
Nashville, (Davidson County), Tennessee 37219

LEGAL OWNER: Pentec Holdings, Inc.
4 Creek Parkway
Boothwyn, Pennsylvania 19061

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Doug Wynd
Pentec Health, Inc.
4 Creek Parkway
Boothwyn, Pennsylvania 19061
(800) 223-4376

DATE FILED: November 14, 2014

PROJECT COST: $142,028

FINANCING: Cash Reserves

PURPOSE FOR FILING: Establishment of a home care organization and the initiation of specialized home health services related to home infusion for patients with implanted intrathecal infusion pumps and patients receiving immunoglobulin-G replacement therapy in all counties of Tennessee except Hancock, Perry and VanBuren Counties.

DESCRIPTION:

Pentec Health, Inc. is requesting approval to establish a home care organization and provide specialized skilled nursing services for patients with surgically implanted intrathecal pumps under physician's orders. The applicant also

proposes providing skilled nursing for patients receiving immunoglobulin (Ig-G) replacement therapy through intravenous or subcutaneous infusion (as an ancillary service). The applicant's proposed specialized home health service will receive pharmacy support for the preparation, packaging and distribution of intrathecal medications from Pentec's pharmacy in Boothwyn, Pennsylvania, a specialty closed door compounding pharmacy that is licensed in Tennessee and other states. An overview of the nature and scope of Pentec nursing and pharmacy responsibilities for the proposed service is summarized on pages 6 and 7 of the 11/25/14 supplemental response.

The applicant initially proposed serving all 95 Tennessee Counties. However, due to HSDA requirements pertaining to publication of the Letter of Intent in a newspaper of general distribution, the service area was changed to a statewide service area that contains 92 Tennessee counties and excludes Hancock, Perry and VanBuren Counties. The applicant's proposed home health organization will operate from a main office located at 424 Church Street, Suite 2000 in Nashville (Davidson County), Tennessee.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

   The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

3. Using recognized population sources, projections for four years into the future will be used.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

   Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

The applicant states that the specialized nature of the proposed skilled nursing

service and the lack of comparable utilization data from existing agencies impacts the ability to provide an estimate of need for specialty infusion therapy services. Following Steps 1-4 above, the Department of Health report that is based on 2013 data indicates that residents of the applicant's proposed 92 county service area will need home health care in 2018; however approximately 182,973 patients are projected to be served in 2018 by existing home health organizations resulting in a net excess or surplus of (80,773).

It appears that this application does not meet the criterion.

5. Documentation from referral sources:

   a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

   During initial staff review, the applicant states that it had been in contact with a number of practitioners in Tennessee. Their names are noted on page 58 of the application. At HSDA request, the applicant provided a December 1, 2014 letter from a physician of Comprehensive Pain Specialists located in Hendersonville (Sumner County) as an attachment to Question 5, Supplemental 2. The physician states that the medical practice is one of few providers in Tennessee that treats patients with intrathecal pumps. Although the physician mentions that his practice treats patients from all over the state, no indication is given regarding the potential number of referrals.

   Since the applicant is requesting a 92 county service area, it appears that this criterion has not been met.

   b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

   According to the applicant's research, there were approximately 1,976 intrathecal pump patients and 1,020 Ig-G patients in Tennessee in calendar year 2014. The applicant notes that patients requiring skilled nursing services for assistance with infusion pump medication refills, titrations, and changes in medical condition would be candidates for referrals by physicians, primarily those practicing in the areas of pain management and spasticity. Approximately 100% of the total projected utilization in Year One amounts to approximately 121 total visits consisting solely of visits Pentec will provide to implanted pump infusion

therapy patients. However, as previously noted, the 1 physician referral letter did not specify the number of potential referrals.

It appears this criterion has been met.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided no letters from potential patients during review of the application. However, there was a 12/1/14 letter from a physician of Comprehensive Pain Specialists in Hendersonville (Sumner County) that described the nature of the drug administration service requiring highly specialized nursing and pharmaceutical services.

Since the applicant is requesting a 92-county service area, it appears that this criterion has not been met.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant states that the proposed services are substantially different from those provided by a traditional home health agency that may offer a variety of skilled nursing, home health aide or other clinical services such as physical therapy. By contrast, the applicant proposes limiting its services to home infusion related services for intrathecal pump infusion pump therapy and Ig-G replacement therapy patients. In response to supplemental staff questions, the applicant remarked that it was unable to confirm the extent, if any, to which other existing agencies treated intrathecal pump patients (please see page 11 of Supplemental 1 and page 11 of Supplemental 2 for further detail). Pentec's proposed specialty infusion services would be provided by trained nursing staff that are required to complete a corporate nurse training program that is approved by the American Nurses Credentialing Center. As such, the applicant maintains that these services and credentials are unique and are not typical of the average Medicare certified home health agency (a comparison of key differences is shown in the table on page 5 of Supplemental 2).

It appears this criterion has been met.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

   a. The average cost per visit by service category shall be listed.

      An average gross charge of $2,517 per skilled nursing visit and an average cost of $2,343 per visit is projected in Year One as reflected in the Projected Data Chart of the application and clarified in the table on page 24 of Supplemental 2. Although there are no known agencies with similar services for comparison, the applicant notes that typical reimbursement by commercial plans is approximately $92 per visit for nursing and $50 - $70 for per diem charges (page 41, Supplemental 1). A Table in the attachment on page 156 of the revised application provides a summary of the applicant's fee schedule for the proposed service.

      It appears this criterion has been met.

   b. The average cost per patient based upon the projected number of visits per patient shall be listed.

      The applicant projects an average daily census of approximately 20 patients per day in Year One. Based on 6 visits per intrathecal pump patient per year, the applicant's projected average charge and cost for these types of patients will be approximately $14,826.00/patient and $13,500.00/patient, respectively, in the first year of the project.

      It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

Pentec Health Inc., an existing, unique provider of specialty infusion therapy services in 30 states accredited by the Joint Commission in both home care and pharmacy, is seeking approval to establish a home health organization and provide skilled nursing services limited to patients with surgically implanted intrathecal infusion therapy pumps or patients receiving immunoglobulin-G (Ig-G) replacement therapy through intravenous or subcutaneous infusion. All nursing services will be provided to patients in their residence statewide (excluding Hancock, Perry and VanBuren Counties), under physician ordered

plans of care. The proposed home health agency will be located in approximately 87 square feet of leased office space at 424 Church Street, Suite 2000 in Nashville, Tennessee.

The applicant's nursing team will be on call to serve patients in the 92 county service area on a 24/7 basis. Patients will have direct contact with his/her assigned nurse through a toll free number or after office hours through a Pentec Health, Inc. central call center that will contact the appropriate nursing team member. Initial staff will consist of current licensed registered nurse employees, including individuals appointed as the proposed agency's administrator and alternate administrator. Additional licensed nursing staff will be assigned in accordance with Pentec Health Inc.'s staffing ratio of one nurse to 40 patients.

Pentec's non-resident licensed Tennessee pharmacy (#4108) will support the applicant's proposed home health operations in Tennessee. The pharmacy is licensed by the State of Tennessee (license # 4108) and is Joint Commission Accredited. The pharmacy is one of two pharmacies owned by Pentec Health, Inc. It is a specialty closed door compounding pharmacy located at Pentec's corporate headquarters in Boothwyn, Pennsylvania (the other Pentec pharmacy is located in Mansfield, Massachusetts). The pharmacy is licensed in all 50 states and the District of Columbia (*note: please see additional clarifying information on page 5 of Supplemental 1 and page 4 of Supplemental 2*). Pentec's Tennessee licensed pharmacy is actively certified for participation in Medicare and TennCare.

The payor types of home health patients to be served by the applicant will be privately insured, self-pay, or medically indigent patients. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid. The applicant will on occasion provide skilled nursing in-home services to Medicare and TennCare infusion patients on a limited basis under its Compassionate Care, No Insurance or Financial Assistance policies, as appropriate. Some financial assistance for these patients will be available on the basis of Pentec's pharmacy certification in both Medicare and TennCare.

The infusion-related in-home skilled nursing service activities required in connection with the target implanted pump infusion therapy or Ig-G replacement therapy patients are listed in detail on page 9 of Supplemental 1. Key activities include medication administration for pump refills in accordance with physician orders; assessment for side effects, adverse reactions, patient and caregiver education, assessment of pump equipment function in accordance with pump manufacturer requirements, assessing intrathecal and IV access sites and surrounding areas for possible complications, recording vital signs and collecting blood specimens when ordered by a physician. These services will be provided

by the applicant's registered nurse employees who are trained through Pentec's certified nursing education program (*a copy of the program was provided in the attachment for Question 5.B of Supplemental 1*).

As noted, the infusion product will be compounded, packaged and shipped from the applicant's licensed pharmacy in Boothwyn, Pennsylvania and delivered by a Pentec driver or Federal Express to the assigned Pentec nurse. In some instances the product may be shipped to the patient's home where it will be received, inspected and authenticated by Pentec's nurse employee prior to administration. Types of infusion products to be administered include refills of intrathecal pump pain medications under physician orders for patients with cancer pain, multiple sclerosis or cerebral palsy and medications for patients receiving Ig-G replacement therapy.

Note to Agency Members: the above is a brief summary of the nature and scope of the proposed in-home skilled nursing service for infusion therapy patients. For more detailed descriptions about the nature and scope of services, including measures taken to reduce the risks associated with these types of patients, please see the HSDA staff questions for Item 4.A – 4.H on pages 6-15 of Supplemental 1 and the TDH questions in Exhibit 2 on pages 29-46 of Supplemental 2.

A description of the types of patients with demonstrated needs for infusion nursing services in the home that may otherwise be unavailable from other home health agencies include the following:

- **Implanted Intrathecal Pump Infusion Therapy** – this highly specialized service is given to a very narrow and complex range of patients who have failed traditional therapy for severe or chronic pain and now rely on implanted drug delivery systems for their treatment. Types of patient conditions include pain secondary to cancer, multiple sclerosis, traumatic brain injury, head trauma, paralysis or stroke. Carefully selected by their physicians, these patients will have a specialized pump implanted in the intrathecal space surrounding the spinal cord during a surgical procedure in an inpatient or outpatient setting and their medication regimen started. Implanted pump infusion therapy may be appropriate for patients who have the care and resources available to manage potential risks such as infection, narcotic withdrawal, drug compounding errors and pump programming errors. Typical patient diagnoses include Chronic Pain Syndrome, Complex Regional Pain Syndrome, Multiple Sclerosis, Cerebral Palsy, Abnormal Involuntary Movement (Spasticity) and Traumatic Brain Injury. (*For further detail regarding the ICD-9 codes that apply to these patients please see page 9, Supplemental 2).*

- **Specialty Patients Requiring Ig-G Replacement Therapy** - Intravenous immunoglobulin, a fraction of blood containing antibodies, is given intravenously or by subcutaneous infusion as a plasma protein replacement therapy to immune and/or auto-immune deficient patients who cannot replace antibodies naturally. The frequency of Ig-G Replacement Therapy is different for 2 types of patients – (1) those with primary immune deficiency, a genetic disorder that typically requires lifetime treatment on a monthly basis; or (2) patients with auto immune deficiency that may require lifetime treatment but more typically have a treatment regimen consisting of three, six or twelve month segments in consecutive daily sessions of several hours per session. Typical patient diagnose include Primary Immune Deficiency and Auto Immune Disorder.

Ownership

The applicant is a Pennsylvania Corporation first formed in 1983 under the name Delaware Valley Home Care Corporation and was later changed to Pentec Health Inc. in September 2006. It is a wholly owned subsidiary of Pentec Holdings, Inc. a Delaware Corporation, which has as its ultimate parent, Pentec Healthcare Infusions, Inc., also a Delaware Corporation. Related information about the applicant is provided below.

- The parent has 4 members with 5% ownership interest or greater, including Norwest Equity Partners IX, LP (69.06%), Norwest Mezzanine partners III, LP (5.06%), DW Healthcare Partners, LP (10.12%) and Frazier Healthcare V, LP (10.12%). Please see the table and chart on pages 101 and 102 of the application.
- The applicant has 2 major operating divisions - Specialty Infusion (includes home health care), and Renal Nutrition.
- The 2 operating divisions are supported by other operating units such as pharmacy, nursing, information services, quality assurance.
- An executive level organizational chart is provided on page 7 of Supplemental 2.
- As noted, Pentec operates a closed door specialty pharmacy with locations in Boothwyn, Pennsylvania and Mansfield, Massachusetts. The pharmacy is licensed in 50 states and supports the prescriptive needs of its intrathecal pump, infusion therapy and renal nutrition patients.
- The Tennessee pharmacy currently only focuses on the supply of renal nutrition products for use by Tennessee residents. It was first licensed in December 2004 (recently renewed through 3/31/2016). The applicant clarified that its pharmacy has the ability, capacity and trained staff to also prepare and supply intrathecal and intravenous compounded products (*please see page 4, Supplemental 2*).

- A table on pages 16 and 17 of Supplemental 1 provides a list of Pentec Health, Inc.'s active pharmacy and home health services for each of the 50 states and District of Columbia.
- Pentec has an active home health agency license in 34 states. It is also pending licensure approval in New Mexico, New York and the District of Columbia.
- The fiscal year end intrathecal pump patient census of Pentec's Infusion Division grew by approximately 67% from 1,303 patients ending December 31, 2011 to 2,177 patients ending December 31, 2013.
- As addressed in the TDH summary, the applicant provided a copy of a $10,000 civil penalty notice and order dated 08/22/2011 from the Indiana State Department of Health for violation of a licensure requirement during the applicant's initial state licensure survey.
- Also provided was copy of a 10/17/2011 letter from the program manager of the Acute Care Division, Indiana State Department of Health indicating that the plan of correction was found to be acceptable.

Facility Information

- The parent office of the proposed project will be in approximately 87 square feet of leased space in an existing office building in downtown Nashville at 424 Church Street.
- The office will be used solely for administrative support purposes as a repository for home health service policies and procedures, personnel records and other required documentation.
- There is no construction, renovation or modification required to implement the proposed project.
- Per Item 6, page 20 of Supplemental 1, branch offices would not be considered unless required with regional licensure requirements. The applicant attributes the nature of its specialized but limited service, its patient scheduling (7 to 10 day in advance of targeted pump refill or "alarm" date) and its nursing staffing plan as key factors in this regard.

Project Need

- The applicant indicates that traditional home health agencies do not typically provide in-home skilled nursing care for patients with surgically implanted intrathecal infusion pumps and patients receiving Ig-G replacement therapy.
- The nature of the proposed service differs from traditional home health agencies. The applicant provided a comparison in the table below.

Comparison of Applicant to Other Types of Home Health Agencies

Variable	Medicare Home Health Agency	Infusion Nursing Agency	Pentec Intrathecal Pump Service
Average Visit Duration	One to Two Hours	Up to six hours	One to Two Hours*
Equipment	Generally not involved	Typically includes infusion equipment	Administration kit (syringes & other disposable items) Pump programmer
Payor	80% Medicare and TennCare Patients	Private Insurance mainly	Mostly private insurance
Age	Approximately 68% Over Age 65+	Majority under Age 65	Approximately 71% under age 65
Service Provided	44% is skilled nursing. Additional services may include therapy, home health aide, and medical social services.	100% specialized skilled nursing	100% specialized skilled nursing
Patient Status	Homebound	Patient may or may not be homebound	May or may not be homebound

**Note: while duration of the visit is comparable, the applicant states that skilled nursing visits occur less frequently – approximately every 30- 60 days.*

- Patients may qualify for intrathecal pump therapy only when all other attempts for relief by the patient's physician have failed.
- Limited supply of physicians with practice specialties in pain management.
- Difficulty by patients to travel to physician for pump refills and office visits, especially patients with limited mobility or who are homebound.
- Discharged hospital patients requiring infusion nursing services either have to travel to the hospital or other outpatient facilities such as physician offices or infusion therapy centers to continue receiving this service.
- Need for accurate, reliable and timely information systems support to maintain patient medical record and facilitate communication with physicians through secure means. Pentec's electronic medical record system and secure web portal for attending physicians appears to be innovative initiatives in addressing this need.

- ***Note to Agency members: The attachment to the Department of Health Report indicated that based on 2013 data, 102,200 service area residents will need home health care in 2018; however 182,973 patients are projected to be served in 2018 resulting in a net excess of (80,773). Please note that this need is calculated for all home health patients, not just those needing home infusion services.***

Service Area Demographics

- The proposed service area was revised from 95 to 92 counties during initial review based on publication in newspapers that did not meet the requirements for "newspapers of general circulation" in accordance with HSDA Rules. Per the TDH project summary, the total population of the 92 county statewide service area is estimated at 6,629,335 residents in calendar year (CY) 2015 increasing by approximately 3.7% to 6,874,743 residents in CY 2019.
- The population of the 3 counties not included in the service area (Hancock, Perry and Van Buren Counties) is estimated at approximately 20,103 residents in 2015 increasing by 0.08% to 20,254 residents in 2019.
- The overall statewide population is projected to grow by 3.7% from 2015 to 2019.
- The 65 and under population will increase by approximately 12% from 1,008,671 in 2015 to 1,129,890 in 2018. The statewide 65 and under population will increase by approximately 12% between 2015 and 2019.
- The latest 2014 percentage of the statewide population enrolled in the TennCare program is approximately 18.1%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

Service Area Historical Utilization

Using licensure and provider utilization records maintained by the Tennessee Department of Health, the applicant identified approximately 157 existing licensed home health agencies in Tennessee. The name of the agency, location of parent office, licensed counties and utilization for 2011 – 2013 is provided in the table on pages 22-26 of Supplemental 1. As a whole, the agencies served approximately 176,910 patients in 2011 decreasing by 0.5% to 175,924 patients in 2013. Utilization for the 3 counties that were excluded from the applicant's proposed service area (Hancock, Perry and Van Buren Counties) increased slightly from 1,168 patients to 1,180 patients during the period.

Note to Agency members: The Joint Annual Report does not capture utilization data specific to implanted intrathecal pump or Ig-G replacement therapy

patients. There is not a known public database available that reports this type of data.

During review in 2012 of a previous Certificate of Need application for home infusion nursing (Coram Alternative Site Services), HSDA staff contacted the Tennessee Association of Home Care (TAHC) regarding home health providers and the Tennessee Hospital Association (THA) regarding hospital-based home care providers.

TAHC indicated the following:

- *TAHC membership applications on file indicate that 224 home health offices (parents and branches) offer infusion therapy services.*
- *Standard home health policy is that first dose should be completed in the hospital setting.*
- *The majority of home health agencies partner with an infusion company for administration of the second dose in the home.*
- *The home health nurse continues to support the patient's needs with observations and reports to the physician. It is unrealistic to think that a home health provider could limit their care to only infusion therapy. Infusion may be the primary need but these are typically patients with multiple chronic illnesses and co-morbidities who need a holistic, multi-disciplinary approach to their health care*
- *The barriers to home infusion therapy are generally noted as staffing and adequate payment. This is a growing issue for all homecare providers as both governmental and commercial payors continue to look to provider payments to cut costs.*
- *Homebound status is only a Medicare issue. An infusion company would be held to the same standard if it were a Medicare-certified home health agency.*

THA's response included that a "typical" home care provider does not provide infusion administration for:

- *Patients requiring 6 hour therapies.*
- *Medicare patients who are not homebound which is a requirement that applies only to Medicare.*
- *Many non-Medicare patients who are not homebound are served*
- *Patients requiring first dose administration*
- *Patients requiring three doses daily*

THA also advised that member home health agencies see patients in every county in the state and that there are pediatric programs often affiliated with

pediatric hospitals such as Vanderbilt, Methodist LeBonheur, and East Tennessee Children's Hospital.

During review of this application and 2 Coram/CVS Certificate of Need projects for specialty infusion services (please see descriptions for CN1406-017A and CN1406-018A at the end of this summary), HSDA staff received confirmation by phone and by an email from a representative of TAHC that the TAHC information provided in 2012 was still accurate at the time the applicant's proposal was under review in 2014.

Applicant's Projected Utilization

- In Year 1 the applicant projects an average daily census (ADC) of 20 patients per day increasing to 52 patients per day in Year 2 (*note: the applicant states that projected utilization focuses solely on intrathecal pump patients*).
- The applicant is projecting 121 total visits in Year 1 increasing to approximately 314 visits in Year 2. The applicant bases the projected intrathecal pump patient visit schedule on approximately 6 skilled nursing visits per patient per year.
- Year 1 projected utilization amounts to approximately 6.0% of the estimated 1,976 intrathecal pump patients in Tennessee in CY2014.
- Utilization for Year 1 is based on ramp-up of Pentec operations in Tennessee – beginning with 5 patients in the first month of operations going forward to 39 patients at year end.
- Of the 39 patients at year end, 20 are commercially insured and 19 are partial-reimbursement patients where Pentec receives compensation for some services rendered (usually medications) but assumes the patient's nursing care as a financial loss in accordance with its Compassionate Care policy. (*Sources: Application, page 36 and Supplemental 1, page 39*).
- Per the table on page 32 of Supplemental 1, the distribution of patients by **Grand Division of Tennessee** at the end of Year 1 is as follows: East (17), Middle (14) and West (8).

Project Cost

Major costs of the $142,028 total estimated project cost are:

- Architectural and Engineering Fee- $28,500 or 20% of total cost
- Office Lease- $8,028 or 5.7% of total cost
- Reserve/Contingency Fund-$100,000 or 70.4% of total cost

For other details on Project Cost, see the Project Cost Chart on page 40 of the application.

Historical Data Chart

- The applicant provided a historical data chart on page 44 of the application for their existing renal and specialty infusion division operations that are active in 30 states of the country. Pentec realized favorable net operating income of $8,458,000 in 2011 decreasing to ($41,262,000) in 2012 and (2,857,000) in 2013.
- As clarified by the applicant on page 39 of Supplemental 1, the negative amounts on line D.4 in the Historical Data Chart are based on tax benefits related to Pentec's net losses in 2012 and 2013.
- Review of the Consolidated Statements of Operations and the notes by the auditor on pages 9, 14 and 15 of audited financial statements confirmed the 2012 and 2013 net losses resulting from what appears to be a $46,482,000 accounting assessment in fiscal year 2012 for "Impairment of Goodwill and Trade names". As noted, the assessment appears to be based on an estimated reduction in Medicare Part D reimbursement rates for renal nutrition services provided by Pentec during the period.
- The applicant states that it expects a favorable net income of $4.2 million for the fiscal period ending December 31, 2014 (*please see page 51 of the revised application for more details*).

Projected Data Chart

The financial performance of the project appears to be favorable as proceeds from operating revenues cover operational costs. Highlights from the Projected Data Chart on page 46 of the revised application and the proformas on pages 123-125 in the attachments are as follows:

- Projected gross operating revenue increases from $304,573 on approximately 121 patient visits (approximately $2,517 per visit) to $853,923 on 314 visits in Year 2 (approximately $2,737 per visit).
- Net operating income is estimated at a loss of -$1,251 in Year One improving to a favorable margin of $117,812 in Year 2.
- Projected NOI calculates to approximately 13.8% of gross operating revenue in Year 2.
- Deductions from operating revenue consist entirely of bad debt estimated at $19,797 increasing to $55,505 in Year 2.
- As noted on page 39 of Supplemental 1 and pages 22 and 24 of Supplemental 2, Pentec's financial statements treat gross revenue as "net patient services operating revenue" and do not record charity care or contractual adjustments, although these amounts are taken into consideration.
- The applicant expects to provide charity care to one patient in Year 1.

Charges

In Year One of the proposed project, the average charge per visit is as follows:

- The proposed average gross charge is $2,517.00 per intrathecal pump patient visit.
- The average deduction for bad debt is $164.00 per patient visit, producing an average net charge of $2,353.00 per patient visit.
- The applicant's expected gross charge per visit in Year 2 is expected to be $2,720 per visit.
- The applicant provided an infusion therapy services fee schedule on page 157 of the revised application.
- The schedule includes charges that consist of the following general categories – per diem, drugs, nursing, supplies and other. As a cross reference, these categories are also reflected in the proforma on page 123 of the application and in the tables on page 21 of Supplemental 2.
- The applicant bases its projected charges on Pentec's infusion therapy operations experience in other states. Per clarification provided on page 41 of Supplemental 1, Pentec's typical reimbursement by commercial plans such as those shown on page 57 of the application averages approximately $92 per visit for visits up to 2 hours and $50-$70 per day for per diem charges.

Medicare/TennCare Payor Mix

The applicant is only certified by Medicare and Medicaid as a pharmacy and durable medical equipment (DME) provider and will not seek Medicare and TennCare certification for the proposed specialty infusion home health agency.

- Even if the applicant wanted to apply for Medicare/TennCare, it may not be eligible since its services are limited to the provision of skilled nursing specialty infusion therapy services. The proposed limited scope of service would not be providing the full range of home health services prescribed by the Medicare Conditions of Participation.
- The applicant states that fee for service Medicare/TennCare would only cover drugs dispensed by its existing licensed Tennessee pharmacy for patients of the proposed agency. They would not cover skilled nursing services to administer them or mange patient conditions (*please see page 52 of the application*).
- While it will not seek Medicare/TennCare certification, Pentec maintains that it will accept traditional fee for service patients of these programs on a limited, compassionate care basis in accordance with existing corporate policies (*source: page 4, Supplemental 1*).
- The applicant's projected payor mix is 86% commercial insurance, 7% Medicare and 7% TennCare in Year 1.

Financing

The project will be funded from cash reserves. Per Mr. Art Rea, Chief Financial Officer of Pentec Health, Inc., Pentec had cash on hand of approximately $7.5 million as of October 31, 2014.

Review of Pentec's audited financial statements submitted with the revised application confirmed the availability of cash reserves to fund the $142,028 proposed project. Per the Consolidated Balance Sheet, there was $3,867,673 in cash for the 12-month period ending December 31, 2013. In addition, Pentec reported total current assets of $20,785,836, total current liabilities of $15,562,693 resulting in a current ratio of 1.34 to 1.0.

Note to Agency Members: Current Ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant plans to use a 40 to 1 patient to nurse staffing ratio for the proposed agency. However, the applicant expects to staff one full time equivalent (FTE) licensed nurse in Year 1 despite the lower projected patient census that is expected for the first full year of the project. In addition, the applicant has allocated a 0.2 FTE Pentec Regional Nurse Manager to the project consistent with its practice in other states.

Licensure/Accreditation

If approved, the proposed Pentec Health, Inc. home health agency will be licensed by the Tennessee Department of Health.

- The applicant provided information regarding the licensing and accreditation of all of its existing home health and pharmacy sites, including its licensed Tennessee pharmacy, on pages 16 and 17 of Supplemental 1. A copy of the Tennessee pharmacy license is found on page 159 of the application.
- As noted, a letter dated October 17, 2011 from the Indiana State Department of Health states that the plan of correction in response to its 8/10/2011 initial state licensure survey was acceptable.
- A copy of Pentec Health Inc.'s 3-year Joint Commission accreditation award effective June 7, 2014 for the Home Health Accreditation Program with copy of applicable sites is shown on pages 162-165 of the application.

Corporate documentation, copies of the office lease and copies of corporate policies and procedures, including Infection Control, Pharmacy Quality Assurance and Pentec's

Performance Improvement Plan are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **two** years.

Note to Agency members: Should the Agency choose to approve this application, Staff recommends the Agency limit any future expansion of services by requiring a new application to expand services beyond implanted intrathecal pump infusion services and Ig-G replacement therapy services rather than a modification request through the General Counsel's Report. This could be accomplished with the following condition:

Home Health Agency services are limited to specialized skilled nursing services under physician ordered plans of care for (1) patients with surgically implanted intrathecal pumps and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion. The expansion of services beyond the home infusion services described in the application will require the filing of a new certificate of need application.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent for other health care organizations in the service area proposing this type of service.

Pending Applications

Implanted Pump Management, CN1407-027, has a pending application that will be heard under simultaneous review with CN1411-046 at the HSDA meeting on March 25, 2015 for the establishment of a home health agency to service intrathecal pump services to patients across all 95 counties in the State of Tennessee. The estimated project cost is **$275,000.**

The Home Option by Harden Healthcare, CN1501-001, has a pending application that will be heard under CONSENT CALENDAR REVIEW at the March 25, 2015 Agency meeting for the initiation of home health services in

Blount, Campbell, Claiborne, Grainger, Monroe, Morgan, Roane and Scott Counties focusing on home health services to eligible individuals covered under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), United States Department of Labor. If approved, the applicant's sister agency, Gentiva Certified Healthcare Corporation, will de-license the same 8 counties. The Home Health Option by Harden is located at 800 Oak Ridge Turnpike, Suite A208, Oak Ridge (Anderson County), TN 37830 and is currently licensed in Anderson, Jefferson, Knox, Loudon, Sevier and Union Counties. The estimated project cost is **$38,000.00.**

Denied Applications:

Home Care Agency of Middle Tennessee, CN1001-001D, was denied at the June 23, 2010 Agency meeting for the establishment of a home care organization focusing on a full range of home health services and skilled nursing psychiatric services for the elderly population in a four (4) county service area including Davidson, Rutherford, Sumner, and Williamson Counties from a parent office located at 5115 Maryland Way, Brentwood, (Williamson County), Tennessee. The estimated project cost was **$69,000.00.** *Reasons for Denial: There is not a need as there are other agencies in the proposed service area that are providing home health services, including services to the mentally ill, and it is not economically feasible to have another agency. The project will not contribute to the orderly development of adequate and effective health care.*

Rainbow Home Health, CN1111-045D, was denied at the February 22, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services, including skilled nursing, physical/occupational/speech therapies, and medical social services for individuals residing in Cheatham County from a home office located at 112 Frey Street in Ashland City (Cheatham County), Tennessee 37015. The estimated cost was **$262,600.00.** *Reasons for Denial: the prevailing reason for the vote leading to the denial of the project (4 ayes, 6 nays, 0 ties) was based on concerns with nature and scope of information provided by the applicant that did not support the need for the project, the economic feasibility or the orderly development of the project.*

Rainbow Home Health, CN1203-013D, was denied at the June 27, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services from a home office located at 112 Frey Street, Ashland City (Cheatham County), Tennessee. The estimated project cost was **$27,950.00.** *Reasons for Denial: the application was denied by unanimous vote based on the following: there was no need due to services being adequately provided by existing licensed agencies in the service area; the project was not economically feasible due to the*

numbers not being justified or showing how the applicant could feasibly provide the service; and the project did not contribute to orderly development as it will impact the utilization and staffing of existing agencies in the service area.

Critical Nurse Staffing, CN1210-049D, was denied at the January 23, 2013 Agency meeting for the establishment of a home care organization located at 575 Oak Ridge Turnpike, Oak Ridge (Anderson County), Tennessee focusing on individuals eligible for benefits under either the Energy Employees Occupational Illness Compensation Program Act or the Federal Black Lung program that reside in Anderson, Campbell, Knox, Loudon, Monroe, Morgan, Roane, and Union Counties. The estimated project cost was **$155,937.00**. *Reasons for Denial: There was no real need - care was being adequately provided by other agencies in the proposed service area and adequate evidence did not support or prove that there was a need for the proposed agency.*

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby, Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was **$177,800.00**. *Reasons for Denial: The need for the proposed agency was not supported in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility - the project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.*

Outstanding Certificates of Need:

Coram Alternate Site Services, Inc. d/b/a Coram Specialty Infusion Services CN1406-018A has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to the provision and administration of home infusion products and related services ancillary to its pharmacy services in a 25 county service area of West Tennessee, including the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, McNairy, Madison, Obion, Perry, Shelby, Stewart, Tipton, Wayne and Weakley Counties. The parent office will be located in its licensed home infusion pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee, 38134. The estimated project cost is **$98,000.00.** *Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram,*

the licensure application has been submitted to the Tennessee Department of Health. The initial licensing inspection for the parent office in Memphis, TN has been scheduled for March 13, 2015. An Annual Project Report is due on or before July 1, 2015.

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, CN1406-017A, has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, and Washington Counties, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is **$95,200.00**. *Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the Tennessee Department of Health. Notice of the inspection date is pending. An Annual Project Report is due on or before July 1, 2015.*

Maxim Healthcare Services, CN1406-015A, has an outstanding Certificate of Need that will expire on October 1, 2016. The project was approved at the August 27, 2014 Agency meeting for the initiation of home health care services in a 5 county service area including Carter, Johnson, Sullivan, Unicoi, and Washington Counties focusing primarily on private duty hourly care to TennCare medically complex pediatric patients. Maxim Healthcare Services seeks an unrestricted home health agency license and will obtain Medicare certification to meet TennCare provider enrollment requirements. The estimated project cost is **$463,825.00.** *Project Status Update: per 2/27/15 e-mail from legal consel for Maxim Health Care Services, the project was appealed but it appears that the parties have reached a settlement and the appeal may be dismissed in the near future. Confirmation of same will follow as soon as possible.*

Hemophilia Preferred Care of Memphis, CN1202-002, has an outstanding certificate of need that will expire on August 1, 2015. The CON was approved at the June 27, 2012 agency meeting for the establishment of a home health agency and the initiation of home health services limited to patients suffering from hemophilia or similar blood disorders who are patients of the pharmacy operated by Hemophilia Preferred Care of Memphis. The estimated project cost

is **$43,000.** *Project Status: The applicant requested and received approval at the June 25, 2014 Agency meeting for a one year extension from August 1, 2014 to August 1, 2015.*

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG
03/04/2015

Letter of Intent

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

NOV 10 14 AM 10:11

LETTER OF INTENT

The Publication of Intent is to be published in the The Tennessean (and others - see Attachment 1) (Name of Newspaper) which is a newspaper of general circulation in Davidson County (and others - see Attachment 1) (County), Tennessee, on or before November 10 (Month / day), 20 14 (Year), for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Pentec Health, Inc. (Name of Applicant) N/A (Facility Type-Existing)

owned by: Pentech Holdings, Inc. with an ownership type of Corporation

and to be managed by: Jamie Schultz, R.N. intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: Establishment of a home care organization and initiation of home health services consisting of specialized skilled nursing services provided under physician-ordered plans of care to (1) patients with implanted intrathecal pumps, and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion, in the patients' places of residence, in all 95 counties in the State of Tennessee. The organization will serve the entire state from its office at 424 Church Street, Suite 2000, Nashville, TN 37219. The estimated project cost is $142,000, including a $100,000 reserve fund.

The anticipated date of filing the application is: November 14, 20 14

The contact person for this project is Doug Wynd (Contact Name) National Sales Director, Specialty Infusion (Title)

who may be reached at: Pentec Health, Inc. (Company Name) 4 Creek Parkway (Address)

Boothwyn (City) Pennsylvania (State) 19061 (Zip Code) 636 / 751-6481 (Area Code / Phone Number)

(Signature) Nov. 03, 2014 (Date) dwynd@pentechealth.com (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

REVISED- COPY -Application-

Pentec Health Inc.

CN1411-046

SECTION A

APPLICANT PROFILE

PENTEC HEALTH, INC.

NOV 25 '14 AM 10:07

1. ***Name of Facility, Agency, or Institution***

Pentec Health, Inc.
Name

424 Church Street, Suite 2000 — Davidson
Street or Route — County

Nashville — TN — 37219
City — State — Zip Code

2. ***Contact Person Available for Responses to Questions***

Doug Wynd — National Sales Director, Specialty Infusion
Name — Title

Pentec Health, Inc. — dwynd@pentechealth.com
Company Name — Email address

4 Creek Parkway — Boothwyn — PA — 19061
Street or Route — City — State — Zip Code

Employee of Pentec Health, Inc. — 636-751-6481 — 610-494-6148
Association with Owner — Phone Number — Fax Number

3. ***Owner of the Facility, Agency or Institution***

Pentech Holdings, Inc. — 800-223-4376
Name — Phone Number

4 Creek Parkway — Delaware
Street or Route — County

Boothwyn — PA — 19061
City — State — Zip Code

(See Attachment, Section A, Applicant Profile, Item 3)

4. ***Type of Ownership of Control (Check One)*** **(See Attachment, Section A, Applicant Profile, Item 4)**

A. Sole Proprietorship _____
B. Partnership _____
C. Limited Partnership _____
D. Corporation (For Profit) X
E. Corporation (Not-for-Profit) _____
F. Government (State of TN or Political Subdivision) _____
G. Joint Venture _____
H. Limited Liability Company _____
I. Other (Specify)_____ _____

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. ***Name of Management/Operating Entity (If Applicable)***

Not Applicable (N/A)

Name

Street or Route

County

City

State

Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. ***Legal Interest in the Site of the Institution (Check One)***

A.	**Ownership**	____	**D.**	**Option to Lease**	____
B.	**Option to Purchase**	____	**E.**	**Other (Specify)** ____	____
C.	**Lease of ____ Years**	X			

(See Attachment, Section A, Applicant Profile, Item 6)
PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

7. ***Type of Institution (Check as appropriate--more than one response may apply)***

A.	Hospital (Specify)____	____	I.	Nursing Home	____
B.	Ambulatory Surgical Treatment Center (ASTC), Multi-Specialty	____	J.	Outpatient Diagnostic Center	____
C.	ASTC, Single Specialty	____	K.	Recuperation Center	____
D.	Home Health Agency	X	L.	Rehabilitation Facility	____
E.	Hospice	____	M.	Residential Hospice	____
F.	Mental Health Hospital	____	N.	Non-Residential Methadone Facility	____
G.	Mental Health Residential Treatment Facility	____	O.	Birthing Center	____
H.	Mental Retardation Institutional Habilitation Facility (ICF/MR)	____	P.	Other Outpatient Facility (Specify)____	____
			Q.	Other (Specify) ____	____

8. **Purpose of Review *(Check) as appropriate--more than one response may apply)***

A.	New Institution	X	G.	Change in Bed Complement [*Please note the type of change by underlining the appropriate response: Increase, Decrease, Designation, Distribution, Conversion, Relocation*]	
B.	Replacement/Existing Facility	____			
C.	Modification/Existing Facility	____			
D.	Initiation of Health Care Service as defined in TCA § 68-11-1607(4) (Specify)____	____	H.	Change of Location	____
E.	Discontinuance of OB Services	____	I.	Other (Specify)____	____
F.	Acquisition of Equipment	____		____	

9. **Bed Complement Data**

Please indicate current and proposed distribution and certification of facility beds.

		Current Beds Licensed	Current Beds *CON	Staffed Beds	Beds Proposed	TOTAL Beds at Completion
A.	Medical					
B.	Surgical					
C.	Long-Term Care Hospital					
D.	Obstetrical					
E.	ICU/CCU					
F.	Neonatal					
G.	Pediatric					
H.	Adult Psychiatric					
I.	Geriatric Psychiatric					
J.	Child/Adolescent Psychiatric					
K.	Rehabilitation					
L.	Nursing Facility (non-Medicaid Certified)					
M.	Nursing Facility Level 1 (Medicaid only)					
N.	Nursing Facility Level 2 (Medicare only)					
O.	Nursing Facility Level 2 (dually certified Medicaid/Medicare)					
P.	ICF/MR					
Q.	Adult Chemical Dependency					
R.	Child and Adolescent Chemical Dependency					
S.	Swing Beds					
T.	Mental Health Residential Treatment					
U.	Residential Hospice					
	TOTAL	N/A	N/A	N/A	N/A	N/A

*CON-Beds approved but not yet in service

10. **Medicare Provider Number** 016727001 / 174583

Certification Type 855S / 855B

11. **Medicaid Provider Number** 3950424 / 1512243

Certification Type Pharmacy / DME

12. **If this is a new facility, will certification be sought for Medicare and/or Medicaid?** No

13. ***Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area.*** **Will this project involve the treatment of TennCare participants?** No **If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted *or plans to contract.***

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

A. 13. (continued)

1. Treatment of TennCare Participants

As indicated in Section A, Applicant Profile, Item 12 of its application, Pentec Health, Inc. presently does not intend to seek Medicare or Medicaid certification for home health. Consequently, it has indicated in Section A.13 of the application that the project will not involve the treatment of TennCare participants.

Services to intrathecal pump patients are not covered under traditional Medicare and Medicaid coverage guidelines. However, Pentec accepts traditional fee-for-service Medicare and Medicaid patients on a limited, compassionate care basis. Pentec has developed a Compassionate Care Policy and a No Insurance Coverage Policy and has implemented these policies in all jurisdictions in which it operates. Approximately 3% of Pentec's total patient census is comprised of compassionate care patients for which no reimbursement is received. Additionally, approximately 61% of its total patient census is comprised of patients for which Pentec receives compensation for some services rendered, but not all. These patients are typically Medicare and Medicaid beneficiaries that do not have a home infusion benefit. In these cases, Pentec is usually reimbursed only for drugs administered and assumes the patient's nursing care at a financial loss. Pentec's budgeting process assumes that 25% of its total patient census will be treated pursuant to its Compassionate Care Policy, meaning that Pentec will receive either partial or no reimbursement. These polices would be implemented and followed by the HHA in Tennessee as elsewhere.

A. 13. (continued)

2. Relationships with Managed Care Organizations

Pentec Health, Inc. has relationships with the following managed care organizations that have plan members located in Tennessee:

Contracted:
Humana, Inc.
Aetna, Inc.
WellPoint, Inc.
Blue Cross and Blue Shield of Alabama
Coventry Health and Life Insurance Company
Windsor Health Plan, Inc.
Independence Blue Cross
Blue Cross and Blue Shield of Nebraska
BlueCross BlueShield of Western New York
BlueShield of Northeastern New York
Blue Cross of Idaho Health Service, Inc.

Out of Network Billing Only:
BlueCross BlueShield of Tennessee
Cigna Corporation
UnitedHealthcare
Trustmark Companies
SummaCare Health Plan, Inc.
American Postal Workers Union Health Plan
Blue Cross Blue Shield of Michigan
U.S. Dept. of Health and Human Services, Pre-Existing Condition Insurance Plan
Blue Cross Blue Shield of North Dakota
Sterling Life Insurance Company
Blue Cross & Blue Shield of Rhode Island
GHI, an EmblemHealth Company
Transamerica Affinity Services
United Mine Workers of America
Alexian Brothers Community Services
CrestPoint Health
MVP Health Care
Providence Health Plan

SECTION B

PROJECT DESCRIPTION

PENTEC HEALTH, INC.

SECTION B: PROJECT DESCRIPTION

I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

1. Introduction

Pentec Health, Inc. ("Pentec") proposes to establish a specialized Home Health Agency ("HHA") in Tennessee to provide specialized nursing services primarily to patients with surgically-implanted medical devices called intrathecal pumps. Pentec may also provide immunoglobulin-G replacement therapy, through intravenous or subcutaneous infusion, as an ancillary service. All nursing services would be provided to patients in their places of residence, in all parts of the state, under physician-ordered plans of care. As a licensed pharmacy, Pentec will also serve its patients' prescriptive needs.

2. Pentec Health, Inc.

Pentec is a unique provider of specialty infusion therapy services to more than 2,250 patients in 30 states. It is accredited by The Joint Commission in both home care and pharmacy. Through its Specialty Infusion division, Pentec provides a limited, specialized home nursing service to complex patients suffering from severe pain or spasticity who have failed traditional therapy and now rely on implanted drug delivery systems for their treatment. These patients represent a narrow, complex and traditionally underserved population. Pentec serves these patients in their places of residence, on a 24/7 basis, with registered nurses who have completed Pentec's ANCC-certified training program. Pentec also operates a specialty closed-door pharmacy to fulfill its patients' prescriptive needs. Pentec is a Pennsylvania corporation that would be the HHA license holder and service provider in Tennessee.

3. Proposed Services

A. Intrathecal Pump Therapy

An intrathecal pump is a complex medical device that delivers highly concentrated medication through a catheter directly into the intrathecal space surrounding the spinal cord. The pump is surgically implanted in an inpatient or outpatient facility (a procedure in which Pentec is not involved). Pump candidates must be selected carefully by physicians trained in interventional pain or spasticity management. These patients typically have been unable to obtain relief from traditional treatment for conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. The relief provided by the intrathecal pump can be significant, but this treatment is only appropriate for those who have the care and resources to manage the associated risks (such as infection, narcotics withdrawal, drug compounding errors, and pump programming errors). Consequently, these patients require access to highly specialized health services for the management, refill and nursing care associated with intrathecal pumps. Pentec is a national provider with the necessary experience, resources and expertise to provide this needed service cost-effectively.

Effective care of intrathecal pump patients requires both the ability to refill medications, which requires a pharmacy license, and the ability to administer medications, which requires skilled nursing services. Pentec's pharmacy staff is specially trained in the preparation of intrathecal drugs and required packaging and delivery systems, and the medication compounding occurs in an absolutely clean, controlled environment. Pentec is presently licensed in Tennessee as a pharmacy. Pentec proposes to provide the necessary nursing services with registered nurses licensed in Tennessee or a compact state. The nursing skills necessary to administer a patient's

medications and effectively monitor the operation of the delivery system are highly specialized. To ensure that its nurses have and maintain the required skills, Pentec has instituted a rigorous in-house program of classroom instruction, field training and proficiency evaluation. All Pentec nurses must successfully complete this program, which is the only such program certified by the American Nursing Credentialing Center (ANCC), and maintain required proficiency.

B. Immunoglobulin-G Replacement Therapy

As an ancillary service, Pentec proposes to provide immunoglobulin ("Ig-G") replacement therapy services to another limited patient population – those with compromised immune systems. Ig-G replacement therapy entails the administration, by IV or subcutaneous infusion, of immunoglobulin, a fraction of blood plasma containing antibodies, to replace antibodies that the patient cannot produce naturally. Ig-G replacement therapy is targeted at two groups: (1) those with primary immune deficiency, a genetic disorder that typically requires lifetime treatment on a monthly basis; and (2) those with auto immune deficiency, which may require lifetime treatment, but more typically is performed in 3-, 6- or 12-month therapy segments, in several consecutive daily sessions of several hours each. Provision of Ig-G replacement therapy would occur in the patient's residence under a physician-ordered plan of care.

4. Need for the Services

Pentec's proposal addresses an unmet health care need. Its in-home care model provides an underserved patient population with access to treatment that may otherwise be unavailable. Pentec treats patients at home because this delivery model improves access in a manner that is more cost-effective than the alternative, which requires patients to travel to a physician's office or a hospital for pump refills and maintenance. Because this area of medicine is so specialized, few physicians provide the service. Consequently, patients may be burdened with long travel times for treatment, or they may be unable to benefit simply because they lack access to proper care on an ongoing, regular basis. In-home delivery also enables physicians to offer this type of drug delivery to patients that may have been deemed too difficult to manage because of their condition or proximity to the physician's practice. Although some licensed HHAs may offer intrathecal pump services on a limited basis, no HHA with comparable experience, resources, technology and training programs is presently licensed in Tennessee.

5. Service Area and Staffing

Pentec's nursing team would be on call to serve patients located anywhere in Tennessee, 24 hours a day, 7 days a week. Patients will be able to reach their assigned nurse provider via a toll-free number, and calls made outside of office hours will be forwarded directly to Pentec's central call center, which in turn will contact the appropriate nursing team member. The nursing team is comprised entirely of registered nurses. The nursing team would be under the supervision of an HHA administrator, who in turn reports to Pentec's Vice President for Nursing Services, Karen McHenry, R.N., M.S.N., who has executive responsibility for all aspects of nursing services at Pentec.

6. Cost, Funding and Financial Feasibility

Pentec estimates that the cost to implement the project would be approximately $42,000, which includes annual rent for its leased office, office equipment, administrative and legal fees, and application fees. In addition, Pentec has budgeted $100,000 as a project reserve or contingency fund, although it does not presently anticipate use of this fund. The entire cost of the project will be funded through internally-generated cash. Pentec's financial projections for the project, which are based largely on its experience in the 10 states in which it has become licensed since 2011, indicate that the project will break even in 2015 (with a year-end patient census of 39) and be profitable in 2016 (with a year-end patient census of 63).

SECTION B: PROJECT DESCRIPTION

II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of $5 million) and other facility projects (construction cost in excess of $2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.

If the project involves none of the above, describe the development of the proposal.

The project does not involve the construction, modification or renovation of a facility.

Pentec has leased an office in Nashville which will be used solely for administrative purposes and not for patient visits. The office is ready for occupancy, so no construction or renovation will be required. The office will be furnished for use by Pentec staff and will be used as a repository for HHA policies and procedures, personnel records, and other documentation required by Tennessee law. However, because patients would be treated in their places of residence by Pentec's highly mobile nursing team members, the office is not essential to the operation of the HHA.

Assuming issuance of the Certificate of Need and subsequent issuance of the HHA license, Pentec would implement project in Tennessee on a small scale, starting with an estimated 5 patients. It would increase the number of patients served by working with physicians in Tennessee with which it has established contacts, and by establishing new physician relationships. Pentec would implement the project with current registered nurse employees who are licensed to practice in Tennessee (or a compact state), who would serve as the initial HHA administrator and alternate administrator. Pentec would employ additional nurses locally as the need develops, based on its typical ratio of one nurse to every 40 patients. Because Pentec is able to manage staffing on a regional basis, it expects that utilization of its services in Tennessee would be close to 100%.

Pentec conservatively projects, for budgeting purposes, that its year-end patient census would be 39 in 2015 and 63 in 2016. However, proprietary commercial market research indicate that there are presently 1,976 intrathecal pump patients in Tennessee, so the number of potential patients is much greater than Pentec's financial projections indicate. In addition, Pentec estimates on the basis of population and the incidence of primary immune deficiency and auto immune deficiency diseases amongst the general populace, that the number of patients in need of Ig-G replacement therapy in Tennessee is approximately 1,020. These potential patients are not taken into effect in Pentec's projections. Pentec further estimates, on the basis of an analysis of intrathecal pump patient diagnosis codes, that approximately 10-15% of intrathecal pump patients also suffer from neuro-muscular disorders that may be treated by

Ig-G replacement therapy. In these cases, Pentec would be able to offer both types of treatment, which no other licensed provider would be able to do.

Pentec has invested heavily in technology, all of which will be available to the Tennessee HHA immediately upon implementation. This technology includes:

- a centralized call center that permits patients and their physicians to contact the responsible nursing team member 24 hours a day, 7 days a week;
- a proprietary, state-of-the-art electronic medical records ("EMR") system that allows access to patients' records from any location with internet service and is updated by Pentec's nurses in real time;
- a physician portal on Pentec's website that allows referring physicians and their staff to have secure 24/7 access to their patients' medical information that resides in the EMR system; permits secure, HIPAA-compliant, two-way electronic communications on items that require attention, like new prescriptions or plan of treatment changes; and provides physicians with immediate access to new information generated by Pentec's nurse during patient visits;
- a patient portal on Pentec's website that enables patients to have secure 24/7 access to their medical records, prescription information, medication schedule and pain or spasticity scores as measured against goals; and also permits secure, HIPAA-compliant communication with Pentec's nursing team; and
- secure, two-way videoconferencing that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the visit.

Pentec is already licensed in Tennessee as a pharmacy (Pharmacy License Number 4108, valid until February 28, 2015). Pentec owns and operates a closed-door specialty pharmacy to fulfill the prescriptive needs of its intrathecal pump patients, and its pharmacy staff is specially trained in the preparation of intrathecal drugs and required packaging and delivery systems. Therefore, in conjunction with the skilled nursing services that Pentec would provide to intrathecal pump patients, Pentec would also provide pharmacy services. Pentec's pharmacy would also have the ability to provide the medications administered to Ig-G replacement therapy patients. No additional investment would be required for Pentec's pharmacy to provide services in Tennessee.

II. B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.

Not applicable (NA). The proposed project does not involve patient beds.

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SECTION B: PROJECT DESCRIPTION

II. C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. **Adult Psychiatric Services**
2. **Alcohol and Drug Treatment for Adolescents (exceeding 28 days)**
3. **Birthing Center**
4. **Burn Units**
5. **Cardiac Catheterization Services**
6. **Child and Adolescent Psychiatric Services**
7. **Extracorporeal Lithotripsy**
8. **Home Health Services**
9. **Hospice Services**
10. **Residential Hospice**
11. **ICF/MR Services**
12. **Long-term Care Services**
13. **Magnetic Resonance Imaging (MRI)**
14. **Mental Health Residential Treatment**
15. **Neonatal Intensive Care Unit**
16. **Non-Residential Methadone Treatment Centers**
17. **Open Heart Surgery**
18. **Positron Emission Tomography**
19. **Radiation Therapy/Linear Accelerator**
20. **Rehabilitation Services**
21. **Swing Beds**

The only health care services on the list above that Pentec proposes to provide is home health services.

The services proposed by Pentec are substantially different from those typically offered by traditional home health agencies, which frequently offer a variety of skilled nursing services, and may offer other therapeutic services or home health aide services. By contrast, Pentec proposes to serve primarily patients with intrathecal pumps. These patients represent a very narrow, complex and traditionally underserved patient population for which there is limited support by traditional home health care and home infusion providers. Market research shows that there are presently 1,976 intrathecal pump patients in Tennessee.

Pentec's in-home patient care model provides a complex and underserved patient population with access to treatment that in many cases would not otherwise be available. Pentec delivers services to patients in their places of residence because this delivery model improves access to a service in a manner that is more cost-effective than the alternative, which requires patients to travel to a physician's office or a hospital for medication refills and pump maintenance. Because intrathecal medicine is so specialized, few physicians provide the service. Consequently, patients may be required to travel great distances for treatment (across state lines, in some cases), or they may be unable to benefit from intrathecal pump therapy simply because they lack access to proper care on an ongoing, regular basis. In-home delivery also enables physicians to offer this type of drug delivery to patients that may have been deemed too difficult to manage because of their condition or proximity to the physician's practice. At the present time, there are no licensed HHAs in Tennessee with the capability of providing intrathecal pump services on a statewide basis, so Pentec's proposal addresses an unmet health care need in Tennessee.

Although the proposed HHA would serve primarily intrathecal pump patients, Pentec would offer Ig-G replacement therapy as an ancillary service. Pentec estimates that approximately 1,020 Tennessee residents are in need of Ig-G replacement therapy, and that approximately 10-15% of intrathecal pump patients suffer from neuro-muscular disorders that are treatable by Ig-G replacement therapy. Pentec would be uniquely positioned to serve these "crossover" patients because no other licensed HHA is capable of providing both services.

SECTION B: PROJECT DESCRIPTION

II. D. Describe the need to change location or replace an existing facility.

Not applicable (NA). The proposed project is new, so there is no change of location or facility replacement.

SECTION B: PROJECT DESCRIPTION

II. E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of $1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. **For fixed-site major medical equipment (not replacing existing equipment):**
   a. **Describe the new equipment, including:**
      1. **Total cost (as defined by Agency Rule);**
      2. **Expected useful life;**
      3. **List of clinical applications to be provided; and**
      4. **Documentation of FDA approval.**
   b. **Provide current and proposed schedules of operations.**

   Not applicable (NA). The proposed project involves no major medical equipment.

2. **For mobile major medical equipment:**
   a. **List all sites that will be served;**
   b. **Provide current and/or proposed schedule of operations;**
   c. **Provide the lease or contract cost.**
   d. **Provide the fair market value of the equipment; and**
   e. **List the owner for the equipment.**

   Not applicable (NA). The proposed project involves no major medical equipment.

3. **Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.**

   Not applicable (NA). The proposed project involves no major medical equipment.

SECTION B: PROJECT DESCRIPTION

III. (A) Attach a copy of the plot plan of the site which must include:

1. **Size of site (in acres);**
2. **Location of structure on the site;**
3. **Location of the proposed construction; and**
4. **Names of streets, roads or highway that cross or border the site.**

A site plan is attached as Attachment, Section B, Project Description, Item III (A).

Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. There will be no new construction or land development in connection with this project. A street plan indicating the location of the Fifth Third Center is attached in lieu of a plot plan.

1. The size of the site (Fifth Third Center) is approximately two acres.

2. The location of the structure on the site is indicated on the attached street plan.

3. Not applicable (NA).

4. The site is bordered by Church Street to the south, Fifth Avenue N. to the west, and Arcade Alley to the east.

SECTION B: PROJECT DESCRIPTION

III. (B) Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/ clients.

The office leased by Pentec is located in a modern, Class A office building that is handicap-accessible and ADA compliant. It is located in downtown Nashville, approximately one-quarter mile from U.S. Highways 41 and 70, and one mile from Interstate Highways 24, 40 and 65. The office is served by public transportation in the form of several city bus routes that stop at the intersection of Church Street and Fifth Avenue North.

Pentec's office will be used solely for administrative purposes, and not for patient visits. Nevertheless, the site is very accessible to all visitors for the reasons described above.

SECTION B: PROJECT DESCRIPTION

IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc.

A floor plan is attached as Attachment, Section B, Project Description, Item IV.

Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. A floor plan of the office suite in which the office is located is attached. The Pentec office is number 2069 as indicated on the floor plan. Pentec and its visitors also have the use of the office suite common areas, including the Business Lounge, Refreshment Bar and restrooms, which are also depicted on the floor plan.

Pentec's office will be used for HHA administrative purposes only. Patients will not be examined or treated in the office.

SECTION B: PROJECT DESCRIPTION

V. For a Home Health Agency or Hospice, identify:

1. **Existing service area by County;**
2. **Proposed service area by County;**
3. **A parent or primary service provider;**
4. **Existing branches; and**
5. **Proposed branches.**

1. Existing Service Area

Not applicable (NA). The proposed project is new.

2. Proposed Service Area

Pentec proposes to serve patients who reside in all 95 counties in the State of Tennessee, listed alphabetically as follows: Anderson, Bedford, Benton, Bledsoe, Blount, Bradley, Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, DeKalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putnam, Rhea, Roane, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, Wayne, Weakley, White, Williamson, and Wilson.

3. Parent or Primary Service Provider

Pentec would be the HHA license holder and service provider in Tennessee. All services would be provided by registered nurses.

4. Existing Branches

Not applicable (NA). The proposed project is new.

5. Proposed Branches

No branches are proposed. Pentec's proven patient care model would enable it to serve patients in their places of residence, at any time of day, anywhere in the State of Tennessee.

SECTION C

GENERAL CRITERIA FOR CERTIFICATE OF NEED

PENTEC HEALTH, INC.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

1. **Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.**

The HHA proposed by Pentec will contribute toward the achievement of each of the State Health Plan's Five Principles for Achieving Better Health. The Principles and the impact that implementation of the proposal will have on each Principle are stated and described below.

Principle 1: Healthy Lives – "The purpose of the State Health Plan is to improve the health of Tennesseans."

Pentec's proposal involves the establishment of an HHA that will provide very specialized services to two complex and underserved categories of patients in Tennessee: those with implanted intrathecal pumps, and those in need of immunoglobulin-G replacement therapy through IV or subcutaneous infusion. Both categories of patient may be considered chronically ill. The proposed services will improve the health of these patients.

Patients with intrathecal pumps typically suffer from conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. For these patients, many of whom have failed to find relief from more traditional treatments, the relief afforded by intrathecal pump therapy can be significant, and often they are able to resume many normal life activities as a result.

The estimated population of intrathecal pump patients in Tennessee is limited – about 1,976 persons at the present time. However, because relatively few physicians practice in this specialty, and because support by traditional home health agencies for these patients is very limited, many patients need to travel great distances to a physician's office or hospital for treatment. For most patients, this means a visit every 30 days, although in some cases the interval may be shorter or longer. For patients who are home-bound or suffer from limited mobility, this travel requirement can be burdensome. Moreover, a missed appointment due to travel-related problems could result in the patient's pump running dry – a potentially life-threatening situation that cannot be allowed to occur. Because Pentec provides services to its patients in their places of residence, and because its specially-trained nurses are available to treat patients 24/7, the proposed HHA will eliminate both the burden of travel on patients and the serious risks to patients that could result from failure to have the pump refilled on time. Although the patient population is small, the health benefits to the affected patients are substantial.

Other Tennesseans who suffer from conditions that are treatable with the intrathecal pump may be unable to benefit from the therapy simply because they lack access to proper care on an ongoing and regular basis. Pentec's in-home patient care model addresses this unmet need.

Pentec estimates that approximately 1,020 Tennesseans are presently in need of Ig-G replacement therapy. Recipients of Ig-G replacement therapy have compromised immune systems: either primary immune deficiency, which typically requires lifetime treatment on a monthly basis, or auto immune deficiency, which may require lifetime treatment, but more typically is performed in 3-, 6- or 12-month therapy segments. Because these patients cannot produce antibodies naturally, Ig-G replacement therapy is necessary to allow them to fight infectious disease and remain healthy.

Principle 2: Access to Care – "Every citizen should have reasonable access to health care."

Intrathecal pump patients and Ig-G replacement therapy patients can be treated in a physician office or a hospital, but this may be burdensome to patients. Many intrathecal pump patients suffer from limited mobility and some are home-bound, while others (particularly those treated for spasticity) are juveniles. For these patients, travel requirements may make access more difficult or may preclude access entirely. For patients with auto immune deficiency, Ig-G replacement therapy is typically administered in 3-, 6- or 12-month therapy segments, in several consecutive daily sessions of several hours each. For these patients, travel for treatment can also be a burden. The proposed services will improve access to necessary care for both patient categories.

Because Pentec's proposal entails the establishment of a specialized HHA that would provide intrathecal pump therapy and Ig-G replacement therapy to patients in their places of residence only, barriers to access caused by patients' limited mobility or home-bound status, or by the need for transportation generally, would be eliminated. Moreover, because Pentec would treat patients in all 95 counties in Tennessee, its services would, by definition, be available to patients who live in all Medically Underserved Areas (MUAs) and Health Provider Shortage Areas (HPSAs) in the state. As a national provider of specialty home infusion services since 1983, Pentec has vast experience with the target patient populations (having had more than 100,000 patients on service) and is uniquely positioned to meet the needs of patients on an individual, case-by-case basis. Each Pentec patient is assigned to one "primary care nurse", which facilitates development of a patient-provider relationship based on mutual trust and communication.

Pentec's proprietary technology would further enhance access to care by the subject patient population. This technology includes a centralized communication system that allows patients to reach their primary care nurse, 24 hours a day, 7 days a week; a patient portal on Pentec's website that enables patients to have secure 24/7 access to their medical records and permits secure, HIPAA-compliant communication with Pentec's nursing team; a physician portal that provides treating physicians secure 24/7 access to their patients' medical information and also allows secure, HIPAA-compliant communication with Pentec; and secure, two-way videoconferencing capability that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the in-home visit.

Principle 3: Economic Efficiencies – "The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's health care system."

Implementation of the proposal by Pentec, an experienced national provider of specialty home infusion services, will introduce economic efficiencies by reducing costs to the health care system in the Tennessee.

First, because the proposed services will be provided to patients in their places of residence, there is strong potential for reduction of use of inpatient and outpatient care. The absence of licensed HHAs providing services to intrathecal pump patients in Tennessee means that these patients presently must travel to a physician's office or hospital for treatment. Pentec believes that reducing the volume of care provided in an office or hospital setting could result in significant health care system cost savings. Research has shown that the costs of care associated with intrathecal pump patients cared for in a traditional physician office setting varies considerably based on patient circumstances. Among patients with pain and spasticity, average annual health

plan expenditures are estimated to be $70,000.[1] Over half of those expenses are for inpatient encounters that may have been averted by a more comprehensive care model such as that provided by Pentec. Research is ongoing to further define the costs of care in the usual care setting versus the Pentec in-home delivery model. However, evidence suggests that the reimbursable costs associated with refills of patients' pumps (medications and the procedure itself) are likely to be lower than the comparable reimbursable costs if the same service were provided by a physician in an office or hospital. Given that the typical patient may have 12 or more refills annually, these savings would accumulate over time.

Second, in emergency situations (caused, for example, by a pump running dry due to a missed appointment), patients may need to visit a hospital emergency department for care, and may need to use ambulance transportation. The proposed services, which would be available to patients in their homes on a 24/7 basis, reduce the incidence of patients' presenting at a hospital emergency department for treatment or using ambulances for transportation to a health care facility.

Delivery of Ig-G replacement therapy in patients' places or residence also has strong potential to reduce use of inpatient care (and to reduce the cost of care), for many of the same reasons described above with respect to intrathecal pump services. An added benefit of in-home care for immune-deficient patients is the reduced risk of hospital-acquired infection (often caused by more virulent and more antibiotic-resistant pathogens than infections that are community-acquired). Reduction of lost productivity (e.g., missed work by patients) due to infection represents an indirect benefit of in-home treatment. In addition, because hospitals typically treat Ig-G replacement patients during the work week, in-home treatment (which can occur on weekends or in the evening) may further reduce lost productivity due to missed work.

Principle 4: Quality of Care – "Every citizen should have the confidence that the quality of health care is continually monitored and standards are adhered to by health providers."

The services proposed by Pentec are **safe, effective, patient-centered, timely, efficient and equitable**.

First and foremost, Pentec has ensured through its rigorous nurse training and ongoing evaluation program that the services provided to patients are **safe**. Intrathecal pump patients require treatment on a regular and continuing basis, and this treatment must be provided by professionals with the required specialized skills. The specific needs of these patients involve primarily the management, refilling, reprogramming and nursing care associated with pumps and the medical conditions treated. Proper maintenance of the pump is essential due to heightened risk of infection and the consequences of pump malfunction. Once the pump is implanted, medication is administered continually into the spine, so the pump must be refilled with the prescribed medications and reprogrammed regularly. Because intrathecal drugs are highly concentrated and do not enter the patient's bloodstream, the side effects inherent with high-dose oral or IV narcotics and oral baclofen are greatly reduced. However, precise dosing is vital and must be carefully monitored. The health benefits to these patients can be substantial, but the associated risks mandate treatment by qualified and experienced health care professionals.

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[1] Burden of Patients with Intrathecal Drug Delivery System – An Administrative Claims-Based Analysis, S.R. Palli, M. Abens, R. A. Quimbo, S. Fisher (2011). This study, which was funded by Pentec, was presented at the 15th Annual North American Neuomodulation Society (NANS) Meeting, Las Vegas, Nevada, December 8-11, 2011; and the full manuscript thereof has been accepted for publication by the peer-reviewed medical journal Neuromodulation.

The proposed services will be provided by specially-trained and certified registered nurses. Although all Pentec nurse providers are licensed as registered nurses by Tennessee or a compact state, they must complete special training to ensure that they have and maintain the skills required to administer patients' medications and monitor operation of the delivery system. This requires a rigorous program of classroom instruction, field training and ongoing proficiency evaluation by practitioners with expertise in treatment of intrathecal pump patients. Pentec's "Primary Care Nurse Training and Certification Program" is the only such program in the United States that has been certified by the American Nursing Credentialing Center (ANCC). In addition, after completion of the training program, Pentec nurses must maintain all required proficiencies on an ongoing basis. To accomplish this, Pentec's Lead Regional Nurse visits all nurses in the field at least annually to conduct an on-site performance evaluation. Pentec nurses must complete an annual evaluation of all applicable standards of performance, and must demonstrate continuing competence in all necessary procedures. Further, Pentec itself is accredited by The Joint Commission in both pharmacy and home care.

Pentec collaborates closely with referring physicians to ensure that therapy provided is **effective**. Because Pentec's patients are all referred by specialists in areas such as pain management, spasticity and neuromuscular disease, and because these patients have typically failed to find relief from alternative therapies, the likelihood that a patient would receive inappropriate or unnecessary therapy is minimized.

Pentec's model of care is **patient-centered** by design. Each patient is assigned to one primary care nurse, and Pentec maintains a low patient-nurse ratio of approximately 40:1. Pentec has developed over many years polices designed to ensure effective, regular communication between nurse, patient and treating physician; respect for patient preferences (e.g., advance directives); awareness of cultural sensitivities; and prompt response to complaints, amongst others. Pentec has invested heavily in technology that allows patients to communicate with their nurse providers anytime, anywhere.

The proposed services are **timely** by definition. Although treatment of patients is always scheduled in accordance with the patient's individual plan of treatment, it is accessible 24/7 and can be delivered anywhere in Tennessee.

As discussed under Principle 3, above, the proposed services are **efficient**. By eliminating unnecessary patient travel and reducing the incidence of inpatient and outpatient care, emergency department visits, and use of EMS, efficient delivery of health care is increased and costs are decreased.

Finally, the proposed services are **equitable**. The entire population of patients with intrathecal pumps is medically underserved at present. Because all intrathecal pump patients referred to Pentec have had their pumps surgically implanted prior to the start of service, Pentec does not have the ability to target specific sub-populations within the larger population of pump patients. However, for the company as a whole, approximately 56% of patients are women, and approximately 29% are age 65 or older. In addition, a significant portion of Pentec's patients may be considered handicapped to a degree, as a result of congenital conditions such as cerebral palsy, the progression of illnesses such as multiple sclerosis, or the occurrence of traumatic events such as stroke, head trauma, and spinal cord or brain injury. Finally, though its "Compassionate Care" policy, Pentec provides services to those without the ability to pay. Pentec's budgeting process assumes that 25% of the total patient census will be treated pursuant to its Compassionate Care policy, meaning that Pentec will receive either no reimbursement, or partial reimbursement, for services provided.

Principle 5: Health Care Workforce – "The state should support the development, recruitment, and retention of a sufficient and quality health care workforce."

Pentec will not only serve Tennesseans with a highly-qualified workforce from inception of the proposal, but it will also provide specialized training and certification to Tennessee nurses at its own expense.

In keeping with Pentec's usual practice, the proposal would be implemented by an administrator and alternate administrator, both registered nurses licensed to practice in Tennessee, both of whom are experienced Pentec employees. As the HHAs patient census increases, these nurses would be supplemented by local hires who would then undergo Pentec's ANCC-certified Primary Care Nurse Training and Certification Program. Eventually, these local employees would assume responsibility for administration of the HHA. In this manner, Pentec's proposal would enhance the quality of the health care workforce in Tennessee.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

The criteria and standards applicable to "Home Health Services" are set forth below, together with Pentec's response to each.

1. *The need for home health agencies/services shall be determined on a county by county basis.*

   Because the patients with intrathecal pumps and the population of patients in need of Ig-G replacement therapy are widely dispersed throughout the general population, Pentec proposes to serve these patients in all 95 counties in the State of Tennessee.

2. *In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.*

   Not applicable (NA). Because of the limited and highly specialized nature of the proposed services, the general formula stated above does not provide an estimate of need for the services.

3. *Using recognized population sources, projections for four years into the future will be used.*

   Not applicable (NA). Because of the limited and highly specialized nature of the proposed services, the rate of general population growth does not provide an estimate of need for the services.

4. *The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area. Based on the number of patients served by home health agencies in the service area, an estimation will be made as to how many patients could be served in the future.*

   Not applicable (NA). Because of the limited and highly specialized nature of the proposed services, there is no comparable licensed HHA in Tennessee that could be used for purposes of utilization analysis.

5. *Documentation from referral sources:*

   a. *The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.*

      (To be provided)

   b. *The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.*

Referrals of patients with intrathecal pumps are typically made by specialists who practice in the areas of interventional pain or spasticity management. These patients have been selected carefully by their treating physicians for intrathecal pump therapy, and their pumps have already been implanted at the start of service by Pentec. Pump patients typically have been unable to obtain relief from traditional treatment for conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. Although there are presently approximately 1,976 Tennesseans with intrathecal pumps, Pentec has conservatively projected for financial purposes that its patient census would be 39 at year-end 2015 and 63 at year-end 2016.

Referrals of patients for Ig-G replacement therapy are typically made by specialists in immune deficiency disease. Although Pentec estimates that approximately 1,020 Tennesseans are in need of Ig-G replacement therapy, Pentec has not taken any of these patients into effect for purposes of financial projections.

c. *The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.*

(To be provided)

d. *The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.*

As indicated throughout its application, Pentec proposes to provide a very specialized type of service that is limited to treatment of patients who have a surgically-implanted intrathecal pump and patients in need of immunoglobulin-G replacement therapy in their places of residence. This service can be categorized as a type of skilled nursing. However, unlike traditional home health agencies, Pentec would not provide other types of therapy services (such as physical, speech or occupational therapy) or home health aide or similar services. In addition, unlike several Tennessee home infusion providers that serve a small number of counties, Pentec would have the capability of providing, and proposes to provide, services to patients located anywhere in Tennessee on a 24/7 basis.

6. *The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.*

a. *The average cost per visit by service category shall be listed.*

Pentec projects, on the basis of its experience nationally and the projected number of Tennessee patients, that the average billed cost per visit for intrathecal pump therapy patients in Tennessee, for the year 2015, would be $2,471, which is the total of the following: drugs ($588), nursing services ($71), supplies ($37) and per diem ($1,775).

For Ig-G replacement therapy patients, the average billed cost per visit is $9,810, which is the product of $109/gram of Ig-G multiplied by 90 grams/visit.

b. *The average cost per patient based upon the projected number of visits per patient shall be listed.*

The average treatment frequency for all intrathecal pump patients is 6 times per year. Therefore, the average annual cost per intrathecal pump patient, based on the average cost per visit stated above, would be $14,826.

Assuming 6 visits per year, the annual cost for Ig-G replacement therapy patients is $58,860.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c).

Not applicable (NA). The proposed project is new, so there is no change of site.

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SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.

Implementation of the proposed services in Tennessee is consistent with Pentec's long-range goals.

First, by providing intrathecal pump therapy to patients who live in Tennessee, Pentec would be closing a significant gap its coverage area in the South, which presently includes the neighboring states of Kentucky, Virginia, North Carolina, Georgia, Alabama and Mississippi. Through its activities and provider relationships in these neighboring states, Pentec is aware of situations in which Tennessee residents with intrathecal pumps presently must travel out of state (e.g., from northwestern Tennessee to a provider in Paducah, Kentucky) due to unavailability of in-home service by licensed Tennessee HHAs.

Second, Pentec is in the process of expanding its Ig-G replacement therapy services in the mid-Atlantic region and the South. Provision of Ig-G replacement therapy services in Tennessee is consistent with this plan. Because these services are also being expanded in neighboring states, failure to provide them in Tennessee would again result in a coverage gap that Pentec desires to avoid.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area.

A map of proposed service area is attached as Attachment, Section C, Need, Item 3.

The proposed service area is all 95 counties in the State of Tennessee. This service area is reasonable for two reasons. First, it would expand access to needed health care services to a patient population that is presently underserved. Because intrathecal pump patients and Ig-G replacement therapy patients tend to be distributed evenly throughout the population, greater concentrations of these patients can be found in larger cities and metropolitan areas such as Memphis, Nashville, Chattanooga and Knoxville, and a provider of specialty home infusion services could capture a significant percentage of Tennessee's patient population while limiting its service area to a small number of counties. However, such a proposal would be contrary to the goals of improved access and equitable provision of services articulated in the State Health Plan, and it has never been Pentec's model in any jurisdiction.

Second, Pentec's proposed service area is reasonable because Pentec has the experience and resources to implement in-home care of intrathecal pump and Ig-G replacement therapy patients on a statewide basis. At present, Pentec provides specialty home infusion services in 30 states through use of its highly-mobile, specially-trained nursing teams. In every case, it provides these services to patients in all parts of the state except where restricted by conditions of licensure (e.g., Kentucky, where Pentec is licensed to serve 116 of 120 counties). Within the past four years, Pentec has obtained appropriate home health licenses and implemented statewide (or near-statewide) service in New Hampshire, Virginia, North Carolina, Indiana, Illinois, Kentucky, Minnesota, Nebraska, Colorado and Texas.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

4. a. Describe the demographics of the population to be served by this proposal.

As noted in the answer to Section C, Need, Item 1, intrathecal pump patients and Ig-G replacement therapy patients are widely distributed throughout the population in general. Moreover, Pentec does not track or otherwise classify its patients on the basis of race or ethnicity. However, for the company as a whole, approximately 56% of Pentec's patients are women, and approximately 29% are age 65 or older. Also, a significant percentage of Pentec's patients may be considered handicapped to some degree as a result of congenital conditions such as cerebral palsy, the progression of illnesses such as multiple sclerosis, or the occurrence of traumatic events such as stroke, head trauma, and spinal cord or brain injury.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

4. b. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

Because Pentec proposes to serve only patients with intrathecal pumps and patients in need of Ig-G replacement therapy, it is appropriate to consider the special needs of these populations specifically, rather than the general population in the service area.

As described in the answer to Section C, Need, Item 1, Pentec's target patient population may be considered chronically ill. Intrathecal pump patients typically suffer from chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. These patients frequently have limited mobility and some may be home-bound. Ig-G replacement therapy patients suffer from primary immune deficiency or auto immune deficiency; they are incapable of producing antibodies to fight infection naturally. Both types of patients require continuing care, typically on a life-long basis. Intrathecal pump patients must have their pumps refilled and reprogrammed at periodic intervals – most typically every 30 days, but in some cases as often as every 10 days, or as infrequently as every 120 days. Patients with primary immune deficiency have a genetic disorder that typically requires lifetime treatment on a monthly basis, while those with auto immune deficiency most often are treated in 3-, 6- or 12-month therapy segments, in several consecutive daily sessions of several hours each.

For intrathecal pump patients, the frequency of treatment, relative lack of licensed in-home providers of intrathecal pump therapy, and limited number of physicians who practice in this area of medicine often means that inconvenient and burdensome travel for pump refills and reprogramming is necessary. This problem is compounded for the home-bound, those with limited mobility, the elderly and pediatric patients. As a consequence, many patients who could benefit from intrathecal pump therapy simply do not have access. Pentec's in-home patient care model is designed to address this fundamental access problem.

Services to intrathecal pump patients are not covered under traditional Medicare and Medicaid coverage guidelines. However, Pentec accepts traditional fee-for-service Medicare and Medicaid patients on a limited, compassionate care basis. Pentec has developed a Compassionate Care Policy and a No Insurance Coverage Policy and has implemented these policies in all jurisdictions in which it operates. Approximately 3% of Pentec's total patient census is comprised of compassionate care patients for which no reimbursement is received. Additionally, approximately 61% of its total patient census is comprised of patients for which Pentec receives compensation for some services rendered, but not all. These patients are typically Medicare and Medicaid beneficiaries that do not have a home infusion benefit. In these cases, Pentec is usually reimbursed only for drugs administered and assumes the patient's nursing care at a financial loss. Pentec's budgeting process assumes that 25% of its total patient census will be treated pursuant to its Compassionate Care Policy, meaning that Pentec will receive either partial or no reimbursement. These polices would be implemented and followed by the HHA in Tennessee as elsewhere.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

5. **Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.**

   At present, no licensed HHA provides both intrathecal pump therapy services and Ig-G replacement therapy services to patients in their places of residence on a 24/7 basis in all counties in the State of Tennessee. Consequently, no data are available for review.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

The following documents are attached at Attachment, Section C, Need, Item 6:

1. Utilization and revenue data for Pentec Health, Inc. as a whole for the fiscal years ended December 31, 2011, 2012 and 2013; and projected utilization and revenue for the proposed Tennessee HHA for years 2015 and 2016.

2. Supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

1. **Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.**

   - **All projects should have a project cost of at least $3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)**

   - **The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.**

   - **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**

   - **For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.**

   The Project Cost Chart is included on the following page.

PROJECT COST CHART

A.	Construction and equipment acquired by purchase:	
1.	Architectural and Engineering Fees	$ 28,500
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	
3.	Acquisition of Site	
4.	Preparation of Site	
5.	Construction Costs	
6.	Contingency Fund	
7.	Fixed Equipment (Not included in Construction Contract)	
8.	Moveable Equipment (List all equipment over $50,000)	
9.	Other (Specify) Miscellaneous office equipment	$ 2,500
B.	Acquisition by gift, donation, or lease:	
1.	Facility (inclusive of building and land)	
2.	Building only	
3.	Land only	
4.	Equipment (Specify)_____	
5.	Other (Specify) Office lease (annual rent)	$ 8,028
C.	Financing Costs and Fees:	
1.	Interim Financing	
2.	Underwriting Costs	
3.	Reserve for One Year's Debt Service	
4.	Other (Specify) Reserve / contingency fund	$100,000
D.	Estimated Project Cost (A+B+C)	$139,028
E.	CON Filing Fee	$ 3,000
F.	Total Estimated Project Cost (D+E)	
	TOTAL	$142,028

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

___ **A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;**

___ **B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;**

___ **C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.**

___ **D. Grants--Notification of intent form for grant application or notice of grant award; or**

X__ **E. Cash Reserves--Appropriate documentation from Chief Financial Officer.**

___ **F. Other—Identify and document funding from all other sources.**

The project will be funded entirely by means of cash reserves. As of December 31, 2013, on a consolidated basis, Pentech Healthcare Infusions, Inc. and subsidiaries, including the principal operating company, Pentec Health, Inc., had cash on hand of $3.9 million. A copy of the audited financial statements of Pentech Healthcare Infusions, Inc. and subsidiaries as of December 31, 2013, is attached as Attachment, Section C, Economic Feasibility, Item 2.

Pentec's Chief Financial Officer, Art Rea, states that as of October 31, 2014, Pentec's cash on hand had increased to $7.5 million.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

The estimated costs of the proposed project are set forth on the Project Costs Chart. These estimates are based on Pentec's prior experience in implementation of services in new states (particularly Kentucky, which also has a Certificate of Need requirement).

As described in the answer to Section B, Project Description, Item II.A, the proposal does not involve any construction or renovation of physical facilities, and this is reflected in the Project Costs Chart. The Legal, Administrative and Consultant Fees of $28,500 reflect the estimated legal fees that will be incurred by Pentec in connection with the Certificate of Need filing and subsequent HHA licensure process. This estimate is derived from experience in other jurisdictions, particularly Kentucky. The estimated cost of miscellaneous office equipment of $2,500 is based on Pentec's typical expenditure in outfitting its administrative offices in other locations, all of which are ready for occupancy when leased. The office lease expense of $8,028 reflects the actual annual rent payable by Pentec for its leased office in Nashville. In addition to these projected costs, Pentec has budgeted an additional amount of $100,000, described as a Contingency/Reserve Fund, to cover any unanticipated costs in connection with the Certificate of Need filing and subsequent HHA licensure process. Including the Contingency/Reserve Fund, the Estimated Project Cost is $139,028. The CON Filing Fee of $3,000 is based on the Estimated Project Cost.

As noted above, the project does not involve construction, so no costs per square foot are included.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

4. **Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).**

   The Historical Data Chart is included on the following page, and notes to the Historical Data Chart follow on the page thereafter. The Projected Data Chart is included on page following the notes to the Historical Data Chart.

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency. The fiscal year begins in January (Month).

	Year 2011	Year 2012	Year 2013
A. Utilization Data (Specify Unit of Measure)	Note 1	Note 1	Note 1
B. Revenue from Services to Patients			
1. Inpatient Services			
2. Outpatient Services	$61,929,000	$76,898,000	$76,214,000
3. Emergency Services			
4. Other Operating Revenue (specify)			
Gross Operating Revenue	$61,929,000	$76,898,000	$76,214,000
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments			
2. Provision for Charity Care	N/A - Not billed	N/A - Not billed	N/A - Not billed
3. Provisions for Bad Debt	$4,003,000	$4,943,000	$3,047,000
Total Deductions	$4,003,000	$4,943,000	$3,047,000
NET OPERATING REVENUE	$57,926,000	$71,955,000	$73,167,000
D. Operating Expenses			
1. Salaries and Wages	$18,398,000	$23,295,000	$26,031,000
2. Physicians' Salaries and Wages			
3. Supplies	$12,555,000	$18,538,000	$18,894,600
4. Taxes	$6,197,000	($5,400,000)	($904,000)
5. Depreciation	$1,171,000	$1,620,000	$1,676,000
6. Rent	$662,000	$933,000	$1,047,000
7. Interest, other than Capital	$2,598,000	$7,472,000	$10,409,000
8. Management Fees			
a. Fees to Affiliates			
b. Fees to Non-Affiliates	$250,000	$454,000	$600,000
9. Other Expenses (specify)	$6,661,000	$64,380,000	$17,028,400
Total Operating Expenses	$48,492,000	$111,292,000	$74,782,000
E. Other Revenue (Expenses) - Net (Specify)			
NET OPERATING INCOME (LOSS)	$9,434,000	($39,337,000)	($1,615,000)
F. Capital Expenditures			
1. Retirement of Principal	N/A	N/A	N/A
2. Interest	N/A	N/A	N/A
Total Capital Expenditures	$976,000	$1,925,000	$1,242,000
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	$8,458,000	($41,262,000)	($2,857,000)

Notes to Historical Data Chart:

1. Utilization Date (Unit of Measure): Because revenues for Pentec Health, Inc. as a whole are derived from both its Renal Nutrition and Specialty Infusion divisions, it is not possible to specify a single unit of measure for purposes of the Historical Data Chart (in contrast to the Projected Data Chart, which reflects Specialty Infusion only and uses average patient census as the unit of measure).

   Pentec's year-end intrathecal pump patient census for the three years shown is as follows:

   2011: 1,303
   2012: 1,783
   2013: 2,177

2. Deductions from Gross Operating Revenue, Line 2, Provision for Charity Care: Pentec does not book revenue for charity care; therefore, no provision is shown in the income statement.

3. Operating Expenses, Line 4, Taxes is shown as a negative number for 2012 and 2013. This reflects the utilization of tax benefits in those years.

4. Operating Expenses, Line 9, Other Expenses includes a one-time extraordinary charge for impairment of goodwill in the amount of $46,482,000.

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year 2015	Year 2016
A. Utilization Data (Average number of patients)	20.2	52.4
B. Revenue from Services to Patients		
1. Inpatient Services		
2. Outpatient Services	304,573	853,923
3. Emergency Services		
4. Other Operating Revenue (Specify)_____		
Gross Operating Revenue	**$304,573**	**$853,923**
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments		
2. Provision for Charity Care	Not billed	Not billed
3. Provisions for Bad Debt	19,797	55,505
Total Deductions	19,797	55,505
NET OPERATING REVENUE	**$284,775**	**$798,418**
D. Operating Expenses		
1. Salaries and Wages	118,993	161,240
2. Physician's Salaries and Wages		
3. Supplies	91,234	260,130
4. Taxes	702	67,676
5. Depreciation	833	1,667
6. Rent	8,028	8,028
7. Interest, other than Capital		
8. Other Expenses (Specify) One-time charges; misc.	63,735	179,366
Total Operating Expenses	**$283,526**	**$678,106**
E. Other Revenue (Expenses) -- Net (Specify)		
NET OPERATING INCOME (LOSS)	**1,249**	**120,312**
F. Capital Expenditures		
1. Retirement of Principal		
2. Interest		
Total Capital Expenditures	**$2,500**	**$2,500**
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	**($1,251)**	**$117,812**

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Please see Attachment, Section C, Need, Item 6, supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Please see Attachment, Section C, Need, Item 6, supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

Pentec's charge schedule will not change based on this proposal. Pentec is reimbursed for its services from nationwide and local insurance providers who set the charge schedule. Pentec bills according to the insurance provider's charge schedules. As such, as shown in Attachment C.I, Question 6, Pentec assumes that the charges for the proposal in Year 1 and Year 2 are equal to the actual charges incurred in 2013 from non-TN states. These figures shown are net charges, before bad debt.

A copy of Pentec's current "Home Infusion Fee Schedule" and "Miscellaneous Intrathecal Fee Schedule" is attached as Attachment, Section C, Economic Feasibility, Item 6.A.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

Not applicable (NA).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.

Under its in-home patient care model, through effective management of nursing staff, Pentec is able to maintain utilization rates at or close to 100%.

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SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.

Pentec has determined that there are presently 1,976 Tennesseans with intrathecal pumps, and it estimates that approximately 1,020 Tennesseans are present or prospective Ig-G replacement therapy patients. Despite these numbers, Pentec has conservatively projected a Tennessee intrathecal pump patient census of 39 at year-end 2015 and 63 at year-end 2016, and it has not included Ig-G replacement therapy patients in its projections at all. Nevertheless, Pentec projects that the Tennessee HHA will have a break-even result for 2015 and a net profit of $120,312 for 2016.

Pentec has the financial resources available to support the project regardless of whether the forecasted results are achieved. Although Pentec had a net loss in 2013 due to the impact of reduced reimbursement rates in its Renal Nutrition division, it currently projects net income of $4.2 million in 2014. As of December 31, 2013, on a consolidated basis, Pentech Healthcare Infusions, Inc. and subsidiaries, including the principal operating company, Pentec Health, Inc., had total assets of $207.6 million, shareholders' equity of $53.9 million, and cash on hand of $3.9 million. As of October 31, 2014, Pentec's cash on hand had increased to $7.5 million.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

1. Participation in Medicare and Medicaid

Pentec follows the NHIA Coding Standards and as such, bills insurance plans for a nursing visit, the drugs dispensed and a daily per diem rate to cover the otherwise non-billable services necessary to render this type of care. Fee-for-service Medicare and Medicaid only cover the drugs dispensed and do not cover the services necessary to administer them or manage the patient's condition. However, Pentec accepts traditional fee-for-service Medicare and Medicaid patients on a limited, compassionate care basis.

2. Service to the Medically Indigent

Pentec has developed Compassionate Care, No Insurance Coverage and Financial Assistance Policies and has implemented them in all jurisdictions in which it operates. Pentec will apply these policies to provide services to patients who are unable to pay for services. The determination of financial hardship or financial assistance to be offered will be based on the patient's ability to pay and according to Pentec's guidelines.

Pentec will attempt to collect, through good faith efforts, all outstanding balances owed by patients. However, there may be instances where the amount owed would create an undue financial hardship. In these cases, part or all of a patient's balance may be waived if financial hardship, according to the company's guidelines, has been reviewed, documented and approved. Additionally, compassionate care may be requested and approved for a limited time period, usually in 90-day increments, due to insurance reasons or other extenuating circumstances.

Formal financial evaluation is required to fairly and informatively establish the level of an individual patient's ability to pay for the portion of the charges that would be his or her responsibility. If a patient is identified (at initial set-up or during the course of therapy) as having difficulty paying the amount described as "the patient's financial responsibility" (amounts owed by the patient or the responsible party), the patient or the responsible party will be asked to complete a financial application to or provide financial information so that a determination of the patient's ability to pay can be determined in accordance with Pentec's Financial Assistance Policy.

Patients with large deductibles, out-of-pocket, coinsurance, co-pay or any other amount that would be the patient's financial responsibility will be eligible for the same financial assistance as all other patients. Because the amounts owed by patients with these types of plans can be more substantial than amounts owed by other patients, they will be analyzed using its commercial co-pay calculator. This information will be collected and used to measure profitability, but this measurement will not affect the decision to start or not start a patient on service.

At present, approximately 3% of Pentec's total patient census is comprised of compassionate care patients for which no reimbursement is received. Additionally, approximately 61% of its total patient census is currently comprised of patients for which Pentec receives compensation for some services rendered, but not all. These patients are typically Medicare and Medicaid

beneficiaries that do not have a home infusion benefit. In these cases, Pentec is usually reimbursed only for the drugs administered and assumes the patient's nursing care at a financial loss. Pentec's budgeting process assumes that 25% of the total patient census will be treated pursuant to its Compassionate Care Policy, meaning that Pentec will receive either no reimbursement, or partial reimbursement.

3. Year One Medicare and Medicaid Revenue

Pentec projects, for the first full year of HHA operation (2015), total revenue of $304,573, of which $43,090, or 14.1%, is from Medicare or Medicaid. As discussed above, this represents primarily revenue from drugs dispensed.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project.

A copy of the audited consolidated financial statements of Pentec Healthcare Infusions, Inc. and subsidiaries (including its principal operating subsidiary, Pentec Health, Inc.) for the year ended December 31, 2013, is attached as Attachment, Section C, Economic Feasibility, Item 2.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.

Because Pentec provides specialty infusion services as a "home health agency" (or the equivalent) in all jurisdictions in which it is active, it did not consider alternatives to licensure as an HHA in Tennessee. However, as discussed in its answer to Section C.I, Question 1, Pentec believes that its in-home delivery model is more cost effective than the existing alternatives. In addition, because access will be improved and risks reduced, as discussed in its answer to Section C.I, Question 1, delivery of intrathecal pump services in the patient's place of residence is also more effective than the existing alternatives.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

ECONOMIC FEASIBILITY

b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Not applicable (NA).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

1. Managed Care Organizations

Pentec has relationships with the following managed care organizations that have plan members located in Tennessee:

Contracted:

a. Humana, Inc.
b. Aetna, Inc.
c. WellPoint, Inc.
d. Blue Cross and Blue Shield of Alabama
e. Coventry Health and Life Insurance Company
f. Windsor Health Plan, Inc.
g. Independence Blue Cross
h. Blue Cross and Blue Shield of Nebraska
i. BlueCross BlueShield of Western New York
j. BlueShield of Northeastern New York
k. Blue Cross of Idaho Health Service, Inc.

Out of Network Billing Only:

a. BlueCross BlueShield of Tennessee
b. Cigna Corporation
c. UnitedHealthcare
d. Trustmark Companies
e. SummaCare Health Plan, Inc.
f. American Postal Workers Union Health Plan
g. Blue Cross Blue Shield of Michigan
h. U.S. Dept. of Health and Human Services, Pre-Existing Condition Insurance Plan
i. Blue Cross Blue Shield of North Dakota
j. Sterling Life Insurance Company
k. Blue Cross & Blue Shield of Rhode Island
l. GHI, an EmblemHealth Company
m. Transamerica Affinity Services
n. United Mine Workers of America
o. Alexian Brothers Community Services
p. CrestPoint Health
q. MVP Health Care
r. Providence Health Plan

2. Nurse Staffing Agencies

Pentec also has existing contracts with two nurse staffing agencies to provide registered nurses to perform Ig-G replacement therapy services only. These are:

a. Critchfield Specialty Infusion Group, LLC
b. Cross Country Staffing, Inc.

3. Physicians and Practices

Pentec has been in contact with a number of practitioners in Tennessee, including the following physicians and practices:

a. Knoxville Neurology Clinic
b. David A. Rankine, M.D. – Neurologist (Chattanooga)
c. Chattanooga Neurology Associates
d. Memphis Neurology
e. Tidence L. Prince, M.D. – Immunology (Knoxville)

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

Pentec is establishing relationships to physicians who practice in the field of intrathecal medicine in Tennessee. These are prospective sources of patient referrals for Pentec. Referral of patients previously treated in physicians' offices may affect those practices' utilization to a limited extent. However, Pentec believes that this would be offset by tangible benefits to the health care system as a whole. First, because the services previously provided in the physician's office (or hospital) would be provided in the patient's place of residence, access to the services would be improved. Second, the reimbursable costs associated with refills of patients' intrathecal pumps (i.e., intrathecal medications and the refill procedure) are likely to be lower than the comparable reimbursable costs if the same service were provided by a physician in an office or in a hospital. Third, the number of incidents in which an intrathecal pump patient presents at a hospital emergency department for treatment would be reduced, resulting in savings to the system. Finally, the need for emergency patient transport to an emergency department or other health care facility for treatment would be reduced, resulting in further savings to the system. Because implementation of the proposed services would have the effect of reducing the cost of services provided to intrathecal pump patients residing in Tennessee, financial competition amongst providers would be enhanced.

Although physicians practicing in the field of intrathecal medicine are capable of treating intrathecal pump patients at their practice locations, there are no licensed HHAs in Tennessee with the capability of treating these patients in their homes, on a 24/7 basis, anywhere in Tennessee. Moreover, because of the need for an HHA to provide not only skilled nursing services but also pharmacy services, the specialized training and ongoing evaluation required of nurse providers and the related investment in training, the relationships with specialists in interventional pain and spasticity management for referrals, and the required investment in technology to permit effective statewide, 24/7, in-home service, the barriers to entry by existing traditional HHAs are very high. Even amongst home health care providers that provide specialty infusion services, there are no participants with comparable nurse training programs or technological capabilities. For these reasons, Pentec expects that the proposed services would result in very little duplication of existing or proposed services.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

3. **Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.**

Pentec staffs its primary care nurses at an average ratio of 40 patients to 1 nurse. Pentec has assumed in this proposal that it will be consistent and staff the Tennessee HHA at the same 40:1 ratio. In the proposal, Pentec has assumed that the HHA would initially be staffed by 1.0 FTE. A full-time primary care nurse will earn $77,500 per year. As the Tennessee patient census increases, additional full-time primary care nurses would be hired. In addition, Pentec has a pool of registered nurses who are licensed to practice in Tennessee and available to provide part-time or backup staffing as the need arises.

Additionally, a 1/5 allocation of a Regional Nurse Manager (0.2 FTE) has been included in this proposal at a salary of $90,000. Pentec's Regional Nurse Managers are not responsible for direct patient care, but oversee primary care nurses responsible for direct patient care. The 1/5 allocation of a Regional Nurse Manager in this proposal is consistent with the manner in which Pentec allocates its Regional Nurse Managers in all of the states in which it operates.

Pentec's full-time nursing staff is eligible for medical benefits, personal time off, and 401-k plan, all of which has been included in this proposal together with the necessary employer payroll taxes. Also included in this proposal are the professional development fees associated with nursing staff (i.e., state registered nurse licensure, etc.), as well as information technology expenses (cell phone and internet) and travel reimbursement. Both the primary care nurse salary of $77,500 and the Nurse Manager salary of $90,000 are above (1) the average professional and technical services industry wage in Tennessee ($70,621) and (2) the highest average wage in the healthcare and social assistance industry wage in Tennessee ($58,602), as reported in the 2013 Quarterly Census of Employment and Wages published by the Tennessee Department of Labor & Workforce Development.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.

The proposed HHA would be staffed entirely with registered nurses. As described in its answers to Section B, Project Description, Item II.A and Section C, Economic Feasibility, Item II.1, Pentec would initially staff the HHA with current employees who are already licensed to practice professional nursing in Tennessee. As the Tennessee patient census increases, Pentec would add local hires in order to maintain its target 40:1 patient to nurse ratio. All such future hires would need to satisfy the requirements of Pentec's "Primary Care Nurse" job description, including a registered nurse license from Tennessee or a compact state; and would need to complete Pentec's nurse training and certification program. Because the salary offered to primary care nurses is above average and is supplemented by an attractive benefits package, Pentec does not anticipate any difficulty in identifying and hiring additional nursing staff.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.

1. Staff Licensure

As noted above in the answer to Section C, Contribution to the Orderly Development of Health, Care, Item 4, the proposed HHA would be staffed entirely by registered nurses licensed to practice in Tennessee. Pentec currently employs full-time registered nurses who are licensed to practice in more than 30 states (including Tennessee) and the District of Columbia, so it has reviewed and understands state board of nursing licensure requirements in its national service area. In addition, Pentec employs a national "nurse regulatory manager" who tracks and ensures compliance with these requirements on an ongoing basis.

The proposed HHA would not have a medical staff.

2. Quality Assurance

Pentec has adopted, and continually updates, comprehensive policies and procedures addressing all aspects of management of its home health operations and all aspects of patient care. These include a full set of policies and procedures on quality assurance entitled the "Performance Improvement Plan."

3. Utilization Review

Pentec produces an annual utilization report that can be provided to the Health Services and Development Agency or the Bureau of Health Licensure and Regulation, as appropriate.

4. Record Keeping

All patient medical records are housed in Pentec's secure EMR system, and they are accessible from any location (including Pentec's administrative office in Nashville) with internet service. All personnel records for the proposed HHA would be kept in Pentec's HR Department at its headquarters in Boothwyn, Pennsylvania, although copies would also be maintained at Pentec's office in Nashville. The Nashville office would also house a full set of Pentec's policies and procedures.

5. Staff Education

Pentec has invested heavily in training for its primary care nurses. Although all Pentec nurse providers are licensed as registered nurses, Pentec nurses must also be specially trained to ensure that they have and maintain the skills required to administer patients' medications and monitor operation of the delivery system, which requires a rigorous program of classroom instruction, field training and ongoing proficiency evaluation by practitioners with expertise in treatment of intrathecal pump patients. Pentec's primary care nurse training program is the only such program in the United States certified by the American Nursing Credentialing Center (ANCC).

Following completion of the nurse training and certification program, Pentec nurses remain responsible for maintaining all required proficiencies on an ongoing basis. To accomplish this, Pentec's Lead Regional Nurse visits all nurses in the field at least once a year for purpose of conducting an on-site performance evaluation. Pentec nurses are required to complete an annual evaluation of all applicable standards of performance, and must demonstrate that they are competent to perform all necessary procedures. In addition, all requirements of the state Board of Nursing must be satisfied.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

As discussed in the answer to Section C, Contribution to the Orderly Development of Health, Care, Item 5, Pentec has designed and implemented a rigorous training and certification program, consisting of classroom and field training, for all of its primary care nurses. However, the proposed services will be delivered in patients' homes throughout Tennessee, rather than in a health care facility. For this reason, access by health professional schools to the services for training purposes would not be practical.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

7. a. **Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

Pentec has reviewed and understands the requirements of the Department of Health, Bureau of Health Licensure and Regulation, Division of Health Care Facilities, regarding licensure of HHAs ("Home Health Agency Procedures for Applying for Licensure of a New Facility"). In addition, it has reviewed and become familiar with the "Standards for Homecare Organizations Providing Home Health Services" as codified in Chapter 1200-08-26 of the Rules of the Tennessee Department of Health and the provisions of T.C.A. § 68-11-201 et seq.

b. **Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.**

Licensure: Tennessee Department of Health, Bureau of Licensure and Regulation, Division of Health Care Facilities
Accreditation: The Joint Commission

c. **If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.**

Pentec is presently licensed as a pharmacy in Tennessee (number 4108; expiration date February 28, 2015). A copy of the license certificate is attached as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c.

Pentec is accredited by The Joint Commission under its Home Care Accreditation Program. Pentec's current date of accreditation is June 7, 2014. Copies of Pentec's accreditation certificate and letter are attached at Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c.

d. **For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.**

Not applicable (NA). Pentec is not an existing licensed HHA.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Pentec received a Notice of Citation from the Indiana State Department of Health dated August 22, 2011, alleging a breach of the licensure requirements of Ind. Code § 16-27-1-15 and 410 Ind. Admin. Code § 17-10-1(a) (*In re the Matter of Pentec Health Inc.* at docket number AC-227-11). A copy of the Order is attached as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 8.

Pursuant to the Order in this matter, Pentec paid a civil penalty in the amount of $10,000 to the Department. Pentec also submitted a plan of correction of the deficiencies found in the initial licensure survey that gave rise to the Notice of Citation and Order. Pentec's plan of correction was accepted by the Indiana State Department of Health on October 17, 2011. A copy of the Department's letter accepting the plan of correction is attached as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 8.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

Not applicable (NA). There have been no such judgments for fraud or theft against any person or entity with more than a 5% ownership interest in Pentec Health, Inc.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Pentec produces an annual utilization report, including the number of patients treated, patient age and sex, patient location by Zip Code, type of treatment, and other relevant data, that can be provided to the Health Services and Development Agency or the Bureau of Health Licensure and Regulation, as appropriate.

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PROOF OF PUBLICATION

Pentec published a "Notification of Intent to Apply for a Certificate of Need" in 15 Tennessee newspapers of general circulation between November 9 and 11, 2014 (depending on the newspapers' dates of publication), as follows:

	City	Newspaper	Date
1.	Bristol	Bristol Herald Courier	November 10, 2014
2.	Chattanooga	Chattanooga Times Free Press	November 10, 2014
3.	Clarksville	The Leaf-Chronicle	November 10, 2014
4.	Cookeville	Herald-Citizen	November 10, 2014
5.	Dyersburg	State Gazette	November 11, 2014[2]
6.	Greeneville	Greeneville Sun	November 10, 2014
7.	Jackson	The Jackson Sun	November 10, 2014
8.	Johnson City	Johnson City Press	November 10, 2014
9.	Kingsport	The Kingsport Times-News	November 10, 2014
10.	Knoxville	Knoxville News Sentinel	November 9, 2014
11.	Memphis	The Commercial Appeal	November 10, 2014
12.	Murfreesboro	The Daily News Journal	November 10, 2014
13.	Nashville	The Tennessean	November 10, 2014
14.	Paris	The Paris Post-Intelligencer	November 10, 2014
15.	Union City	Union City Daily Messenger	November 10, 2014

A copy of the Notification is attached. In addition, copies of the newspaper pages containing the Notification are also attached.

[2] Publication was scheduled for November 10, 2014, but the notice was omitted form that edition due to a newspaper error. The notice was printed in the November 11, 2014, edition instead.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. § 68-11-1609(c): _____

Assuming the CON approval becomes the final agency action on that date; indicate the number of days **from the above agency decision date** to each phase of the completion forecast.

Phase	DAYS REQUIRED	Anticipated Date (MONTH/YEAR)
1. Architectural and engineering contract signed		
2. Construction documents approved by the Tennessee Department of Health		
3. Construction contract signed		
4. Building permit secured		
5. Site preparation completed		
6. Building construction commenced		
7. Construction 40% complete		
8. Construction 80% complete		
9. Construction 100% complete (approved for occupancy		
10. *Issuance of license	60	April 1, 2015
11. *Initiation of service	15	April 15, 2015
12. Final Architectural Certification of Payment		
13. Final Project Report Form (HF0055)		

For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

Commonwealth of Pennsylvania

Department of State

CERTIFICATE OF INCORPORATION

Office of the Secretary of the Commonwealth

To All to Whom These Presents Shall Come, Greeting:

Whereas, *Under the provisions of the Laws of the Commonwealth, the Secretary of the Commonwealth is authorized and required to issue a "Certificate of Incorporation" evidencing the incorporation of an entity.*

Whereas, *The stipulations and conditions of the Law have been fully complied with by*

DELAWARE VALLEY HOME CARE CORP.

Therefore, Know Ye, *That subject to the Constitution of this Commonwealth, and under the authority of the Laws thereof, I do by these presents, which I have caused to be sealed with the Great Seal of the Commonwealth, declare and certify the creation, erection and incorporation of the above in deed and in law by the name chosen hereinbefore specified.*

Such corporation shall have and enjoy and shall be subject to all the powers, duties, requirements, and restrictions, specified and enjoined in and by the applicable laws of this Commonwealth.

Given *under my Hand and the Great Seal of the Commonwealth, at the City of Harrisburg, this* 28th *day of* April *in the year of our Lord one thousand nine hundred and* eighty-three *and of the Commonwealth the two hundred* seventh

William R. Davis

Secretary of the Commonwealth

0770579

WRITTEN CONSENT OF THE SOLE DIRECTOR OF

PENTECH INFUSIONS, INC.

The sole director of Pentech Infusions, Inc., a Pennsylvania corporation (the "Corporation"), in lieu of a meeting of the Board of Directors, pursuant to Section 1727(b) of the Pennsylvania Business Corporation Law of 1988, as amended, hereby consents to and adopts the following resolutions with the full force and effect as if they had been duly adopted at a meeting held pursuant to notice:

AMENDMENT TO ARTICLES OF INCORPORATION

WHEREAS, Section 1914(c) of the Pennsylvania Business Corporation Law of 1988, as amended, permits the board of directors of a corporation to amend the Corporation's Articles of Incorporation to effect a change in the Corporation's name;

WHEREAS, the sole director has determined that a change in the Corporation's name is in the best interest of the Corporation.

NOW, THEREFORE, BE IT

RESOLVED: That the name of the Corporation be changed from Pentech Infusions, Inc. to Pentec Health, Inc.

RESOLVED: That the Articles of Incorporation of the Corporation be amended such that the Articles of Amendment of the Articles of Incorporation (the "Amendment") shall read in the form of Exhibit A attached hereto; that such Amendment is hereby declared to be advisable and in the best interests of the Corporation.

RESOLVED: That the sole director of the Corporation be, and hereby is, authorized and directed to do or cause to be done any and all such other acts and things and to execute and deliver any and all such further documents as he may deem necessary or appropriate to carry into effect the full intent and purpose of the foregoing resolutions, the taking of any such actions or the execution or delivery of any such documents by the sole director to be conclusive evidence that the same were authorized by this resolution.

The undersigned has executed this Written Consent of Sole Director as of the 19th day of September, 2006.

Richard Lester, Sole Director

STATE OF TENNESSEE
Tre Hargett, Secretary of State
Division of Business Services
William R. Snodgrass Tower
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

SAUL EWING LLP
MARONETTA F MILLER
FL 7
2 N 2ND ST
HARRISBURG, PA 17101-1619

Request Type: Certified Copies
Request #: 143735

Issuance Date: 10/30/2014
Copies Requested: 1

Document Receipt

Receipt # : 1685421	Filing Fee:	$20.00
Payment-Check/MO - SAUL EWING LLP, HARRISBURG, PA		$20.00

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that **Pentec Health, Inc.**, Control # 644762 was formed or qualified to do business in the State of Tennessee on 11/18/2010. Pentec Health, Inc. has a home jurisdiction of PENNSYLVANIA and is currently in an Active status. The attached documents are true and correct copies and were filed in this office on the date(s) indicated below.

Tre Hargett
Secretary of State

Processed By: Sheila Keeling

The attached document(s) was/were filed in this office on the date(s) indicated below:

Reference #	Date Filed	Filing Description
6794-2049	11/18/2010	Initial Filing
6842-1698	03/04/2011	Registered Agent Change (by Entity)
A0102-2539	02/01/2012	2011 Annual Report (Due 04/01/2012)

ATTACHMENT

SECTION A, APPLICANT PROFILE, ITEM 4

1. Ownership of Applicant.
2. Statement re: Financial Interests in Health Care Institutions.
3. Ownership / Organizational Chart.

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1. Ownership of Applicant

A. Pentec Health, Inc. (Applicant) is owned by the following:

Name	Address	County	Telephone No.	Equity Interest
Pentech Holdings, Inc.	4 Creek Parkway Boothwyn, PA 19061	Delaware	800-223-4376	100.0%

B. Pentech Holdings, Inc. is owned by the following:

Name	Address	County	Telephone No.	Equity Interest
Pentec Healthcare Infusions, Inc.	4 Creek Parkway Boothwyn, PA 19061	Delaware	800-223-4376	100.0%

C. Pentec Healthcare Infusions, Inc. is owned by the following (5% interest or greater):

Name	Address	County	Telephone No.	Equity Interest
Norwest Equity Partners IX, LP	80 South 8th Street Suite 3600 Minneapolis, MN 55402	Hennepin	612-215-1600	69.06%
Norwest Mezzanine Partners III, LP	80 South 8th Street Suite 3600 Minneapolis, MN 55402	Hennepin	612-215-1600	5.06%
DW Healthcare Partners, LP	1413 Center Drive Suite 220 Park City, UT 84098	Summit	435-645-4050	10.12%
Frazier Healthcare V, L.P.	601 Union Square Suite 3200 Seattle, WA 98101	King	202-621-7200	10.12%
All other shareholders (aggregate)				5.64%
Total				**100.00%**

2. Financial Interests in Health Care Institutions

Neither Pentec Health, Inc. nor its owner, Pentech Holdings, Inc., has any financial or ownership interest in a Health Care Institution as defined in T.C.A. § 68-11-1602(7).

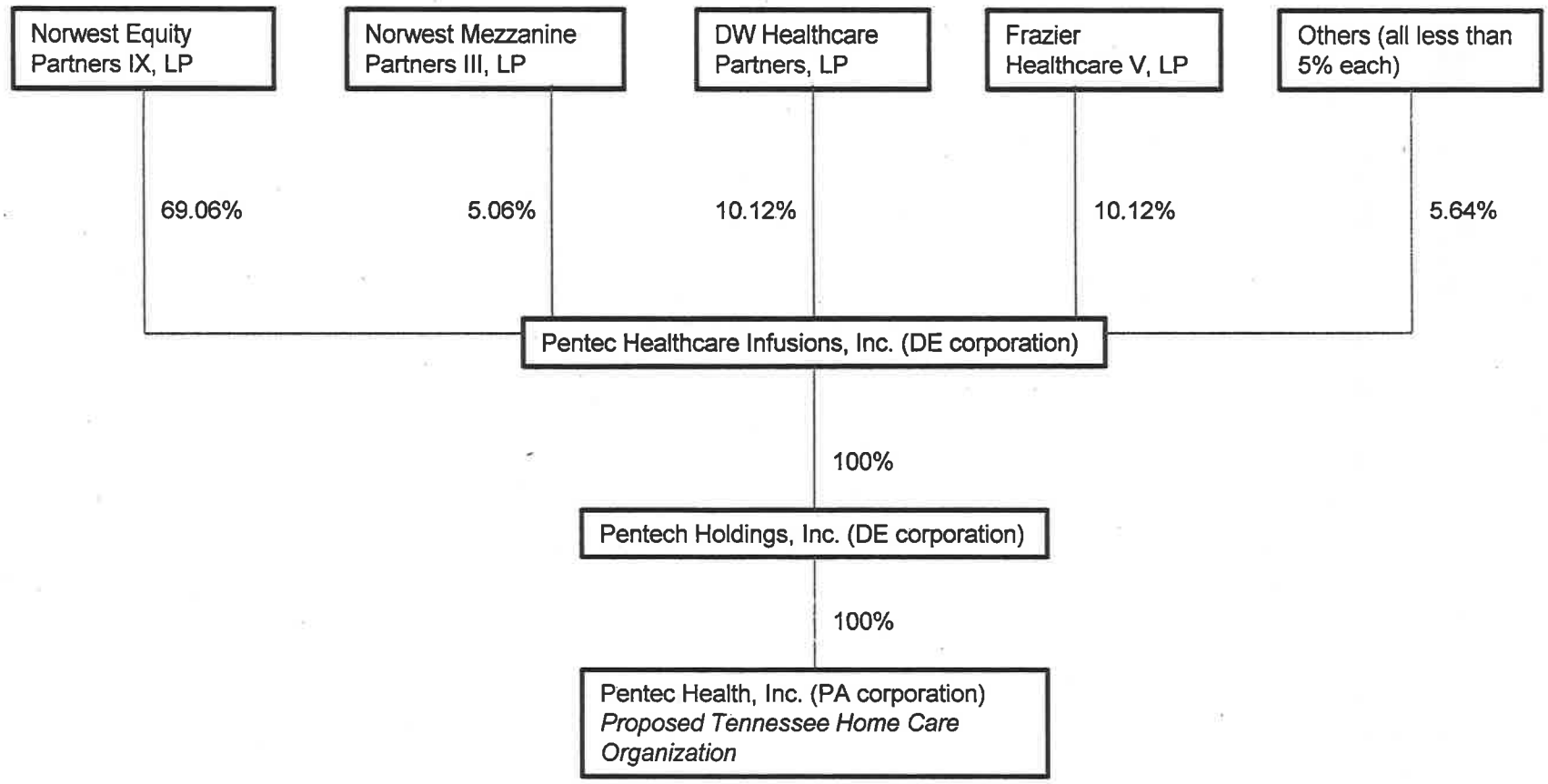
3. Ownership / Organizational Chart

An ownership / organizational chart is attached on the following page.

Pentec Health, Inc.

Organizational / Ownership Structure

As of June 30, 2014



Ownership interests in Pentech Healthcare Infusions, Inc. indicated above are fully diluted; includes vested options only

ATTACHMENT

SECTION B, PROJECT DESCRIPTION, ITEM III(A)

Site plan – Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219.

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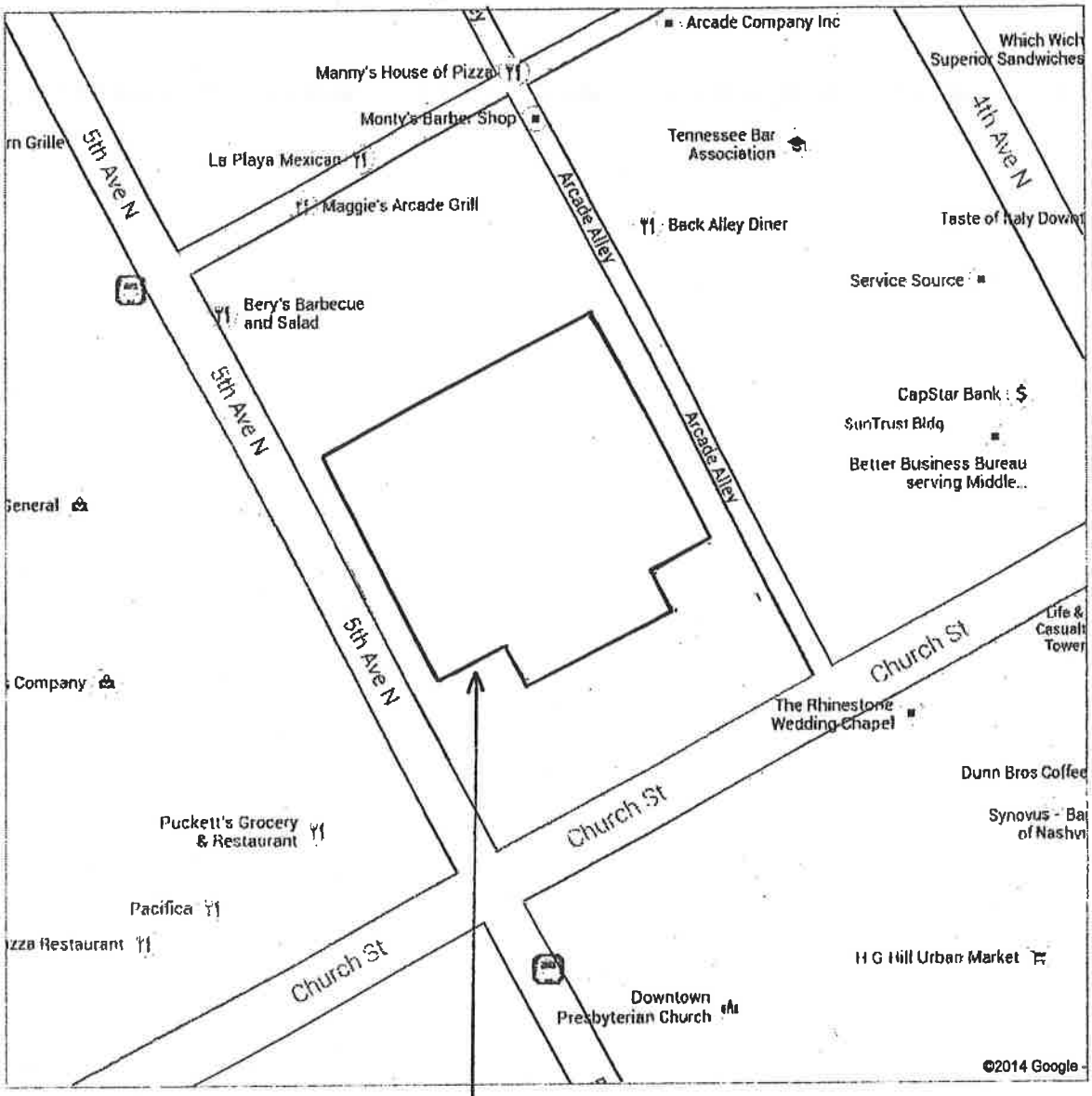
[redacted]

Address **424 Church St**
Nashville, TN 37219



FIFTH THIRD CENTER

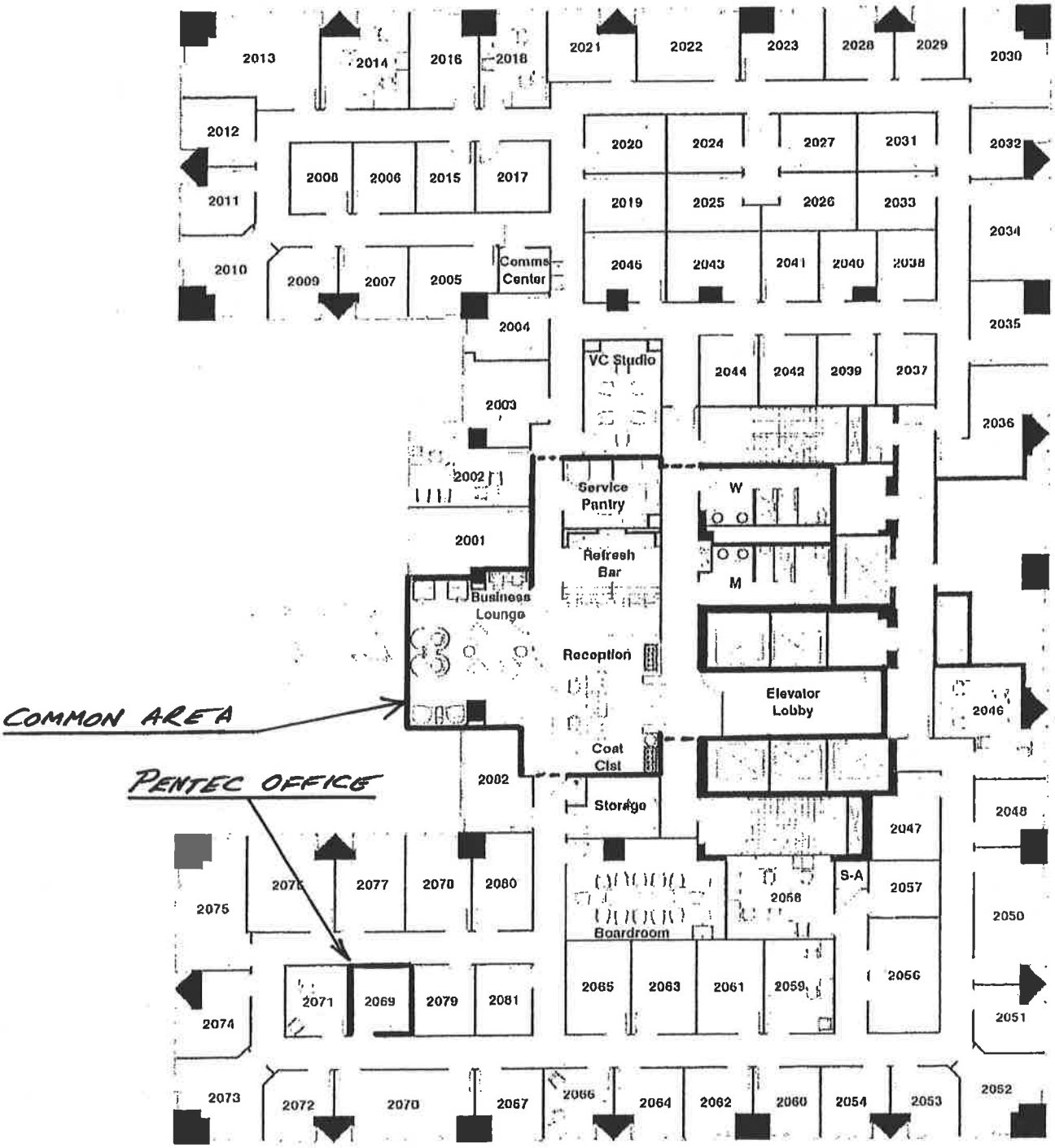
ATTACHMENT

SECTION B, PROJECT DESCRIPTION, ITEM IV

Floor plan – Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219.

Fifth Third Center

424 Church Street
Suite 2000
Nashville, TN 37219
P: 615.651.7300
F: 615.651.7301



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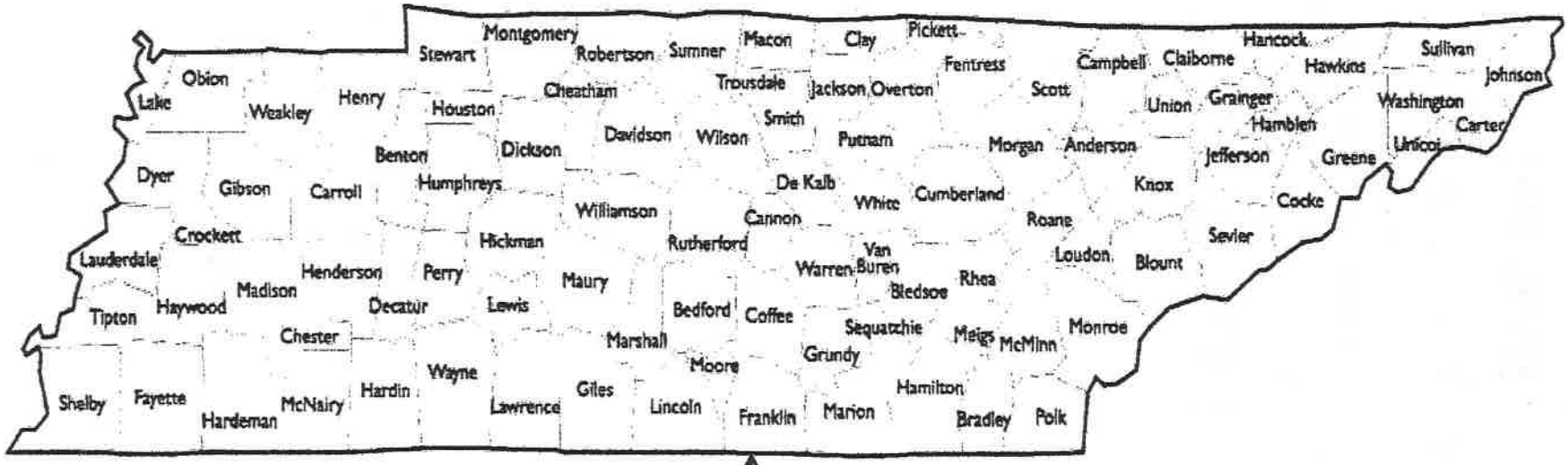
ATTACHMENT

SECTION C, NEED, ITEM 3

Map of the Proposed Service Area.

TENNESSEE COUNTY MAP



PROPOSED SERVICE AREA
ALL 95 COUNTIES IN TENNESSEE

ATTACHMENT

SECTION C, NEED, ITEM 6

1. Utilization and revenue data for Pentec Health, Inc. as a whole for the fiscal years ended December 31, 2011, 2012 and 2013; and projected utilization and revenue for the proposed Tennessee HHA for years 2015 and 2016.

2. Supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

TOTAL COMPANY	2011				2012				2013			
	Capacity	Actual Utilization	Revenue	Avg Charge Per Unit	Capacity	Actual Utilization	Revenue	Avg Charge Per Unit	Capacity	Actual Utilization	Revenue	Avg Charge Per Unit
Per Diem	228,659	100%	13,937,317	$ 60.95	308,513	100%	18,563,320	$ 60.17	360,117	100%	20,962,099	$ 58.21
Drugs	7,021	100%	4,459,033	$ 635.10	9,802	100%	5,279,747	$ 538.64	13,227	100%	7,779,988	$ 588.19
Nursing	5,067	100%	451,612	$ 89.13	6,354	100%	585,109	$ 92.09	10,535	100%	746,571	$ 70.87
Supplies	1,602	100%	77,537	$ 48.40	3,188	100%	112,774	$ 35.37	5,242	100%	191,475	$ 36.53
Renal	14,764	100%	42,462,541	$ 2,876.09	24,683	100%	52,608,800	$ 2,131.37	24,948	100%	43,025,968	$ 1,724.61
Other	N/A	N/A	540,913	N/A	N/A	N/A	-252,004	N/A	N/A	N/A	3,507,865	N/A
Total Institution Revenue				$ 61,928,953				$ 76,897,746				$ 76,213,967

TN ONLY	Year 1				Year 2				
	Capacity	Actual Utilization	Revenue	Avg Charge Per Unit	Capacity	Actual Utilization	Revenue	Avg Charge Per Unit	
Per Diem	3,796	100%	220,940	$ 58.21	10,573	100%	615,467	$ 58.21	
Drugs	128	100%	75,441	$ 588.19	366	100%	215,101	$ 588.19	
Nursing	94	100%	6,688	$ 70.87	269	100%	19,070	$ 70.87	
Supplies	41	100%	1,503	$ 36.53	117	100%	4,285	$ 36.53	
Other	N/A	N/A	0	N/A	N/A	N/A	0	N/A	
Total			$ 304,573				$ 853,923		$ 33,287,995
Total TN Revenue				$ 304,573				$ 853,923	

Footnotes: TN Only Year 1 and Year 2 modeled after capacity usage in a state entered two years ago with an implanted pump count similar to TN.
Pentec experienced reimbursement rate declines on its Renal offering in mid-2012. These rate declines did not impact the specialty infusion rates associated with the services that Pentec is proposing for TN.

TN - Years 1-2 Census, Revenues and Proft

Year 1

	Total Census	3rd Party Census	3rd Party Per Diem Revenue	3rd Party Nursing Revenue	3rd Party Drug Revenue	3rd Party Supply Revenue	3rd Party Total Revenue	Medicare/Medicaid Census	Medicare/Medicaid Per Diem Revenue	Medicare/Medicaid Nursing Revenue	Medicare/Medicaid Drug Revenue	Medicare/Medicaid Supply Revenue	Medicare/Medicaid Total Revenue	Total Revenue
Month 1	5	3	$5,239	$83	$935	$19	$6,276	2	$45	$55	$623	$12	$737	$7,012
Month 2	5	3	$5,239	$83	$935	$19	$6,276	2	$45	$55	$623	$12	$737	$7,012
Month 3	8	4	$6,985	$111	$1,247	$25	$8,367	4	$91	$111	$1,247	$25	$1,473	$9,841
Month 4	8	4	$6,985	$111	$1,247	$25	$8,367	4	$91	$111	$1,247	$25	$1,473	$9,841
Month 5	13	7	$12,224	$193	$2,182	$43	$14,643	6	$136	$166	$1,870	$37	$2,210	$16,853
Month 6	19	10	$17,463	$276	$3,117	$62	$20,919	9	$204	$249	$2,806	$56	$3,315	$24,233
Month 7	23	12	$20,955	$332	$3,741	$75	$25,102	11	$250	$304	$3,429	$68	$4,051	$29,154
Month 8	26	13	$22,702	$359	$4,053	$81	$27,194	13	$295	$359	$4,053	$81	$4,788	$31,982
Month 9	27	14	$24,448	$387	$4,364	$87	$29,286	13	$295	$359	$4,053	$81	$4,788	$34,074
Month 10	31	16	$27,940	$442	$4,988	$99	$33,470	15	$341	$415	$4,676	$93	$5,524	$38,994
Month 11	38	19	$33,179	$525	$5,923	$118	$39,745	19	$431	$525	$5,923	$118	$6,998	$46,743
Month 12	39	20	$34,925	$553	$6,235	$124	$41,837	19	$431	$525	$5,923	$118	$6,998	$48,835
Totals			$218,284	$3,455	$38,968	$776	$261,483		$2,656	$3,234	$36,474	$727	$43,090	$304,573

-77,500	Allocation of RN - salary (1 FTE)
-7,440	Allocation of RN - payroll tax
-11,625	Allocation of RN - other benefits
-18,000	Allocation of RM - salary
-1,728	Allocation of RM - payroll tax
-2,700	Allocation of RM - other benefits
-91,234	COGS
-19,797	Bad Debt
-18,884	Selling expenses
-8,028	Lease expense
-45,686	G&A
1,951	EBT
-702	Taxes
1,249	Net Income

Year 2

	Total Census	3rd Party Census	3rd Party Per Diem Revenue	3rd Party Nursing Revenue	3rd Party Drug Revenue	3rd Party Supply Revenue	3rd Party Total Revenue	Medicare/Medicaid Census	Medicare/Medicaid Per Diem Revenue	Medicare/Medicaid Nursing Revenue	Medicare/Medicaid Drug Revenue	Medicare/Medicaid Supply Revenue	Medicare/Medicaid Total Revenue	Total Revenue
Month 1	41	21	$36,672	$580	$6,547	$130	$43,929	20	$454	$553	$6,235	$124	$7,366	$51,295
Month 2	45	23	$40,164	$636	$7,170	$143	$48,113	22	$499	$608	$6,858	$137	$8,102	$56,215
Month 3	46	23	$40,164	$636	$7,170	$143	$48,113	23	$522	$636	$7,170	$143	$8,471	$56,583
Month 4	58	29	$50,642	$801	$9,040	$180	$60,664	29	$658	$801	$9,040	$180	$10,680	$71,344
Month 5	62	31	$54,134	$857	$9,664	$192	$64,848	31	$704	$857	$9,664	$192	$11,417	$76,265
Month 6	62	31	$54,134	$857	$9,664	$192	$64,848	31	$704	$857	$9,664	$192	$11,417	$76,265
Month 7	62	31	$54,134	$857	$9,664	$192	$64,848	31	$704	$857	$9,664	$192	$11,417	$76,265
Month 8	62	31	$54,134	$857	$9,664	$192	$64,848	31	$704	$857	$9,664	$192	$11,417	$76,265
Month 9	63	32	$55,881	$884	$9,976	$199	$66,940	31	$704	$857	$9,664	$192	$11,417	$78,357
Month 10	63	32	$55,881	$884	$9,976	$199	$66,940	31	$704	$857	$9,664	$192	$11,417	$78,357
Month 11	63	32	$55,881	$884	$9,976	$199	$66,940	31	$704	$857	$9,664	$192	$11,417	$78,357
Month 12	63	32	$55,881	$884	$9,976	$199	$66,940	31	$704	$857	$9,664	$192	$11,417	$78,357
Totals			$607,703	$9,618	$108,486	$2,161	$727,968		$7,764	$9,452	$106,615	$2,124	$125,955	$853,923

-111,406	Allocation of RN - salary (1.4 FTE)
-10,695	Allocation of RN - payroll tax
-16,711	Allocation of RN - other benefits
-18,000	Allocation of RM - salary
-1,728	Allocation of RM - payroll tax
-2,700	Allocation of RM - other benefits
-260,130	COGS
-55,505	Bad Debt
-52,943	Selling expenses
-8,028	Lease expense
-128,088	G&A
187,988	EBT
-67,676	Taxes
120,312	Net Income

ATTACHMENT

SECTION C, ECONOMIC FEASIBILITY, ITEM 2

Audited financial statements of Pentech Healthcare Infusions, Inc. and subsidiaries (including the principal operating company, Pentec Health, Inc.) as of December 31, 2013.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

~~Year Ended December 31, 2013 and for the Period~~
From June 1, 2012 (Inception) Through December 31, 2012

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

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Statements of Operations	4
Statements of Changes in Stockholders' Equity	5
Statements of Cash Flows	6 - 7
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Mayer Hoffman McCann P.C.
An Independent CPA Firm

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Plymouth Meeting, Pennsylvania 19462
610 862-2200 ph
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INDEPENDENT AUDITORS' REPORT

To the Board of Directors of

Pentec Healthcare Infusions, Inc.

We have audited the accompanying consolidated financial statements of Pentec Healthcare Infusions, Inc. & Subsidiaries, which comprise the consolidated balance sheets as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, and the related notes to financial statements.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Member of Kreston International - a global network of independent accounting firms

Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pentec Healthcare Infusions, Inc. & Subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for the year ended December 31, 2013 and the period from June 1, 2012 (inception) through December 31, 2012, in accordance with accounting principles generally accepted in the United States of America.

Mayer Hoffman McCann P.C.

Plymouth Meeting, Pennsylvania
June 26, 2014

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2013 and 2012

ASSETS

	2013	2012
CURRENT ASSETS		
Cash	$ 3,867,673	$ 5,313,945
Accounts receivable, net of allowance for losses (2013 - $1,576,499; 2012 - $1,832,833)	12,350,668	9,906,726
Inventories	1,611,314	1,127,077
Prepaid expenses and other current assets	524,875	1,100,873
Prepaid income taxes	272,871	537,932
Deferred tax asset	2,158,435	1,419,904
TOTAL CURRENT ASSETS	20,785,836	19,406,457
PROPERTY AND EQUIPMENT, at cost, net of accumulated depreciation and amortization	2,463,693	2,913,950
OTHER ASSETS		
Goodwill	74,033,677	74,033,677
Tradenames	2,700,000	2,700,000
Amortizable intangibles, net	105,119,491	113,237,271
Deferred financing costs, net	2,343,969	2,833,155
Deposits and other long-term assets	164,434	66,792
TOTAL OTHER ASSETS	184,361,571	192,870,895
TOTAL ASSETS	$ 207,611,100	$ 215,191,302

LIABILITIES

	2013	2012
CURRENT LIABILITIES		
Current portion of long-term debt	$ 4,535,923	$ 7,089,000
Current portion of capital leases	85,460	217,836
Accounts payable	2,349,710	2,076,636
Accrued payroll and related liabilities	4,624,469	1,621,612
Credits due payors	2,255,578	989,390
Other accrued expenses	1,711,553	863,882
TOTAL CURRENT LIABILITIES	15,562,693	12,858,356
LONG-TERM LIABILITIES		
Long-term debt, less current portion above	97,214,213	103,678,430
Capital leases, less current portion above	-	87,946
Deferred tax liabilities	40,892,350	42,989,669
Deferred rent	5,960	28,386
TOTAL LONG-TERM LIABILITIES	138,112,523	146,784,431
TOTAL LIABILITIES	153,675,216	159,642,787

STOCKHOLDERS' EQUITY

CAPITAL CONTRIBUTED		
Preferred stock, $.001 par value; 1,100,000 shares authorized, 987,855 shares issued and outstanding	988	988
Common stock, $.001 par value; 2,750,000 shares authorized, no shares issued or outstanding	-	-
Additional paid-in capital	98,787,487	98,785,555
TOTAL CAPITAL CONTRIBUTED	98,788,475	98,786,543
ACCUMULATED DEFICIT	(44,852,591)	(43,238,028)
TOTAL STOCKHOLDERS' EQUITY	53,935,884	55,548,515
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 207,611,100	$ 215,191,302

See Notes to Financial Statements

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PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Year ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

	2013	2012
NET PATIENT SERVICES OPERATING REVENUE	$ 76,213,967	$ 43,213,481
COST OF PATIENT SERVICES	29,824,278	17,450,879
GROSS MARGIN	46,389,689	25,762,602
OPERATING EXPENSES		
Sales and marketing	8,508,141	5,542,946
General and administrative (2012 includes approximately $1,717,000 of acquisition costs)	16,951,619	10,193,710
Depreciation and amortization	1,675,617	1,008,862
Amortization, intangibles	8,325,471	4,848,036
Provision for bad debts	3,046,089	2,809,716
Impairment of goodwill and tradenames	-	46,482,000
Stock-based compensation	1,932	1,043
TOTAL OPERATING EXPENSES	38,508,869	70,886,313
OPERATING INCOME (LOSS)	7,880,820	(45,123,711)
OTHER INCOME (EXPENSES)		
Loss on disposal of property and equipment	(14,055)	(11,462)
Interest income	24,226	13,272
Interest expense	(10,409,291)	(6,115,314)
NET OTHER INCOME (EXPENSES)	(10,399,120)	(6,113,504)
LOSS BEFORE INCOME TAX BENEFIT	(2,518,300)	(51,237,215)
INCOME TAX BENEFIT	(903,737)	(7,999,187)
NET LOSS	$ (1,614,563)	$ (43,238,028)

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Issuance of stock, June 1, 2012 (Inception)	987,855	$ 988	-	$ -	$ 98,784,512	$ -	$ 98,785,500
Stock-based compensation	-	-	-	-	1,043	-	1,043
Net loss	-	-	-	-	-	(43,238,028)	(43,238,028)
Balances, December 31, 2012	987,855	988	-	-	98,785,555	(43,238,028)	55,548,515
Stock-based compensation	-	-	-	-	1,932	-	1,932
Net loss	-	-	-	-	-	(1,614,563)	(1,614,563)
Balances, December 31, 2013	987,855	$ 988	-	$ -	$ 98,787,487	$ (44,852,591)	$ 53,935,884

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (1,614,563)	$ (43,238,028)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation and amortization	10,001,088	5,856,898
Amortization of deferred financing costs	569,186	277,795
Deferred rent	(22,426)	(52,685)
Loss on disposal of property and equipment	14,055	11,462
Stock-based compensation	1,932	1,043
Unrealized loss on interest rate cap	18,361	80,655
Deferred income taxes	(2,835,850)	(7,873,909)
Provision for bad debts	3,046,089	2,809,716
Accrued interest on subordinated long-term debt	2,868,003	2,717,430
Loss on impairment of goodwill and tradenames	-	46,482,000
Decrease (increase) in operating assets		
Accounts receivable, net	(5,490,031)	(3,229,444)
Inventories	(484,237)	261,514
Prepaid expenses and other current assets	557,637	(241,458)
Prepaid income taxes	265,061	(831,064)
Increase (decrease) in operating liabilities		
Accounts payable	273,074	(226)
Accrued payroll and related liabilities	3,002,857	(144,393)
Credits due payors	1,266,188	124,121
Other accrued expenses	847,671	(252,133)
NET CASH FLOWS FROM OPERATING ACTIVITIES	12,284,095	2,759,294
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(1,241,671)	(645,178)
Proceeds from sale of property and equipment	2,256	-
Purchase of business, net of cash	-	(202,833,547)
Cash paid for amortizable intangibles	(207,691)	(285,307)
Deposits and other long-term assets	(97,642)	(4,652)
NET CASH FLOWS FROM INVESTING ACTIVITIES	(1,544,748)	(203,768,684)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from long-term debt	-	110,000,000
Repayment of long-term debt	(11,885,297)	(1,950,000)
Repayments under capital leases	(220,322)	(130,540)
Payment of deferred financing costs	(80,000)	(253,625)
Purchase of interest rate cap	-	(128,000)
Proceeds from issuance of preferred stock	-	98,785,500
NET CASH FLOWS FROM FINANCING ACTIVITIES	(12,185,619)	206,323,335
NET INCREASE (DECREASE) IN CASH	(1,446,272)	5,313,945
CASH, BEGINNING OF PERIOD	5,313,945	-
CASH, END OF PERIOD	$ 3,867,673	$ 5,313,945

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

	2013	2012
Cash paid:		
Interest	$ 6,921,553	$ 3,018,099
Income taxes	$ 2,144,130	$ 985,716

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies

Basis of presentation - The accompanying consolidated financial statements include the accounts of Pentec Healthcare Infusions, Inc. ("Infusions") and its wholly-owned subsidiary Pentech Holdings, Inc. ("Holdings") and its wholly-owned subsidiaries, Pentec Health, Inc. ("Health"), Delaware Valley Home Care, Inc. ("DVHC"), and Pentech Home Health, Inc. ("PHH") (collectively, the "Company" or "Pentec Health"), which were acquired on June 1, 2012 (see Note 2). All significant transactions between the companies have been eliminated in consolidation.

Nature of business - Health, which started operations approximately thirty years ago, is a national, privately held, specialty infusion services company focused on providing complex pharmaceutical products and clinical services to nonhospitalized patients via cost effective methods. The Company is headquartered in Boothwyn, Pennsylvania. The Company has focused on therapies for patients suffering from chronic renal failure, chronic pain management and spasticity. The Company is reimbursed for its services by private insurance companies, Medicare under Part B and Part D, and various state Medicaid programs.

Use of estimates - The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and concentration of credit risk - The Company maintains its cash at one bank which, at times, may exceed the federally insured limit.

Revenue and cost recognition - Revenue is reported at the estimated net realized amounts from third-party payors and others for pharmaceutical products and services provided to patients. These services primarily involve the distribution of specialty drugs to patients' homes or dialysis centers. Revenue is billed based upon the Company's usual and customary charges for the products and services provided, with reimbursement often indexed to Average Wholesale Price. Revenue is recognized upon confirmation of delivery of the products to the patient.

The amount of revenue recorded is based on the volume of pharmaceutical products and services provided during a given period and is based on contractual terms for the patients under healthcare plans for which there are formal agreements, historical collection experience, historical trends of refunds and payor payment adjustments, and regulatory compliance issues.

Revenue recognition uncertainties inherent in the healthcare industry are addressed in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 954-605, "Revenue Recognition for Health Care Entities." As specified in the guidance, net revenue recognition and allowances for uncollectible billings require the use of estimates of the amounts that will ultimately be realized considering, among other items, the retroactive adjustments that may be associated with regulatory reviews, audits, billing reviews and other matters. Estimates for future audits and adjustments, which may be based on differences in the interpretation of healthcare contracts, are recorded currently as a reduction of revenue and reflected as an accrued liability.

If in a subsequent period it is determined that the original estimate of revenue was incorrect, revenue would be adjusted in that subsequent period. Infusions' adjustments have historically not been material to results of operations or financial position.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Revenue and cost recognition (continued) - Cost of patient services include all pharmaceutical costs and supplies, direct labor, subcontracting, equipment costs, as well as indirect costs related to providing medical goods to patients such as shipping and handling costs, ancillary supplies, and repair and maintenance costs of delivery vehicles.

Accounts receivable and allowance for losses - Accounts receivable are reported net of contractual adjustments and allowance for losses. The majority of the Company's accounts receivable is due from private insurance carriers and government healthcare programs such as Medicare or Medicaid.

The Company records an allowance for losses in each period based on several factors, including past accounts receivable collection history and the balance and aging composition of accounts receivable.

Inventories - Inventories, consisting of pharmaceuticals and medical supplies, are stated at the lower of cost (first-in, first-out method) or market.

Property and equipment - All property and equipment are stated at cost. Depreciation and amortization are computed on the straight-line method over the following estimated useful lives:

Assets	Estimated Useful Lives
Furniture and office equipment	7 Years
Medical equipment	3 - 10 Years
Medical equipment under capital lease	Life of Lease
Computer software and equipment	3 Years
Vehicles	5 Years
Leasehold improvements	Life of Lease

Upon retirement or disposal of property and equipment, the costs and accumulated depreciation or amortization are removed from the accounts, and any gain or loss is reflected in operations. Expenditures for maintenance and repairs are charged to operations when incurred.

Impairment of long-lived assets - In accordance with FASB ASC 360, "Accounting for the Impairment or Disposal of Long-Lived Assets," when events or circumstances warrant a review, the Company will assess recoverability of its long-lived assets from future operations using pre-tax undiscounted cash flows derived from the lowest asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the long-lived asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows. As of December 31, 2013 and 2012, management believes that the carrying value of these assets has not been impaired.

Goodwill and intangible assets - Goodwill represents the difference between the purchase cost of an acquired business and the fair market value of the identifiable tangible and intangible net assets acquired. In accordance with FASB ASC 350-20, goodwill and tradenames that have an indefinite life are not amortized but are reviewed for impairment annually or more frequently if certain indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Goodwill and intangible assets (continued) - FASB ASC 350 requires a two-step process be performed to analyze whether or not goodwill has been impaired. Step one requires that the fair value of the reporting unit be compared to its carrying value. If the fair value of the reporting unit is higher than its carrying value, no impairment is indicated and there is no need to perform the second step of the process. If the fair value of the reporting unit is lower than its carrying value, step two must be evaluated. Step two requires that a hypothetical purchase price allocation analysis be done to reflect the implied fair value of goodwill. This implied fair value is then compared to the carrying value of goodwill. If the fair value is lower than the carrying value, impairment must be recorded (see Note 3).

The fair value measurements employed by the Company's impairment evaluations were generally based on a discounted cash flow approach and review of market data, which falls within Level 3 of the fair value hierarchy.

Amortizable intangible assets represent, primarily, customer relationships, proprietary technology, covenants not-to-compete, and internally developed software, which have determinate useful lives. Customer relationships, proprietary technology, covenants not-to-compete, and internally developed software are amortized over the expected life of the assets or term of the agreement, as indicated below, using the straight-line method. Amortization expense was $8,325,471 and $4,848,036 for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively.

Costs incurred in connection with developing a patent for a nutritional product called Proplete ® have been capitalized and are amortized over the estimated life of the patent, using the straight-line method. The following is a summary of amortizable intangible assets, net of accumulated amortization, as of December 31, 2013 and 2012:

	Expected Life or Term (Years)	2013	2012
Cost			
Customer relationships	13 - 40	$ 79,500,000	$ 79,500,000
Covenant not-to-compete agreements	3 - 5	4,200,000	4,200,000
Proprietary technology	20	32,600,000	32,600,000
Internally developed software	3	1,500,000	1,500,000
Patents	17	492,998	285,307
Total cost		118,292,998	118,085,307
Accumulated amortization		13,173,507	4,848,036
Amortizable intangibles, net		$ 105,119,491	$ 113,237,271

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PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Goodwill and intangible assets (continued) - Annual amortization of customer relationships, covenant not-to-compete agreements, proprietary technology, internally developed software, and patents for each of the next five years is as follows:

Years Ending December 31,		
2014	$	8,332,205
2015	$	8,040,538
2016	$	6,959,982
2017	$	6,725,538
2018	$	6,725,538
Thereafter	$	68,335,690

Deferred financing costs - Costs incurred to secure the Company's long-term debt are being amortized on the straight-line method over the term of the related debt, six years. Accumulated amortization as of December 31, 2013 and 2012 was $846,981 and $277,795, respectively. Amortization expense for the year ended December 31, 2013 and for the period from June 1, 2012 (Inception) through December 31, 2012, was $569,186 and $277,795 respectively, and is included in interest expense. Annual amortization of deferred financing costs for each of the next five years is as follows:

Years Ending December 31,		
2014	$	556,496
2015	$	523,163
2016	$	523,163
2017	$	523,163
2018	$	217,984

Stock-based compensation plan - The Company is required to recognize compensation expense for options granted over the vesting period of the option commencing with the date the option is granted. The Company accounts for stock option awards using the fair market value method.

Income taxes - The Company is required to recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized in its consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Accounting for derivative instruments and hedging activities - The Company accounts for its derivative instruments and hedging activities under FASB ASC 815. FASB ASC 815 requires the Company to measure every derivative instrument (including certain derivative instruments embedded in other contracts) at fair value and record them in the consolidated balance sheets as either an asset or liability.

As part of the credit agreement the Company entered into on June 1, 2012, the Company was required to obtain an interest rate cap. The changes in fair value of the interest rate cap are recorded in earnings.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Accounting for uncertain tax positions - The Company accounts for the effect of any uncertain tax positions based on a "more likely than not" threshold applied to the recognition of the tax positions being sustained based on the technical merits of the position under scrutiny by the applicable taxing authority. If a tax position or positions are deemed to result in uncertainties of those positions, the unrecognized tax benefit is estimated based on a "cumulative probability assessment" that aggregates the estimated tax liability for all uncertain tax positions.

The Company files a consolidated U.S. federal income tax return as well as various state income tax returns. The Company does not believe there will be any material changes in its unrecognized tax positions over the next twelve months. The Company has not incurred any interest or penalties. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the consolidated financial statements as general and administrative expenses.

Fair value measurements - The Company follows FASB ASC 820 which defines fair value and establishes a hierarchy for reporting the reliability of input measurements used to assess fair value for all assets and liabilities. Fair value is defined as the selling price that would be received for an asset, or paid to transfer a liability, in the principal or most advantageous market on the measurement date. The hierarchy established prioritizes fair value measurements based on the types of inputs used in the valuation technique. The inputs are categorized into the following levels:

Level 1 - Observable inputs such as quoted prices in active markets for identical assets or liabilities;

Level 2 - Directly or indirectly observable inputs for quoted and other than quoted prices for identical or similar assets and liabilities in active or nonactive markets; and

Level 3 - Unobservable inputs not corroborated by market data, therefore requiring the entity to use the best information available in the circumstances, including the entity's own data assumptions.

The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. FASB ASC 820 was applied to the Company's outstanding derivatives effective December 31, 2013 and 2012.

The following table sets forth the Company's financial asset that was accounted for at fair value on a recurring basis:

	Fair Value Measurements as of December 31, 2013			
	Level 1	Level 2	Level 3	Balance
Assets				
Interest rate cap	$ -	$ 7,650	$ -	$ 7,650

	Fair Value Measurements as of December 31, 2012			
	Level 1	Level 2	Level 3	Balance
Assets				
Interest rate cap	$ -	$ 26,011	$ -	$ 26,011

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Fair value measurements (continued) - The interest rate cap agreement, which is included in prepaid expenses and other current assets on the accompanying consolidated balance sheets, is recorded at fair value based upon valuation models utilizing the income approach and commonly accepted valuation techniques that use inputs from closing prices for similar assets and liabilities in active markets as well as other relevant observable market inputs at quoted intervals such as current interest rates, forward yield curves, implied volatility, and credit default swap pricing. The Company does not believe the ultimate amount that could be realized upon settlement of the interest rate cap agreement would be materially different from the fair values currently reported.

The inputs or methodology used to measure fair value of such a financial asset may not be necessarily indicative of all of the risks associated with such financial assets.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, net, accounts payable, accrued expenses, credits due payors, and capital leases approximate the respective fair values due to the short maturities for those instruments. The recorded amount of the debt approximates the fair value due to the variableness of the associated interest rate.

(2) Business acquisition

On June 1, 2012, Infusions acquired all of the outstanding preferred and common stock of Holdings. The total purchase price was approximately $200,000,000. In connection with the acquisition, $11,750,000 was placed in escrow as security against certain financial and legal contingencies, and was settled in September 2013.

The acquisition was accounted for using the purchase method of accounting in accordance with ASC 805, "Business Combinations," and, accordingly, the Company's consolidated results of operations include the results of the Company from the acquisition date.

In connection with the acquisition, the Company raised approximately $99,000,000 with the sale of preferred stock. The Company also obtained approximately $78,000,000 of long-term debt, a revolving credit obligation of approximately $7,000,000, and $32,000,000 of subordinated debt. No amount was borrowed on the available revolving credit obligation at the time of the acquisition. Also, in connection with the acquisition, the Company incurred approximately $1,717,000 of acquisition costs, which are included in general and administrative expenses on the consolidated statements of operations.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(2) **Business acquisition (continued)**

A summary of the total consideration and assets acquired in the acquisition as of June 1, 2012, is as follows:

Consideration	
Equity raised	$ 98,786,000
Debt incurred	110,000,000
Liabilities assumed (including $50,665,000 of deferred tax liabilities)	57,299,000
Total consideration	266,085,000
Assets acquired	
Cash	5,952,000
Accounts receivable	9,487,000
Inventories	1,389,000
Prepaid expenses and other current assets	812,000
Deferred tax asset	1,221,000
Property and equipment	3,289,000
Deferred financing costs	2,857,000
Deposits and other long-term assets	62,000
Customer relationships	79,500,000
Noncompete agreements	4,200,000
Proprietary technology	32,600,000
Internally developed software	1,500,000
Tradenames	19,300,000
Total assets	162,169,000
Goodwill	$ 103,916,000

The goodwill arising from the acquisition consists largely of expected future earnings and cash flows from the continued growth of the Company.

(3) **Goodwill and Tradenames**

As discussed in Note 2, Infusions acquired goodwill and tradenames in connection with the acquisition of Holdings. Goodwill represents the excess of purchase price over the fair value of net assets acquired. Under FASB ASC 350, goodwill and intangible assets that have indefinite lives are reviewed for impairment annually or more frequently if certain indicators arise. Infusions has evaluated the carrying value of goodwill and its identifiable intangible assets that have indefinite lives as of December 31, 2013 and 2012, utilizing discounted cash flows, among several different valuation approaches. After evaluating the discounted cash flows, management concluded that the carrying value of goodwill and tradenames did not exceed their fair values at December 31, 2013; thus, no impairment occurred during the year ended December 31, 2013. However, for the period from June 1, 2012 (Inception) through December 31, 2012, after evaluating the discounted cash flows, management concluded that the carrying value of goodwill and tradenames exceeded their fair values at December 31, 2012, and, therefore, were impaired. In accordance with FASB ASC 350, these intangible assets will continue to be assessed on an annual basis, and impairment, if any, will be recorded as a charge against income from operations.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(3) Goodwill and Tradenames (continued)

In July 2012, the Company recognized that the Medicare Part D reimbursement rates were being significantly decreased for the two key ingredients in their Proplete® formula used in servicing the Company's renal patients. This sudden change in the reimbursement rate resulted in an immediate Medicare Part D reimbursement rate decrease of more than 75%. Due to this substantial decrease in the reimbursement rates, the Company has revised and modified its projected future revenue and cash flow forecasts. The effect these changes had on the period from June 1, 2012 (inception) through December 31, 2012's actual gross margin as compared to budgeted gross margin for the same period was significant with actual gross margin declining from a budgeted 74.2% to an actual 63.1% for the renal division. The Company believes that this reduction in reimbursement rates and related profitability trends will continue for the foreseeable future and thus will have a significant negative effect on the estimated future operating results and cash flows. The Company reduced its work force during November 2012, in response to these uncertainties.

The first step of the FASB ASC 350 impairment analysis consists of a comparison of the fair value of the goodwill and tradenames with its carrying amount. The fair value was determined based on an average of four different valuation approaches. Based on this analysis, the Company determined the carrying amount of the goodwill and the tradenames was in excess of their respective fair values. As such, the Company was required to perform the second step analysis in order to determine the amount of the goodwill and tradenames impairment. The second step analysis consisted of comparing the implied fair value of the goodwill and tradenames with the carrying amount of the goodwill and tradenames, with an impairment charge resulting from any excess of the carrying value of the goodwill and tradenames over the respective implied fair values. Based on the second step analysis, the Company concluded that the goodwill and tradenames were impaired by approximately $29,882,000 and $16,600,000, respectively, as of December 31, 2012. As a result, the Company recorded a noncash goodwill impairment charge which is included in operating expenses totaling $46,482,000 for the period from June 1, 2012 (inception) through December 31, 2012.

The determination as to whether a write-down of goodwill and other indefinite-lived intangibles is necessary involves significant judgment based on short-term and long-term projections of the Company. The assumptions supporting the estimated future cash flows, including profit margins, long-term forecasts, discount rates and terminal growth rates, reflect the Company's best estimates.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(4) **Property and equipment**

The following is a summary of property and equipment, net of accumulated depreciation and amortization, as of December 31, 2013 and 2012:

	2013	2012
Cost		
Furniture and office equipment	$ 282,714	$ 162,968
Medical equipment	177,624	85,632
Medical equipment under capital lease	356,547	394,697
Computer software and equipment	2,530,378	1,919,514
Vehicles	2,812	6,812
Leasehold improvements	1,766,892	1,349,779
Total cost	5,116,967	3,919,402
Accumulated depreciation and amortization	2,653,274	1,005,452
Property and equipment, net	$ 2,463,693	$ 2,913,950

Depreciation and amortization expenses for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, was $1,675,617 and $1,008,862, respectively. During the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, the Company disposed of depreciated property and equipment with an original cost of approximately $44,000 and $15,000, respectively, and net book value of approximately $16,000 and $11,000, respectively.

(5) **Major customers, vendors and concentration of credit risks**

The Company provides nutritional and pharmaceutical products to patients nationally. The Company grants credit to these customers by accepting assignment on medical claims filed seeking reimbursement. Consequently, the Company's ability to collect amounts due from its payor sources may be affected by the creditworthiness of these payors and the possible subsequent review of claims for medical appropriateness and insurance coverage. Management believes these risks are mitigated as the Company secures authorizations prior to beginning service.

Patients are referred to the Company by dialysis centers owned by third parties. As of December 31, 2013 and 2012, there was one referral source that generated 34% and 31.5% of patient census, respectively.

One payor accounted for approximately 23% and 16% of revenues for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively. Accounts receivable from this payor as of December 31, 2013 and 2012 was approximately $7,005,000 and $2,597,000, respectively. Also approximately 26% and 33% of revenues for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively, were paid by approximately 50 unique third-party payors under the Medicare Part D program. Accounts receivable from payors under the Medicare Part D program was approximately $1,474,000 and $1,011,000 as of December 31, 2013 and 2012, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(5) Major customers, vendors and concentration of credit risks (continued)

The Company has contracts with various vendors for the purchase of pharmaceuticals and medical supplies. One vendor accounted for approximately 50% and 59% of purchases for these products for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively. The Company believes that it would be able to either obtain its inventory from other companies or take alternative steps to obtain similar products in certain cases. The Company owed the vendor approximately $680,000 and $749,000 as of December 31, 2013 and 2012, respectively.

(6) Revolving credit facility

In June 2012, the Company obtained a new revolving credit facility of $7,000,000, of which $0 was outstanding as of December 31, 2013 and 2012, respectively. Borrowing is limited to a borrowing base calculation of the difference of EBITDA multiplied by the maximum Senior Debt to EBITDA ratio allowed under the credit agreement (ranging from 2.00 to 3.50) less outstanding senior debt.

The revolving credit facility matures on May 31, 2018. The interest rate is either the prime rate plus an applicable margin ranging from 4.00% to 4.50% or LIBOR plus an applicable margin ranging from 5.00% to 5.50% (with a floor of 1.25% for LIBOR) at the Company's option and is subject to certain debt covenants. As of December 31, 2013 and 2012, the interest rate for the facility was based on LIBOR at a rate of 6.5%. The facility is cross-collateralized with the credit agreement (see Note 7).

On December 31, 2012, the Company entered into a First Amendment ("First Amendment") to its revolving credit facility. The First Amendment modified the available credit facility to be the lesser of the revolving loan commitment or $2,500,000, provided that the Company deliver the consolidated financial statements and a covenant compliance certificate demonstrating that the Senior Debt to EBITDA ratio as of the last day of a computation period is less than 3.50 to 1.00. Borrowing is limited to a borrowing base calculation of the difference of EBITDA multiplied by the maximum Senior Debt to EBITDA ratio allowed under the credit agreement (ranging from 3.50 to 7.00) less outstanding senior debt. The interest rate is either the prime rate plus an applicable margin ranging from 4.0% to 5.0% or LIBOR plus an applicable margin ranging from 5.0% to 6.5% (with a floor of 1.25% of LIBOR) at the Company's option and is subject to certain debt covenants.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(7) **Long-term debt**

As of December 31, 2013 and 2012, the Company's long-term debt obligations consisted of the following:

	2013	2012
Credit agreement payable to several banks with quarterly principal payments ranging from $907,185 to $1,814,369 with a final payment of approximately $38,764,000, plus monthly interest (6.5% as of December 31, 2013). The quarterly payments are due from September 30, 2012 through May 31, 2018.	64,164,703	$ 76,050,000
Subordinate credit agreement payable with principal and all accrued interest due May 31, 2018. Due to the amendment noted below, all interest (14% as of December 31, 2013) is to be considered payment-in-kind, including $5,585,433 and $2,717,430 accrued as of December 31, 2013 and 2012, respectively.	37,585,433	34,717,430
Long-term debt	101,750,136	110,767,430
Less current portion	4,535,923	7,089,000
Long-term debt, net of current portion	$ 97,214,213	$ 103,678,430

Scheduled annual maturities of long-term debt as of December 31, 2013 are as follows:

Years Ending December 31,	
2014	$ 4,535,923
2015	5,443,107
2016	6,350,292
2017	7,257,476
2018	78,163,338
	$ 101,750,136

On June 1, 2012, the Company entered into a senior credit facility for a term loan totaling approximately $78,000,000. The proceeds of the loan were used to purchase Holdings from its stockholders (see Note 2). The term of the loan is amortized over twenty-four quarterly payments of principal ranging from approximately $907,185 to $1,814,369 from December 2013 through May 2018, with a balloon payment of approximately $38,764,000 due in May 2018. Interest is based on whether or not the term loan is considered to be a "Base Rate Loan" or a "LIBOR" loan. If the term loan is considered to be a "Base Rate Loan," the Company pays interest equal to the bank's prime rate, plus an applicable margin. If the Company opts to engage in a LIBOR contract, the term loan is considered to be a "LIBOR" loan and the Company pays interest equal to the sum of the LIBOR applicable to each interest period and the applicable margin. Interest is paid based on the loan contract term. The term loan includes various financial and nonfinancial covenants, including a minimum EBITDA, leverage ratios, and a minimum fixed coverage ratio.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(7) Long-term debt (continued)

On December 31, 2012, the Company entered into a First Amendment to its term loan. The First Amendment modified certain loan covenants, including but not limited to: modified the interest rate pricing grid (applicable margin); required quarterly mandatory prepayments of any cash on hand in excess of $5 million beginning March 31, 2013, until senior leverage is less than 4.00 times; modified the excess cash flow percentage; updated the reporting requirements; modified the definitions of EBITDA and fixed charges and limited the payments of the subordinated debt, related-party management fees, and senior management bonuses.

In connection with the First Amendment, the Company is required to pay the higher result of either the excess cash flow calculation as defined in the agreement, as of December 31, 2012, or the required excess cash sweep prepayment noted above, as of March 31, 2013. The prepayment, which was made in April 2013, was applied in the inverse order of maturities due on the term loan. This required prepayment of approximately $3,189,000 was included in the current portion of the long-term debt included in the consolidated balance sheet as of December 31, 2012. The scheduled annual maturities provided above have been modified for this required prepayment.

Prior to the First Amendment, the interest rate for the term loan was either the prime rate, plus an applicable margin ranging from 4.0% to 4.5%, or LIBOR (with a floor of 1.25%), plus an applicable margin ranging from 5.0% to 5.5%, at the Company's option. As of December 31, 2013, the Company had chosen the LIBOR option (6.5%). The loan facility also required an annual prepayment based on excess cash flows and an interest rate cap. The annual prepayment based on excess cash flows is applied ratably on the remaining outstanding debt. Collateral for the loan consists substantially of all of the assets of the Company.

In May 2013, the Company made a voluntary prepayment of $5,000,000. The voluntary prepayment is applied to the outstanding principal, results in lower quarterly principal payments and interest payments, and was credited towards the 2013 excess cash flow calculation.

The Company entered into a 48-month interest rate cap in July 2012, for approximately $128,000. The Company is exposed to interest rate risk primarily through its borrowing activities. The Company's long-term borrowing is a variable rate instrument.

The Company designated the interest rate cap as a fair value hedge. As of December 31, 2013 and 2012, there has been a reduction in the fair value of the hedge to approximately $8,000 and $26,000, respectively. The change in the interest rate cap was recorded in operations and is included in interest expense in the accompanying consolidated statements of operations.

On June 1, 2012, the Company entered into a credit facility for a subordinate term loan totaling approximately $32,000,000. The proceeds of the loan were used to purchase Holdings from its stockholders (see Note 2). The term of the loan requires a one-time principal payment in June 2018, along with all unpaid interest. Interest is due quarterly. In September 2012, the Company obtained a waiver from the first interest payment, which continued through the quarter ended March 31, 2013 - these payments were deemed payment-in-kind interest and added to the outstanding loan balance. The subordinate term loan includes various financial and nonfinancial covenants, including a minimum EBITDA, fixed charge ratio, and leverage ratios. For the year ended December 31, 2013 and for the period of June 1, 2012 (inception) through December 31, 2012, the interest rate for the subordinate term loan was 14% per year (2% of which is considered payment-in-kind, which is added to the principal on a quarterly basis).

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(7) Long-term debt (continued)

On December 31, 2012, the Company entered into a First Amendment to its subordinate term loan. The First Amendment modified certain loan covenants, including but not limited to: deferred all interest payments until certain senior leverage requirements are met; updated the reporting requirements; modified the definitions of EBITDA and fixed charges, and deferred the payment of related-party management fees to the extent not permitted to be paid per the terms of the senior credit facility.

For the reporting period ending March 31, 2013, the Company had met the required senior leverage requirements to resume making interest payments. On June 30, 2013, the Company resumed making interest payments.

In December 2013 and March 2014, the Company obtained waivers from paying the respective quarterly interest payments - these payments were deemed payment-in-kind interest and added to the outstanding loan balance.

(8) Commitments and contingencies

Operating leases - The Company conducts its operations at its facility located in Boothwyn, Pennsylvania.

The Company has a lease for corporate office space. The corporate office is leased under a seven-year noncancelable operating lease expiring in 2015, which provides for monthly rental payments of $45,943, with an option to renew the lease for an additional five years.

As part of the lease, the Company was provided a build-out allowance of $565,000 which reduces rent expense over the term of the lease. Leasehold improvements incurred in connection with the lease are amortized over the life of the lease.

The Company has two addendums to the above lease for additional space. The addendums are leases for approximately four years, expiring in 2015, which provide for monthly rental payments ranging from $8,043 to $8,862, for both addendums.

During 2013, the Company entered into new operating leases for additional office space and medical equipment. The office lease, with monthly rental payments of $4,170, expires in May 2016, and may be extended for two additional three-year terms. The medical equipment leases, with monthly payments of $2,250, expire in April 2018.

Total rent expense for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, was approximately $1,573,000 and $886,000, respectively. Included in rent expense is approximately $568,000 and $533,000, respectively, related to medical equipment and $92,000 and $41,000, respectively, related to office space, which is leased on a month-to-month basis for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, The medial equipment leases contain an option to enter into a capital lease with that vendor.

Capital leases - The Company has two capital leases for certain medical equipment with a value of $316,194 and $93,375, respectively, as of June 1, 2012. The leases are payable in monthly installments of $32,640 and $5,880, respectively, including interest at 13%, through March 31, 2014 and November 30, 2014, respectively. As of December 31, 2013 and December 31, 2012, the accumulated depreciation related to the assets purchased under these two capital leases is $289,337 and $117,821, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(8) Commitments and contingencies (continued)

Future annual minimum lease commitments under all capital and noncancelable operating leases as of December 31, 2013, are as follows:

Years Ending December 31,	Capital Leases	Operating Leases
2014	$ 159,280	$ 842,214
2015	-	784,619
2016	-	47,849
2017	-	27,000
2018	-	9,000
Total minimum lease payments	159,280	$ 1,710,682
Less amount representing interest and service fees	73,820	
Present value of net minimum lease payments	85,460	
Less current portion of the capital lease obligation	85,460	
	$ -	

Subsequent to December 31, 2013, the Company entered into two capital leases for certain medical equipment with a value of approximately $309,000 and $2,022,000, respectively. The terms of each lease is four years and the monthly payments are $7,321, including interest at 6.5%, and $94,200, including interest at 13%, respectively.

Legal - The Company is subject to claims which arise in the ordinary course of business. Management believes that the ultimate outcome of these claims will not have a material effect on the Company's financial position or results of operations.

(9) Equity transactions

Preferred stock - In June 2012, the Company authorized 1,100,000 shares with a par value of $0.001. The Company has designated that 1,000,000 shares are convertible to common stock and issued 987,855 shares of Series A Convertible preferred stock.

Conversion - Each share of the issued Series A preferred stock is convertible, at the option of the holder, at any time, into a number of fully paid and nonassessable shares of common stock that is equal to the Series A Preferred Stock Liquidation Value as of the conversion date divided by the Series A Conversion Price. The Series A Conversion Price is $100.00.

The Company shall have the right to cause some or all of Series A preferred stock to be automatically converted at any time after the date of issuance of such shares at the conversion rate stated above. In case of any conversion of part of the shares of Series A preferred stock at the time outstanding, the shares to be so converted shall be selected pro rata from among the holders thereof.

Dividends - The holders of the Series A preferred stock are entitled to receive cumulative cash dividends at the annual rate of ten percent (10%) of the Series A original issue price ($100.00) for each share of Series A preferred stock outstanding. Such dividends shall be cumulative in nature and paid in full before any dividend or other distribution shall be paid or declared. Such dividends began accruing as of the original issue date. As of December 31, 2013 and 2012, cumulative undeclared dividends were approximately $15,640,000 and $5,762,000, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(9) Equity transactions (continued)

Liquidation preference - In the event of any liquidation, dissolution or winding up of the Company, the holders of the Series A preferred stock are entitled to receive prior to, and in preference to, any distribution to the common stockholders, an amount equal to the greater of (A) an amount equal to (x) the number of shares of Series A preferred stock held by such holder multiplied by (y) the then applicable Series A preferred Stock Liquidation Value or (B) the amount that would be payable in such Liquidation with respect to shares of common stock issuable to such holder upon the conversion of shares of Series A preferred stock held by such holder had such shares of Series A preferred stock been converted into common stock immediately prior to such Liquidation. In the event that upon liquidation or dissolution, the assets are insufficient to permit the payment to preferred stockholders of the full preferential amounts, then all assets legally available for distribution are to be distributed ratably among the holders of the shares of Series A preferred stock.

Voting rights - Each Series A preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which such holder's shares are convertible.

Common stock - As of December 31, 2013 and 2012, the Company has authorized the issuance of 2,750,000 shares of common stock, with a par value of $0.001 as follows:

Issued and outstanding common stock	-
Reserved under stock option plan	151,083
Reserved for Series A preferred stockholders	987,855
Unreserved	1,611,062
Total authorized	2,750,000

The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights of the holders of the Series A preferred stock and by the Board of Directors, upon any issuance of the preferred stock of any series. The holders of common stock are entitled to one vote for each share held at all meetings of stockholders. All shares of common stock will be identical and will entitle holders to the same rights and privileges.

(10) Stock option plan

In June 2012, the Board of Directors adopted the Pentec Healthcare Infusions, Inc. 2012 Stock Option Plan, which allows for the issuance of options, from time to time. The common shares available under the Plan is 151,083 common shares.

During the period from June 1, 2012 (inception) through December 31, 2012, the Company granted certain key individuals options to purchase 55,203 shares of the Company's stock at $100.00, which was intended to approximate the estimated fair value of the stock on the grant date (Pool A). The estimated value for these options is $0.15 per option based on the valuation of the options. The options vest over five years from the date of grant, with 20% vesting on the first anniversary of the grant date and then 20% of the remaining options vesting each year, thereafter. The options are exercisable from the time they vest through a period of ten years from the date of grant. Total compensation expense related to these options issued during 2012, in accordance with FASB ASC 718, is approximately $8,300 which will be recognized over the five-year vesting period. The amount of expense recognized during the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, is approximately $1,700 and $1,000, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(10) Stock option plan (continued)

During the period from June 1, 2012 (inception) through December 31, 2012, the Company granted certain key individuals, options to purchase 55,203 shares of Company stock at $100, which was intended to approximate the estimated fair value of the stock on the grant date (Pool B). The options vest when there is a change of control and an internal rate of return of at least 15% and a cash-on-cash return of at least 2.25 times, as defined in the agreement. The estimated value for these options is $0.01 per option based on the valuation of the options. Total compensation related to these options issued in 2012, in accordance with FASB ASC 718, is approximately less than $1,000 which will be recognized over the requisite service period. Total compensation expense related to these options recognized during the year ended December 31 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, is approximately $300 and $100, respectively.

During the period from June 1, 2012 (inception) through December 31, 2012, the Company granted certain key individuals options to purchase 34,865 shares of the Company's stock at $100, which was intended to approximate the estimated fair value of the stock on the grant date. The options vest when there is a change of control and an internal rate of return of at least 20% and a cash-on-cash return of at least 3.5 times (Pool C) as defined in the agreement. The estimated value for these options is $0.00001 per option based on the valuation of the options. Total compensation related to these options issued in 2012, in accordance with FASB ASC 718, is approximately less than $1 which will be recognized over the requisite service period. Total compensation expense recognized during both the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, is less than $1.

Subsequent to December 31, 2013, the vesting requirements of Pools B and C were modified. The vesting condition related to the internal rate of return requirement was eliminated from both pools and the cash-on-cash requirement was reduced to at least 1.5 times for Pool B and at least 2.5 times for Pool C. There was no modification to the change of control vesting requirement.

During the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, the Company recognized approximately $2,000 and $1,000 as compensation costs relate to all options issued, respectively. The remaining unrecognized compensation cost of approximately $5,700 will be recognized over the remaining vesting period of up to approximately three years.

For options granted during the period from June 1, 2012 (inception) through December 31, 2012, the Company calculated the fair value of the options using the Black-Scholes option valuation model that uses the assumptions noted in the following table. The Company calculated its expected volatility using the average of several comparable public companies. The Company elected to use the average of comparable companies because it did not have a trading history for its stock. The Company chose comparable companies that are closely related to its industry and averaged them to give a better representation of the expected volatility. The Company uses historical data to estimate option exercise and employee termination within the valuation model. The expected term of options granted is derived from the output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk-free interest rate for periods within the contractual life of the option is estimated based on the U.S. Treasury yield curve in effect at the time of grant.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(10) Stock option plan (continued)

The assumptions used and the calculated fair values of the options issued from June 1, 2012 (inception) through December 31, 2012, were as follows:

	Pool A	Pool B	Pool C
Expected dividend yield	0%	0%	0%
Risk-free interest rate	0.51%	0.25%	0.17%
Weighted average expected life in years	4	2	1
Expected volatility factor	35%	35%	35%
Weighted average fair value of options granted	$0.15	$0.01	$ 0.00001

The following is an analysis of options to purchase shares of the Company's stock issued and outstanding:

	Total Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Total options outstanding, June 1, 2012	-	$ -	
Granted	145,271	$ 100	
Total options outstanding, December 31, 2012	145,271	$ 100	2.32 years
Granted	-		
Exercised	-		
Expired/cancelled	-		
Total options outstanding, December 31, 2013	145,271	$ 100	1.46 years
Total options exercisable, December 31, 2013	11,041	$ 100	

A summary of the status of the Company's nonvested options as of December 31, 2013 and 2012, and changes during 2013 and 2012, is presented below:

Nonvested options	Options	Weighted Average Grant-Date Fair Value
Nonvested, June 1, 2012	-	$ -
Granted	145,271	0.06
Vested	-	-
Nonvested, December 31, 2012	145,271	0.06
Granted	-	
Vested	(11,041)	0.06
Nonvested, December 31, 2013	134,230	$ 0.06

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(11) Related-party transactions

On June 1, 2012, the Company entered into three Management Services Agreements with companies related to certain preferred stockholders to perform certain services for the Company, including consulting, financial analysis, marketing, and general support services as reasonably requested by the Board of Directors. The contracts are for a term of ten years with annual payments due of $600,000, payable quarterly. The expense under these agreements approximated $600,000 and $350,000 for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively; however, the payment of the management fee has been suspended in connection with the restructuring of the long-term debt on December 31, 2012 (see Note 7). Interest on unpaid management fees will accrue at an annual rate of 6.0% compounded monthly. As of December 31, 2013 and 2012, $631,543, and $150,000 is payable to the related party, respectively. Interest expense for the year ended December 31, 2013 was $31,543. There was no interest expense for the period from June 1, 2012 (inception) through December 31, 2012. In connection with the acquisition (see Note 2), the Company recorded approximately $333,000 as a receivable in prepaid and other current assets for expenses paid by the Company on the seller's behalf. The Company was paid by the seller in 2013 after the escrow related to the sale was settled.

(12) Retirement plan

The Company has a contributory profit sharing plan, as defined under Section 401(k) of the U.S. Internal Revenue Code, covering substantially all employees. During the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, the Company made contributions to this plan at a rate of 3% of the participating employees' compensation. Company contributions are subject to a vesting schedule. The employee becomes 100% vested with respect to the employer contributions after completing six years of service. Employer contributions during the year ended December 31, 2013 and for the period of June 1, 2012 (inception) through December 31, 2012, were approximately $381,000 and $180,000, respectively.

(13) Income taxes

The income tax benefit for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, consisted of the following:

	2013	2012
Current income taxes (benefit)		
Federal	$ 1,533,843	$ (201,400)
State	398,270	76,122
	1,932,113	(125,278)
Deferred income tax benefit		
Federal	(2,359,215)	(6,420,644)
State	(476,635)	(1,453,265)
	(2,835,850)	(7,873,909)
Total income tax benefit	$ (903,737)	$ (7,999,187)

Included in the 2012 deferred tax benefit above is approximately $6,300,000 related to the impairment of the tradenames (see Note 3).

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(13) Income taxes (continued)

Deferred income taxes reflect the effect of temporary differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the carrying amounts used for income tax reporting purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2013 and 2012 are as follows:

	2013	2012
Current deferred tax assets (liabilities):		
Accounts receivable reserves	$ 711,797	$ 993,154
Inventory	49,747	37,504
Accrued expenses	1,582,096	464,754
Federal benefit of state deferred	(114,788)	(75,508)
Prepaid assets	(70,417)	-
Total current deferred tax assets	2,158,435	1,419,904
Long-term deferred tax assets (liabilities):		
Book basis in excess of tax - intangible assets	(43,322,091)	(45,558,971)
Federal benefit of state deferred, net of current portion	2,139,780	2,276,866
Tax basis in excess of book - depreciation	250,423	292,436
Interest rate cap	39,538	-
Total long-term deferred tax liabilities	(40,892,350)	(42,989,669)
Net deferred income taxes	$ (38,733,915)	$ (41,569,765)

(14) Industry conditions

As part of ongoing business operations, the Company and its customers are subject to legislative and regulatory changes that may impact operations and the level of reimbursement received from third-party payors, including Medicare and certain private payors. The Company's reimbursement is determined by agreements that the Company negotiates with those payors or their benefit manager representatives. Due to the changing political and healthcare climate, the termination or modification of the agreements could affect the Company's reimbursement from these sources. These changes could have a material effect on the Company's results of operations and cash flows and its ability to repay the Company's obligations. Given the current reimbursement landscape, the Company continues to add sales personnel and expand the Company's market penetration, improve operational efficiencies, and reduce costs to mitigate the impact on results of operations, where possible. As presented in the accompanying consolidated financial statements, the Company increased annualized revenues and cash flows from operations. The Company has been in compliance with its financial covenants, which are monitored by the Company on a regular basis. Also, over the past two years, the Company has agreed to new reimbursement rates with the Company's two largest payor groups, representing over 50% of consolidated net revenues. None of the Company's other payors represent more than 10% of the consolidated net revenues. Subsequent to December 31, 2013, the Company received a written communication from the U.S. Food and Drug Administration ("FDA") as a follow up to the FDA's inspection of the Company during the year ended December 31, 2013. The Company has provided the FDA with its written response within the requested timeframe. The Company has not yet received any additional communication from the FDA.

(15) Subsequent events

Subsequent events have been evaluated through June 26, 2014, the date these consolidated financial statements were available to be issued.

ATTACHMENT

SECTION C, ECONOMIC FEASIBILITY, ITEM 6.A

Home Infusion Fee Schedule, Pentec Health, Inc.

HOME INFUSION FEE SCHEDULE

CODE	DESCRIPTION	Charge
S9328	Home infusion therapy, implanted pump pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	$100.00
S9363	Home infusion therapy, antispasmotic therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	$80.00
S9338	Immunotherapy - IVIG administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	$175.00
S9490	Corticosteroid-(Solumedrol) administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	$135.00
S9379	Infusion therapy, not otherwise classified	$100.00
S9364	TPN < 1 Liter	$175.00
S9365	TPN 1 Liter	$185.00
S9366	TPN >1.0 – 2.0 Liters	$280.00
S9367	TPN >2.1 – 3.0 Liters	$300.00
S9368	TPN >3 Liters	$320.00
99601	Home infusion/specialty drug administration, per visit (up to 2 hours);	$225.00
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)	$112.50
SS	HOME INFUSION SERVICES PROVIDED IN THE INFUSION SUITE OF THE IV THERAPY PROVIDER	N/A
SD	SERVICES PROVIDED BY REGISTERED NURSE WITH SPECIALIZED, HIGHLY TECHNICAL HOME INFUSION TRAINING	N/A
SH	SECOND CONCURRENTLY ADMINISTERED INFUSION THERAPY	N/A

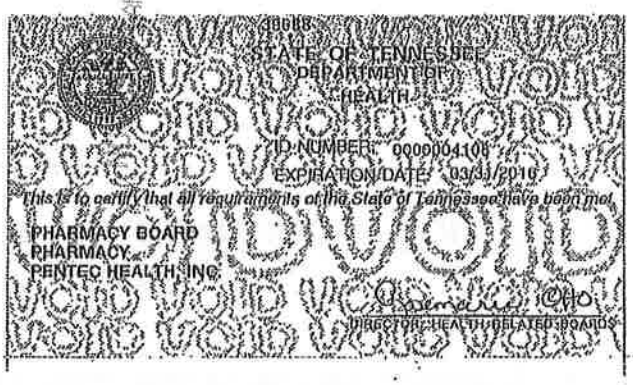
MISCELLANEOUS INTRATHECAL FEE SCHEDULE

CODE		CHARGE
A4220	Refill Kit for Implantable Infusion Pump	$60.00
95990	Re-filling and maintenance of implantable pump	$400.00
62368	Analysis with re-programming of Intrathecal Pump	$200.00
62367	Analysis without re-programming of Intrathecal Pump	$150.00
98969	E-Visit by Non-Physician Healthcare Provider for Established Patients	$45.00
98966	Telehealth Visit by NON-Physician 5-10 minutes	$15.00
98967	Telehealth Visit by Non-Physician 11-20 minutes	$30.00
98968	Telehealth Visit by Non-Physician 21-31 minutes	$45.00
99366	Medical team conference with interdisciplinary team of health care professionals, face-to-face with patient and/or family, 30 minutes or more, participation by nonphysician qualified health care professional	$55.00
99368	Medical team conference with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more; participation by nonphysician qualified health care professional	$45.00

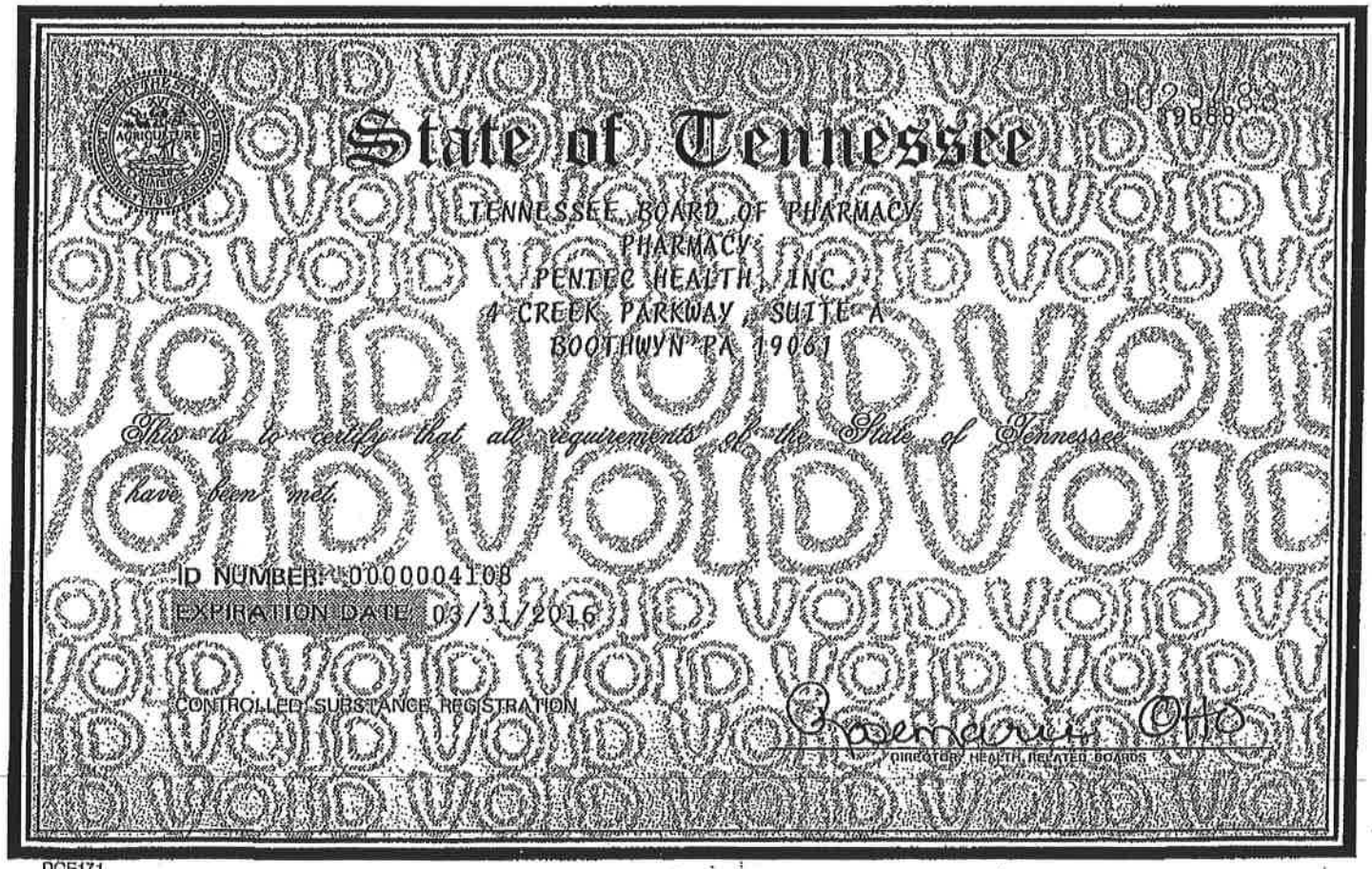
ATTACHMENT

SECTION C, CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE, ITEM 7.c

1. Tennessee Pharmacy License, Pentec Health, Inc.
2. Accreditation Certificate and Letter from The Joint Commission, Pentec Health, Inc.



PHARMACIST-IN-CHARGE
PENTEC HEALTH, INC.
4 CREEK PARKWAY, SUITE A
BOOTHWYN PA 19061-3132



DOF171

Pentec Health, Inc.

Boothwyn, PA

has been Accredited by

The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the

Home Care Accreditation Program

June 7, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin, MD
Chair, Board of Commissioners

Organization ID #10297
Print/Reprint Date: 06/30/2014

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.

The Joint Commission

October 9, 2014

Joe Cosgrove
Chief Executive Officer
Pentec Health, Inc.
4 Creek Parkway, Suite A
Boothwyn, PA 19061

Joint Commission ID #: 10297
Program: Home Care Accreditation
Accreditation Activity: Measure of Success
Accreditation Activity Completed: 10/09/2014

Dear Mr. Cosgrove:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

- Comprehensive Accreditation Manual for Home Care

This accreditation cycle is effective beginning June 07, 2014. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the Centers for Medicare and Medicaid Services (CMS), state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,

Mark Pelletier

Mark G.Pelletier, RN, MS

Chief Operating Officer

Division of Accreditation and Certification Operations

Accreditation Quality Report

- > Summary of Accreditation Quality Information
- > Accredited Programs
- > Accreditation National Patient Safety Goals
- > Sites and Services
- > Accreditation History
- > Download Accreditation PDF Report
- > Accreditation Quality Report User Guide

Symbol Key

- The organization has met the National Patient Safety Goal.
- The organization has not met the National Patient Safety Goal.
- The goal is not applicable for this organization.

Quality Report

Summary of Accreditation Quality Information

Pentec Health, Inc.
Org ID: 10297
4 Creek Parkway, Suite A
Boothwyn, PA 19061
(484)480-2222
www.pentechealth.com

Accreditation Programs	Accreditation Decision	Effective Date	Last Full Survey Date	Last On-Site Survey Date
Home Care	Accredited	6/7/2014	6/6/2014	6/6/2014

Accreditation programs recognized by the Centers for Medicare and Medicaid Services (CMS)

Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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National Patient Safety Goals and National Quality Improvement Goals

			Compared to other Joint Commission Accredited Organizations	
			Nationwide	Statewide
Home Care	2014 National Patient Safety Goals	See Detail	✓	N/A *

* State results are not calculated for the National Patient Safety Goals.

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Sites and Services

*** Primary Location**

An organization may provide services not listed here. For more information refer to the Quality Report User Guide .

Locations of Care	Available Services
Diversified Management Services- DBA: Pentec Health, LLC 1722 Ninth Street Wichita Falls, TX 76301	**Services:** • Home Health, Non-Hospice Services • Pharmacy, Clinical Consulting Services • Pharmacy/Dispensary,General Services • Skilled Nursing Services
Integrated Neurology Services, LLC-VA office DBA: Pentec Health, LLC 7115 Leesburg Pike Suite 201 Falls Church, VA 22043	**Services:** • Home Health, Non-Hospice Services • Pharmacy, Clinical Consulting Services • Pharmacy/Dispensary,General Services • Skilled Nursing Services
Pain Consultants of Alabama, LLC DBA: Pentec Health, LLC 7101 US Highway 90, Suite 192 Daphne, AL 36526	**Services:** • Home Health, Non-Hospice Services • Pharmacy, Clinical Consulting Services • Pharmacy/Dispensary,General Services • Skilled Nursing Services
Pain Rehabilitation Group of Wichita Falls, TX DBA: Pentec Health	**Services:** • Home Health, Non-Hospice Services

4301 Maplewood Avenue Suite A
Wichita Falls, TX 76308

- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services

Pentec Health
DBA: Pentec Health
14301 First National Bank Parkway,
Omaha, NE 68154

Pentec Health, Illinois
5600 North River Road, Suite 800
Rosemont, IL 60018

Pentec Health, Inc
DBA: Pentec Health, Inc
1615 Poydras Street, Suite 900
New Orleans, LA 70112

Pentec Health, Inc
DBA: Pentec Health
950 Bannock Street, Suite 1100
Boise, ID 83702

Pentec Health, Inc
DBA: Pentec Health
9393 West 110th Street, 51 Corporate Woods, Suite 500
Overland Park, KS 66210

Pentec Health, Inc
DBA: Pentec Health
14301 First National Bank
Omaha, NE 68154

Pentec Health, Inc
DBA: Pentec Health
1915 NW AmberGlen, 4th Floor
Beaverton, OR 97006

Pentec Health, Inc
DBA: Pentec Health
220 North Main Street, Suite 500
Greenville, SC 29601

Pentec Health, Inc
DBA: Pentec Health
222 S. Main Street, 5th Floor
Salt Lake City, UT 84101

Pentec Health, Inc
DBA: Pentec Health
1201 Pacific Avenue, 6th floor
Tacoma, WA 98402

Pentec Health, Inc
DBA: Pentec Health, Inc
232 Market Street
Flowood, MS 39232

Pentec Health, Inc
DBA: Pentec Health, Inc
300 International Drive, Suite 100
Buffalo, NY 14221

Pentec Health, Inc
DBA: Pentec Health, Inc
2700 Corporate Drive, Suite 273
Birmingham, AL 35242

Services:

- Home Health, Non-Hospice Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services

Pentec Health, Inc
DBA: Pentec Health, Inc
10955 Westmoor Drive, 4th floor
Broomfield, CO 80021

Pentec Health, Inc.
DBA: Pentec Health
609 SW 8th Street, 6th floor
Bentonville, AR 72712

Pentec Health, Inc.
DBA: Pentec Health Inc.
120 Forbes Boulevard
Mansfield, MA 02048

Services:
- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services

Pentec Health, Inc.
DBA: Pentec Health, Inc
250 Monroe NW, Suite 400
Grand Rapids, MI 49503

Pentec Health, Inc., Boothwyn, PA *
4 Creek Parkway, Suite A
Boothwyn, PA 19061

Services:
- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Implanted Infusion Pumps and Supplies
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services

Pentec Health, Indiana
48 N. Emerson Avenue, Suite 300, Office #240
Greenwood, IN 46143

Pentec Health, Iowa
305 2nd Avenue SE Suite 200
Cedar Rapids, IA 52401

Pentec Health, Minnesota
DBA: Pentec Health
Fith Street Towers 100 South Fifth Street, Suite 1900
Minneapolis, MN 55402

Pentec Health, North Carolina
Landfall Executive Suites, 1213 Culbreth Drive, Suite 140
Wilmington, NC 28405

Pentec Health, Texas
18756 Stone Oak Parkway, Suite 200
San Antonio, TX 78258

Tampa Pain Relief Center, Inc.
DBA: Pentec Health, Inc
100 West Gore Street, Suite 500
Orlando, FL 32806

Services:
- Home Health, Non-Hospice Services
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary,General Services
- Skilled Nursing Services

- Top -

The Joint Commission obtains information about accredited/certified organizations not only through direct observations by its employees **...Read more.**

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ATTACHMENT

SECTION C, CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE, ITEM 8

1. Order, Indiana State Department of Health, *In re the Matter of Pentec Health, Inc.*
2. Letter Accepting Plan of Correction of Pentec Health, Inc., Indiana State Department of Health

ORDER

WHEREFORE, the Director, pursuant to the Health Commissioner's determination that violations have occurred, **ORDERS** Pentec Health, Inc. to pay a civil penalty totaling Ten thousand dollars ($10,000.00) to the Indiana State Department of Health. Payment of the imposed civil penalty should be made payable to the Indiana State Department of Health and may be submitted to:

Indiana State Department of Health
Attn: Cashier's Office
2 North Meridian Street, Suite 2-C
Indianapolis IN 46204-3006

If Pentec Health, Inc. wishes to seek administrative review and/or a stay of effectiveness of this *Notice of Citation* pursuant to Ind. Code §4-21.5-3-6(d) and §4-21.5-3-2(e), it must petition the State Health Commissioner, in writing, within eighteen (18) days after this Notice of Citation is mailed to Pentec Health, Inc. The petition must include facts demonstrating that:

a. the petitioner is the person to whom the Order is specifically directed;
b. the petitioner is aggrieved or adversely affected by the Order; and
c. the petitioner is entitled to review under any law.

If no petition for review or stay of effectiveness is timely filed, this Order becomes a FINAL ORDER at that time.

Any petition for review and/or petition for stay of effectiveness must be submitted in writing to:

Indiana State Department of Health
Attn: Office of Legal Affairs
2 North Meridian Street, Suite 3-H
Indianapolis, IN 46204-3006

So ORDERED this 22nd day of August, 2011.

INDIANA STATE DEPARTMENT OF HEALTH
DIVISION OF ACUTE CARE

Randy Snyder

Randy Snyder, Director
Division of Acute Care

Indiana State
Department of Health
An Equal Opportunity Employer

Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

CMS CERTIFICATION Number (CCN):
MEDICAID VENDOR Number:
FACILITY Number: 012608

October 17, 2011

Karen McHenry
Administrator
Pentec Health Inc
4 Creek Parkway, Suite A
Boothwyn, PA 19061

RE: Event ID: 6FVZ11

Dear Karen McHenry:

On **October 5th, 2011** the Division of Acute Care received your Plan of Correction in response to the **Initial State Licensure** survey on August 10, 2011 of Pentec Health Inc. The Plan of Correction you submitted has been found to be acceptable.

Sincerely,

Kelly Hemmelgarn

Kelly Hemmelgarn, BSN, RN
PHNSS-Program Director
ISDH/Acute Care Division
317/233/7541

SUPPLEMENTAL
#1

SUPPLEMENTAL #1
November 25, 2014
9:50 am

PENTEC HEALTH, INC.

SUPPLEMENT NO. 1

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

NOVEMBER 2014

SUPPLEMENTAL #1
November 25, 2014
9:50 am

1. **Filing of the Application**

   Please review page 3 of the application form, specifically the FILING THE APPLICATION section. The application as submitted should be formatted in to follow the manner discussed where answers to each question are provided in the body of the application. Only attachments supporting the answers should be provided and labeled as such.

   Applications should have all pages numbered. All attachments should be attached to the back of the application, be identified by the applicable item number of the application, and placed in alpha-numeric order consistent with the application form.

   Specific to Section A, please enter all Section A responses on the form with attachments placed as described in the preceding paragraph. Specific to Sections B. and C., please answer all questions on 8 ½" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response (the applicant's use of bold font for the questions is appreciated). Please add the attachments as described in the first paragraph above.

   Please submit a revised application that follows the guidelines provided above.

   Pentec's application as submitted has been reformatted in the manner described above and has been submitted simultaneously with this Supplement No. 1.

SUPPLEMENTAL #1
November 25, 2014
9:50 am

2. **Section A, Item 6**

Please identify the size, in square feet, of the office, the number of occupants that will use the office and provide a brief comparison of the rental rate to other similar professional office space in Nashville. Please also compare the $8,028 lease rate in the Project Cost Chart to the estimated fair market value (FMV) of the space (prorated for the size of the space to be leased). This comparison is necessary in order to confirm that the cost used in the chart is the higher amount per Agency Statute. Documentation of the office space's FMV from the owner/landlord would be appreciated with your response.

Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. The office itself contains 87 square feet. In addition, Pentec and its visitors also have the use of the office suite common areas, including the Business Lounge, Refreshment Bar, Videoconferencing Room and restrooms. Excluding restrooms and the receptionist's area, this common area contains approximately 1,200 square feet.

The annual rental for Pentec's 87 square foot office is $8,028, which equals an annual rate of $92.28 per square foot. However, as noted above, this rate includes the use of office suite common areas, and also includes utilities, telephone lines, internet service, a shared receptionist, business and IT support, covered parking and secure 24-hour access.

Estimates of fair market rent for Class A office space in downtown Nashville vary. However, the average asking rent for 2014 has been reported at $23.10 per square foot by Colliers International / Nashville, a member company of Colliers International Property Consultants. The "Nashville Office Market Snapshot" report for Third Quarter 2014 by Cassidy Turley, published by the *Nashville Post* on October 1, 2014, states that quoted rates for new Class A office buildings in downtown Nashville are $33.00 - $35.00 per square foot.

Because of the amenities included in Pentec's annual rent, a direct comparison to fair market rental rates for Class A office space in downtown Nashville is difficult. However, based on current estimates of fair market rent for Class A office space in downtown Nashville it is reasonable to conclude that Pentec's actual rent expense as shown in the Project Costs Chart is higher than the FMV rate.

3. **Section A, Applicant Profile, Item 13**

Why has the applicant decided not to provide intrathecal pump home infusion and immunoglobulin-G replacement therapy services (Ig-G services) to TennCare/ Medicare enrollees? Is the service a covered service by these payors? Please discuss.

Pentec has already contracted with TennCare as a pharmacy (and DME) provider, although the products supplied at present relate only to Pentec's Renal Nutrition services, and not to its Specialty Infusion services. The intrathecal pump services for which Pentec would seek reimbursement from the patient's insurer has four components: medication; nursing services; supplies; and "per diem". As indicated in its answer to Section C, Need, Item 1.a.6 of Pentec's application, regarding proposed charges, Pentec estimates that average billed cost per visit for an intrathecal pump patient would be $2,471, which includes medication ($588), nursing services ($71), supplies ($37) and per diem ($1,775). Medicare and TennCare would cover medication and may cover supplies, but would not cover nursing services or per diem. Although Pentec frequently receives less than full reimbursement from payors, it would not be able to cover the cost of providing the service to TennCare or Medicare enrollees without reimbursement for per diem. (A list of services covered by the per diem charge is attached to this Supplement as Attachment to Question 3.)

Please clarify if TennCare and/or Medicare enrollees will be provided infusion services as out-of-network or under some other arrangement.

Pentec provides services to the medically indigent under its Compassionate Care, No Insurance Coverage and Financial Assistance Policies, which are discussed in greater detail its application at Section C, Economic Feasibility, Item 9.

Services provided to TennCare and Medicare enrollees would be in-network, but for the reason noted above, Pentec cannot cover the cost of providing these services with the reimbursement that is available under these programs.

Since the applicant does not plan to seek Medicare/TennCare provider certification, where would enrollees be referred for its services? If a home health provider is not located, would an enrollee be referred back to his/her personal physician for infusion services, including pump refills? Please clarify.

If a means of coverage cannot be identified, a TennCare enrollee would be referred back to his or her personal physician, either for services or for the physician's referral to another agency. If necessary, a Pentec nurse could perform the nursing services in the office of the treating physician if the physician is unable to do so. However, as noted above, Pentec accepts traditional fee-for-service Medicaid (and Medicare) patients on a limited, compassionate care basis pursuant to existing policies that would be implemented in Tennessee. Approximately 3% of Pentec's nationwide patient census is comprised of compassionate care patients for which no reimbursement is received. Approximately 61% of its total patient census is comprised of patients for which Pentec receives compensation for some services rendered, but not all.

SUPPLEMENTAL #1
November 25, 2014
9:50 am

In other parts of the application, the applicant states that home health patients in Tennessee have limited, if any, access to intrathecal pump home infusion services and Ig-G replacement therapy services. Given the applicant's existing licensed pharmacy operations in Tennessee how have its intrathecal pump patients been receiving skilled nursing services over the past several years? Please clarify.

At present, Pentec has no intrathecal pump patients in Tennessee, and its pharmacy does not deliver intrathecal medications to Tennessee.

Pentec operates a closed-door compounding pharmacy with two locations: one at its headquarters in Boothwyn, Pennsylvania, and the other in Mansfield, Massachusetts. The pharmacy is appropriately licensed in all 50 states, including Tennessee, and the District of Columbia. Pentec's pharmacy operations in Tennessee are presently limited to Renal Nutrition. Pentec's pharmacy provides renal nutrition products (and limited DME) to patients in Tennessee. These patients are typically treated in traditional renal dialysis settings, rather than in the home.

4. Section B, Project Description, Item I

Please provide responses for each item that follows:

A. Please describe the process planned for compounding/preparation, shipping, delivery and safeguard of medications. Please describe who will be receiving the medications and the method of safeguarding shipment of same. Please also identify the name, address, license #, etc. of the pharmacy that will support the proposed Pentec HHA in Tennessee.

Pentec operates a closed-door, specialty, sterile compounding pharmacy with locations in Boothwyn, Pennsylvania and Mansfield, Massachusetts. The pharmacy is accredited by The Joint Commission and recognized as a Center of Excellence through Dynalab's Continuous Quality Improvement Program.

Every Pentec-dispensed medication starts with an individual prescription from a physician. There are multiple steps involved in the transformation of a physician's order to the end product that reaches a patient. The pharmacy is responsible for dispensing, compounding, clinical consulting and the delivery/shipping process. Every prescription is reviewed by Pentec pharmacists to ensure the following: correct dose, frequency, diluent, concentration, stability and compatibility. Medications are always prepared in an ISO Class 5 environment using strict aseptic technique to minimize any chance of contamination. Pentec compounded sterile products ("CSPs") are custom-prepared to meet the individual needs of each patient.

A detailed description of the quality assurance measures employed by Pentec's pharmacy is attached to this Supplement as Attachment to Question 4.A.

Shipping of medication from the Pentec pharmacy is scheduled in conjunction with the next scheduled patient visit through use of Pentec's electronic medical records and scheduling system. Coordinated scheduling ensures that medication is shipped shortly before it needs to be delivered and administered. All shipments of medication are packed by a registered pharmacist at the Pentec pharmacy in a cooled, sealed and tamper-proof box. In addition to the medication, the box contains syringes that will be used to administer the medication, which are protected by tamper-proof caps, and a sharps disposal container for safe and proper disposal of used syringes. The box is accompanied by a shipping manifest that includes patient name, delivery date, physician, nurse, and medication description; and three signature lines that indicate: (i) that the box was packed and checked by a Registered Pharmacist, (ii) that the box was delivered/shipped, and (iii) that it was received by the nurse. Actual shipping is by a Pentec driver or by Federal Express. The nurse verifies that the contents of the box match the shipping manifest, and then either faxes or scans / emails the signed manifest to Pentec's Specialty Infusion staff, who deliver it to the Pentec pharmacy. The Pentec pharmacy then matches its copy of the shipping manifest with the copy returned by the nurse.

In some instances, the Pentec nurse will deliver the medication to the patient and administer the medication on the day of receipt. However, if the nurse receives the medication in advance, he or she will place the medication and syringes in a small locked box that is then placed in a refrigerator for temperature control. The box requires a key to be opened. The nurse will be instructed by Pentec during his or her orientation

SUPPLEMENTAL #2
December 10, 2014
10:13 am

3. **Section B, Project Description, Item I**

Please include a brief summary of the applicant's organizational structure in the executive summary, including method for oversight by the governing body.

Pentec Health, Inc. is a Pennsylvania business corporation that was organized in 1983. Its *ownership* structure is described and depicted in the Attachment, Section A, Applicant Profile, Item 4, at pages 100-102 of Pentec's revised CON application.

Pentec is *organized* into two principal operating divisions: Specialty Infusion (which includes home health care operations) and Renal Nutrition. Both the Specialty Infusion and the Renal Nutrition divisions are headed by Robert Provonche, Executive Vice President, who reports directly to Pentec's President, CEO and Board Chairman, Joseph Cosgrove. Pentec also operates a closed-door, specialty pharmacy that supports the Specialty Infusion and Renal Nutrition divisions by compounding and supplying drugs for intrathecal delivery and renal nutrition products. Pentec's pharmacy operations are headed by Barbara Knightly, Vice President, Pharmacy, who also reports directly to the President and CEO. Pentec's nursing services, which primarily support the Specialty Infusion division, are headed by Karen McHenry, R.N., M.S.N., Vice President, Nursing Services, who reports directly to the President and CEO. Financial management of Pentec, including the Specialty Infusion division, is under the direction of Art Rea, the Chief Financial Officer. An executive-level organizational chart is attached to this Supplement No. 2 as Attachment to Question 3.

The Board of Directors provides oversight of Pentec in accordance with the requirements of Pennsylvania law. The Board has regular meetings on a quarterly basis and special meetings as needed; and also takes action in between meetings by unanimous written consent. In addition, the President and CEO (who is also Chairman of the Board of Directors) has telephone contact with various Board members on an almost-daily basis.

In addition, Pentec's nurse management team (including the Vice President of Nursing Services and the Regional Nurse Managers) meets on a weekly basis to discuss HHA matters. Information from this meeting is communicated to the HHA nursing staff during structured monthly meetings, and otherwise as needed.

to purchase the box and will be reimbursed by Pentec. On the day of the patient visit, the medication and syringes will be removed from the box, placed in a delivery bag for transportation, and taken by the nurse to the patient's treatment location for administration. Depending on the outside air temperature, the delivery bag will be placed in an insulated container to be kept cool or to avoid freezing during transport. Upon arrival at the patient's treatment location, the nurse will take the delivery bag inside. The contents will be removed and a delivery ticket will be signed by the patient (or caregiver, if applicable). The medication will then be administered by the nurse.

Pentec's Pennsylvania pharmacy would support operations in Tennessee. The pharmacy is owned by Pentec Health, Inc., and it is located at 4 Creek Parkway, Boothwyn, Pennsylvania 19061. Its Pennsylvania pharmacy license number is PP413743L, and its Tennessee pharmacy license number is 4108.

4. B. Should a patient served by Pentec require home health services for conditions other than those related to the intrathecal pump home infusion products, how does the applicant intend to respond to these needs across all counties of Tennessee based on a staff of one registered nurse in Year 1? Will these services be provided directly by the applicant's nursing staff or will the applicant seek to refer the patient out to another licensed home health agency to provide the skilled nursing care not related specifically to the infusion service?

Services will be coordinated with, and patients will be referred to, another licensed agency that can meet the other needs that patients may have not related to home infusion services. Pentec's nurse case manager will assist the patient, his or her family, and caregivers, with community resources if the need is identified. Pentec's assigned primary care nurse ensures that referrals are made as necessary, initiates and continues communication and coordination of care with others involved, and ensures the established plan of care is known and implemented in collaboration with the attending physician.

For budgeting and financial projection purposes, Pentec has allocated 1.2 FTE nurses to Tennessee for the first year of operation. However, this does not necessarily mean that one full-time nurse would be responsible for treatment of all Tennessee patients. Pentec nurses based in Kentucky, Virginia and North Carolina who are also licensed to practice in Tennessee could be assigned to specific patients, depending on location. Pentec anticipates that additional nursing staff based in Tennessee would be hired as the patient census increases. Given that patients typically require one visit every 30-60 days, statewide coverage has not proved to be a problem in any state in which Pentec operates.

4. C. **Please define specific types of services patients are likely to require and discuss what special needs and care the patient and/or caregiver will require for the proposed skilled nursing intrathecal pump and Ig_G replacement therapy services. In your response, please identify those the minimum skilled nursing activities that must be provided as a condition of HHA licensure in Tennessee such as taking & recording patient vital signs and drawing blood and other fluids for lab tests.**

The services that Pentec proposes to offer would be very limited. The primary service provided would be skilled nursing services for complex patients with severe, chronic pain or spasticity who have failed traditional therapy and who now relay on intrathecal pumps for drug delivery. As an ancillary service, Pentec would also offer immunoglobulin-G replacement therapy services, by either IV or subcutaneous infusion, to patients whose immune systems are compromised. The skilled nursing activities required in connection with treatment of these patients include:

1. Knowledge of medications administered/instilled/infused including common side effects, any possible adverse reactions, and actions to implement if an adverse reaction occurs; and educating patients, their families and caregivers with respect to the same.
2. Accessing various intrathecal pumps using supplies in appropriate kits provided by the particular intrathecal pump manufacturer.
3. Use of programmer with certain types of intrathecal pumps. (When use of a programmer is required, items that can be programmed can include medication changes and adjustments.)
4. Assessing intrathecal and intravenous access sites and surrounding areas for possible complications.
5. Taking and recording vital signs.
6. Collecting blood specimens when ordered by physician.
7. Establishing peripheral intravenous access for intravenous Ig-G infusion when patient does not present with long term access already in place.
8. Knowledge and use of an anaphylaxis kit with intravenous Ig-G when needed.
9. Basic life support: cardiopulmonary resuscitation.

4. D. Please clearly identify the responsibilities of the patient's physician, the pharmacy that will be contracted to support the HHA's specialty infusion services (including compounding pharmacy, if applicable), the home health agency (including administrator, director of nurses and home infusion RN), and any others associated with the care of the patient for intrathecal pump and Ig-G services.

The patient's physician will refer the patient to Pentec for treatment, order the patient's plan of care, and prescribe all medication to be provided to the patient. In addition, the physician will review the patient's plan of care at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

Because Pentec operates a closed-door specialty pharmacy with particular expertise in the preparation and compounding of the medications prescribed for Pentec patients, it will not be contracting with another pharmacy. Rather, Pentec's pharmacy will supply all medication required by Tennessee patients directly.

The responsibilities and required qualifications of the Administrator of the Tennessee HHA are set forth in a written job description, a copy of which is attached to this Supplement as Attachment to Question 4.D. The Administrator will designate in writing a qualified alternate who will act in the absence of the Administrator. The responsibilities and required qualifications of Pentec primary care nurses are also set forth in a written job description, a copy of which is also attached in Attachment to Question 4.D.

4. E. **Has the applicant collaborated with existing HHAs and state professional HHA association(s) to identify and assess the need for its specialty IP and Ig-G services? Were any existing service providers identified in the assessment? If so, why aren't these arrangements working in TN? Please describe the applicant's planning and research efforts in this regard in preparing for the development of its certificate of need application. In your response, please include any documentation from representatives indicating their participation in preparing an assessment of the need for the proposed HHA.**

Pentec has not collaborated with any existing Tennessee home health agencies for intrathecal pump nursing services because no existing licensed agency has the same level of expertise in this specialized area of service. Pentec is aware that Professional Home Health provides services to intrathecal pump patients in a limited number of counties in Tennessee, and that Basic Home Infusion may also provide this service in Tennessee. Coram Specialty Infusion has the capability of providing intrathecal pump services, but recently announced its decision to discontinue this service nationally.

Pentec has contracted with commercial providers of health care market intelligence to provide data with respect to intrathecal pump use nationwide.

Pentec is aware that there are established providers of Ig-G replacement therapy in Tennessee such as Coram Specialty Infusion (in Middle Tennessee). Pentec seeks authority to provide Ig-G replacement therapy as an ancillary service, particularly to "crossover" patients who have intrathecal pumps but would also benefit from Ig-G replacement therapy. To Pentec's knowledge, no licensed agency in Tennessee provides both intrathecal pump therapy and Ig-G replacement therapy.

4. F. The applicant is proposing a statewide, topographically diverse service area covering all rural and urban Tennessee counties. Discuss how the applicant's 1 registered nurse intends to service approximately 39 patients representing 234 skilled nursing visits in Year One statewide from a single location in Nashville focusing on a 24/7 hour response time?

For budgeting and financial projection purposes, Pentec has allocated 1.2 FTE nurses to Tennessee for the first year of operation. However, this does not necessarily mean that one full-time nurse would be responsible for treatment of all Tennessee patients. Pentec nurses based in Kentucky, Virginia and North Carolina who are also licensed to practice in Tennessee could be assigned to specific patients, depending on location. Further, Pentec anticipates that additional nursing staff based in Tennessee would be hired as the patient census increases. Given that patients typically require one visit every 30-60 days, statewide coverage has not proved to be a problem in any state in which Pentec operates. Pentec has established a target patient-to-nurse ratio of 40:1 in its operations in other states and has determined through experience that statewide coverage at that ratio is manageable, even in large states such as Texas.

Pentec recognizes that provision of services to patients throughout Tennessee may require its nurses to travel long distances. However, because of the nature of the services provided by Pentec and the patient population it serves, proximity of patients is much less important than would be the case with a traditional home care provider.

As noted above, patients must have their intrathecal pumps refilled and reprogrammed at regular intervals. Because consequences of a pump running dry are serious and sometimes life-threatening, this cannot be allowed to happen, and Pentec has implemented procedures to ensure that it does not happen. Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances. In addition, each Pentec primary care nurse (the nurse assigned to a particular patient) is backed up by one or more other nurses who are available to provide care to the primary care nurse's assigned patient if the need arises. Finally, Pentec has a sufficient number of nurses licensed to practice in Tennessee to ensure that full coverage is always available.

Additionally, all Pentec patients (and/or their representatives, if applicable) are educated on the signs and symptoms of medication withdrawal and overdose and the need to seek medical attention in such an event. In addition, Pentec nurses monitor pump battery life and advise patients in advance of the need to have the batteries replaced. (Intrathecal pumps are implanted surgically and batteries must be replaced in a surgical procedure.) However, a malfunction of an intrathecal pump is not an event that can be addressed by a Pentec contingency plan. As with any medical emergency, a patient with a malfunctioning intrathecal pump will need to seek immediate medical attention.

4. G. Please provide brief descriptions of the following: (1) how potential diversions will be handled such as those that could involve the loss or theft of controlled substances; (2) the level of physician involvement in the provision of services to the proposed home health agency's patients; (3) the technology to be used to facilitate the nursing service across the entire state such as the use of video conferencing during in-home patient visits.

1. Diversion

Pentec has developed a shipping, storage and delivery protocol that is designed to ensure continuous Pentec custody of all medication until the time it is administered to the patient and thereby keep the risk of loss or diversion to an absolute minimum. Shipping of medication from the Pentec pharmacy is scheduled in conjunction with the next scheduled patient visit through use of Pentec's electronic medical records and scheduling system. Coordinated scheduling ensures that medication is shipped shortly before it needs to be delivered and administered. All shipments of medication are packed by a registered pharmacist at the Pentec pharmacy in a cooled, sealed and tamper-proof box. In addition to the medication, the box contains syringes that will be used to administer the medication, and these are protected by tamper-proof caps. The box is accompanied by a shipping manifest that includes patient name, delivery date, physician, nurse, and medication description; and three signature lines that indicate: (i) that the box was packed and checked by a Registered Pharmacist, (ii) that the box was delivered/shipped, and (iii) that it was received by the nurse. Actual shipping is by a Pentec driver or by Federal Express. The nurse verifies that the contents of the box match the shipping manifest, and then either faxes or scans / emails the signed manifest to Pentec's Specialty Infusion staff, who deliver it to the Pentec pharmacy. The Pentec pharmacy then matches its copy of the shipping manifest with the copy returned by the nurse.

In some instances, the Pentec nurse will deliver the medication to the patient and administer the medication on the day of receipt. However, if the nurse receives the medication in advance, he or she will place the medication and syringes in a small locked box that is then placed in a refrigerator for temperature control. The box requires a key to be opened. The nurse will be instructed by Pentec during his or her orientation to purchase the box and will be reimbursed by Pentec. On the day of the patient visit, the medication and syringes will be removed from the box, placed in a delivery bag for transportation, and taken by the nurse to the patient's treatment location for administration. Depending on the outside air temperature, the delivery bag will be placed in an insulated container to be kept cool or to avoid freezing during transport. Upon arrival at the patient's treatment location, the nurse will take the delivery bag inside. The contents will be removed and a delivery ticket will be signed by the patient (or caregiver, if applicable). The medication will then be administered by the nurse.

In the unlikely event of theft of a controlled substance during the process described above, appropriate state or local law enforcement authorities would be notified immediately. Because patient visits are scheduled well in advance of the "alarm date" described above in the answer to Question 4.F, delivery of replacement medication would be completed sufficiently far in advance to avoid any risk to the patient.

SUPPLEMENTAL #1
November 25, 2014
9:50 am

2. Physician Involvement

The patient's physician will refer the patient to Pentec for treatment, order the patient's plan of care, and prescribe all medication to be provided to the patient. In addition, the physician will review the patient's plan of care (developed by the assigned primary care nurse with physician input) at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

Treating physicians will have 24/7 access to patient records and real-time updates following patient visits through use of Pentec's proprietary Physician Portal, located on its website, which provides physicians with secure access to patients' medical information and also allows secure, HIPAA-compliant secure, two-way videoconferencing capability ("eVisit") that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the in-home visit.

3. Technology

Pentec nurses utilize a secure HIPAA-compliant proprietary electronic medical records ("EMR") and communication system for patient care scheduling, documentation, communications, and reporting. This proprietary EMR system is purpose-built to address assessment and record keeping needs of the intrathecal pump patient. All data from a patient encounter is entered into the system by the primary care nurse to ensure accuracy and timeliness of data entry. Individual patient outcomes are recorded and tracked against the patient's plan of treatment at each encounter. All data – physical assessments, pain or Ashworth scores, pump telemetries, prescriptions, refill dates, alarm dates, etc. – are available 24/7/365 to physicians and their staff via Pentec's proprietary Physician Portal.

4. H. Please discuss how the applicant intends to develop, manage, implement, supervise and maintain patients' plans of care, including plans to manage patient pain.

The patient's plan of care is developed by the patient's primary care nurse in collaboration with the patient and his or her physician. The plan of care is implemented at the patient's start of care, and upon any changes in the patient's status or prognosis. The patient's primary care nurse manages the plan of care by initiating at the start of care and identifying and reporting any changes to the physician that could change the patient's plan of care and treatment goals. If no change to the plan of treatment is noted by the primary care nurse, the plan of care will be maintained as signed and noted during previous certification period, with renewal submitted for physician signature. Patient pain is addressed in the plan of care by intrathecal pump medications and patient treatment goals, as appropriate.

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4. I. Please identify the owner's experience in other states and identify any active licenses. Please also note the status of Medicare/Medicaid certification and accreditation. A suggested template to use is provided in the table below.

Pentec Heath Home Health and Pharmacy Licenses and Accreditation

State	Pharmacy (License #)	Home Health (License #)	Medicare and Medicaid Certified?	Accreditation?	Addresses
Alabama	112799 (Non-resident) 201458 (Mail order)	Not Required[1]	Note 4	Note 5	7101 US Hwy. 90, Suite 192 Daphne, AL 39581 2700 Corporate Dr., Suite 273 Birmingham, AL 35242
Alaska	990	NA[2]	Note 4	Note 5	
Arizona	Y004336	Not Required	Note 4	Note 5	
Arkansas	OS02201	NA	Note 4	Note 5	609 SW 8th St., 6th Floor Bentonville, AR 72712
California	NRP 740	NA	Note 4	Note 5	
Colorado	5533	04L578	Note 4	Note 5	10955 Westmoor Dr., 4th Floor Westminster, CO 80021
Connecticut	PCN.0000387	Not Required	Note 4	Note 5	
District of Columbia	NRX11004418	Pending[3]	Note 4	Note 5	1875 I St. NW, 5th Floor Washington, DC 20006
Delaware	A9-0001115	Not Required	Note 4	Note 5	
Florida	PH 17905	Not Required	Note 4	Note 5	100 West Gore St., Suite 500 Orlando, FL 32806
Georgia	Not Required	Not Required	Note 4	Note 5	
Hawaii	PMP-392	NA	Note 4	Note 5	
Idaho	2034MS	NA	Note 4	Note 5	
Illinois	54.017968	4000334	Note 4	Note 5	5600 N. River Rd., Suite 800 Rosemont, IL 60018
Indiana	64000300A	11-012608-1	Note 4	Note 5	48 N. Emerson Ave., Ste. 300 Greenwood, IN 46143
Iowa	3602	Not Required	Note 4	Note 5	305 2nd Avenue SE Cedar Rapids, IA 52401
Kansas	22-10406	A046221	Note 4	Note 5	9393 West 110th St., Ste. 500 Overland Park, KS 66210
Kentucky	PA1197	720358 (MHS)	Note 4	Note 5	
Louisiana	PHY.005655-OS	Not Required	Note 4	Note 5	1615 Poydras St., Suite 900 New Orleans, LA 70112
Maine	MO40001318	NA	Note 4	Note 5	
Maryland	P04099	R2565	Note 4	Note 5	
Massachusetts	Not Required	Not Required	Note 4	Note 5	120 Forbes Boulevard Mansfield, MA 02048
Michigan	5301008358	Not Required	Note 4	Note 5	250 Monroe NW, Suite 400 Grand Rapids, MI 49503
Minnesota	263902	29528	Note 4	Note 5	100 S. 5th St., Suite 1900 Minneapolis, MN 55402
Mississippi	04557/07.1	Not Required	Note 4	Note 5	232 Market Street Flowood, MS 39232
Missouri	2012025471	Not Required	Note 4	Note 5	
Montana	2232	NA	Note 4	Note 5	
Nebraska	603	HHA201312	Note 4	Note 5	14301 1st National Bank Pkwy. Omaha, NE 68154
Nevada	PH02052	NA	Note 4	Note 5	
New Hampshire	NR0140	03941	Note 4	Note 5	
New Jersey	28RO00021500	HP0082000	Note 4	Note 5	
New Mexico	PH00002805	Pending	Note 4	Note 5	100 Sun Ave. NE, Suite 650 Albuquerque, NM 87109

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State	Pharmacy (License #)	Home Health (License #)	Medicare and Medicaid Certified?	Accreditation?	Addresses
New York	26488	Pending	Note 4	Note 5	300 International Dr., Ste. 100 Williamsville, NY 14221
North Carolina	9320	HC4486	Note 4	Note 5	1213 Culbreth Drive, Ste. 140 Wilmington, NC 28405
North Dakota	560	NA	Note 4	Note 5	
Ohio	NTP.021460900	Not Required	Note 4	Note 5	
Oklahoma	99-1133	NA	Note 4	Note 5	
Oregon	RP-0002005-CS	NA	Note 4	Note 5	1915 NW Amber Glen, 4th Fl. Beaverton, OR 97006
Pennsylvania	PP413743L	Not Required	Note 4	Note 5	4 Creek Parkway Boothwyn, PA 19061
Rhode Island	PHN09809	NA	Note 4	Note 5	
South Carolina	13999	NA	Note 4	Note 5	220 N. Main St., Suite 500 Greenville, SC 29601
South Dakota	400-0600	Not Required	Note 4	Note 5	
Tennessee	4108	Pending	Note 4	Note 5	
Texas	23805	013924	Note 4	Note 5	18756 Stone Oak Parkway San Antonio, TX 78258 4301 Maplewood Ave., Ste. A Wichita Falls, TX 76308
Utah	6517607-1708	NA	Note 4	Note 5	222 S. Main St., 5th Floor Salt Lake City, UT 84101
Vermont	36.0086621	Not Required	Note 4	Note 5	
Virginia	214000859	HCO13944	Note 4	Note 5	7115 Leesburg Pike, Suite 201 Falls Church, VA 22043
Washington	PHNR.FO.00058078	NA	Note 4	Note 5	1201 Pacific Ave., 6th Floor Tacoma, WA 98402
West Virginia	MO0560330	Not Required	Note 4	Note 5	
Wisconsin	209-43	Not Required	Note 4	Note 5	
Wyoming		NA	Note 4	Note 5	

Notes:

1. Home Health License "Not Required" means that Pentec's Specialty Infusion operations in these states do not require licensure as a HHA under applicable state law.

2. Home Health License "NA" means that Pentec's Specialty Infusion division is not active in these states.

3. Home Health License "Pending":
   a. Pentec has received a CON (No. 14-0-1) for a HHA in the District of Columbia and has submitted its HHA licensure application, which is presently under review.
   b. Pentec has submitted HHA licensure applications in New Mexico and New York, both of which are under review.
   c. Pentec has submitted CON application CN1411-046 in Tennessee.

4. Pentec has not sought Medicare certification for HHA services, only state licensure.

5. Pentec is accredited by The Joint Commission. Pentec's accreditation certificate and letter, and related information from The Joint Commission, is attached to its application as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c.

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5. **Section B, Project Description, Item II.C.**

Please also briefly discuss the following:

A) **From the applicant's experience, please provide an estimate of the additional health care delivery cost savings, such as elimination of hospital stays, outpatient visits, etc., which could be realized by initiation of this new service.**

Pentec does not presently have data relating to cost savings realized to the health care system through elimination of unnecessary hospital stays, outpatient visits, ambulance transportation, and the like. However, through its experience in other states, Pentec has become familiar with situations in which substantial cost savings could be realized through implementation of the proposed services. In addition, research (discussed in Pentec's application at Section C, Need, Item 1) has shown that Among patients with pain and spasticity, average annual health plan expenditures are estimated to be $70,000. Over half of those expenses are for inpatient encounters that may have been averted by a more comprehensive care model such as that provided by Pentec.

B) **From the applicant's experience, please discuss how the proposed service will safeguard against potential errors, such as medication errors that could result in serious harm or death.**

All nurses attend an intensive, ANCC (American Nurses Credentialing Center) certified training program upon hire. Performance Improvement initiatives focus on patient safety to ensure safe patient care. Those initiatives include, but are not limited to, root-cause analysis, safety checklist implementation, chart audits, and self-learning modules to enhance learning and promote excellent, safe, quality care. A copy of Pentec's Nurse Training Program Policy and Procedure, describing its ANCC-certified training program, is attached to this Supplement as Attachment to Question 5.B.

C) **Please describe how the governing body of the proposed HHA will monitor and enforce compliance with all patient safety standards of care that apply to the project.**

The Board of Directors of Pentec Health, Inc., its governing body, oversees all standards of care involving patient safety with direct reports from Pentec's executive team, including the Vice President of Nursing and Vice President of Pharmacy. The Board also receives direct reports from the Pharmacy and Specialty Infusion divisions quarterly as part of Pentec's ongoing corporate performance improvement process, as documented in its annual Performance Improvement Plan. In addition, the Board receives direct reports from Pentec's Corporate Compliance officer with details of process improvement initiatives and demonstrations of continued compliance. A copy of Pentec's 2014 Performance Improvement Plan is attached to this Supplement as Attachment to Question 5.C.

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5. D) **Please identify any plans for the use of telemedicine to support patient care activities. What measures will be taken to ensure that the applicant and physicians participating in this service will comply with the Department of Health's Board of Medical Examiner's Rules (0880-02-.16) for registration & licensing? What measures will be taken to comply with patient confidentiality?**

Pentec anticipates that its Tennessee patient referrals would come from physicians located within Tennessee, and, as such, the Telemedicine Licensure rules set forth at Section 0880-02-.16 of the Rules of the Tennessee Board of Medical Examiners would not be implicated. That said, through its experience in other states, Pentec is aware that intrathecal pump patients, in particular, are sometimes required to travel across state lines for treatment and could benefit from in-home treatment. In any such situation involving a Tennessee resident and an out-of-state physician referred to Pentec for treatment in Tennessee, Pentec would ascertain prior to the start of care, through consultation with the referring and a licensure check whether 1) the out-of-state physician is duly licensed in accordance with Section 0880-02-.06(2), or 2) one of the exemptions from licensure set forth at Section 0880-02-.06(6) applies.

In the event that an out-of-state were to use Pentec's videoconferencing capability through its Physician Portal in connection with the practice of telemedicine, the communication is secure. Pentec's eVisit platform utilizes HIPAA compliant Hypertext Transfer Protocol Secure (HTTPS) communications protocol for secure video conferencing with the patient's care team directly from a patient's home during a visit. For maximum patient confidentiality, Pentec only facilitates this service with patient, Pentec care team (nurse, pharmacist) and the patient's physician. Conferences are not recorded.

6. **Section B, Project Description, Item V (Home Health Agency)**

Item 4 – Please explain the rationale for a parent office without any branch offices located in the applicant's proposed 95 county state-wide service area. What consideration was given to locating branch offices in distinct geographic areas, in order to reduce driving times or distance requirements, and ensure access to a sufficient workforce such as nursing staff for skilled nursing services?

As discussed in greater detail in the answer to Question 4.F, Pentec recognizes that provision of services to patients throughout Tennessee may require its nurses to travel long distances. However, because of the nature of the services provided by Pentec and the patient population it serves, proximity of patients is much less important than would be the case with a traditional home care provider. Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances. In addition, each Pentec primary care nurse (the nurse assigned to a particular patient) is backed up by one or more other nurses who are available to provide care to the primary care nurse's assigned patient if the need arises. Finally, Pentec has a sufficient number of nurses licensed to practice in Tennessee to ensure that full coverage is always available.

Because of the nature of the services provided, Pentec nurses do not necessarily travel from an office to conduct patient visits, and Pentec has not found branch offices to be necessary in other large states. That said, Pentec has considered branch or second offices in jurisdictions with regional licensure requirements. For example, Pentec is presently considering the opening of a second office in Kansas in order to serve patients in the central part of that state.

7. **Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services, Items 1 through 4)**

   Based on the applicant's experience with home health agency operations in other states such as Alabama, Virginia, and North Carolina, please complete the table below to identify some of the key obstacles the applicant has encountered in other states:

	2012	2013
Total intrathecal pump (IP) home infusion patients	1,783	2,177
Number of IP home patients whose infusion has been delayed	0	0
Number of days of delay in initiation of IP home infusion services	0	0
Number of additional days in the hospital due to delays in initiation of IP services	NA	NA

All *initial* intrathecal pump therapy service is done by the patient's physician, Pentec does not initiate these services in a hospital setting or otherwise. Therefore, there are no delays relating to the initiation of intrathecal pump therapy services to report. Moreover, the possibility of intrathecal pump patients experiencing delays in subsequent treatment is eliminated by careful coordination of patient care with treating physicians as the key to prevention. Also, Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances occur.

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Review of the Tennessee Department of Health "Licensed Facilities" report on the Department's website revealed that there are approximately 157 home health agencies (HHA) presently licensed to serve In Tennessee.

Because the scope of the project includes the creation of a home health agency, the applicant must include all existing licensed HHAs authorized to serve the statewide service area in order to apply the need formula correctly and identify the net need for any additional agencies at this time and four years in the future (CY2018).

Please complete the table in Exhibit 1 below by identifying all licensed home health agencies, the counties they are licensed to serve, and their most recent utilization as reported to the Department of Health in the Joint Annual Report (JAR).

Exhibit 1

Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Accredo Health Group, Inc.	79456	Shelby	6 (6)	9	14	20
Advanced Home Care, Inc.	82051	Sullivan	8 (8)	2,825	2,583	2,245
Advanced Home Care, Inc.	30021	Greene	4 (4)	385	526	762
Alere Women's and Children's Health, LLC	33423	Hamilton	13 (13)	18	52	74
Alere Women's and Children's Health	79466	Shelby	7 (7)	357	401	417
Alere Women's and Children's Health, LLC	19654	Davidson	14 (14)	140	196	202
Amedisys Home Health	67024	Overton	11 (11)	1325	1277	1453
Amedisys Home Care	26054	Franklin	15 (15)	1015	1074	1150
Amedisys Home Care	79146	Shelby	3 (3)	882	938	1060
Amedisys Home Health	19674	Davidson	14 (14)	2834	2943	5182
Amedisys Home Health	90121	Washington	6 (6)	2496	2384	1821
Amedisys Home Health	33103	Hamilton	19 (19)	3358	3342	2878
Amedisys Home Health	79386	Shelby	4 (4)	2411	1806	1934
Amedisys Home Health	75054	Rutherford	7 (7)	543	554	661
Amedisys Home Health Care	47202	Knox	27 (27)	5267	5420	5354
Amedisys Home Health Care	57075	Madison	19 (19)	2489	2586	2741
Amedisys Home Health Care	10031	Carter	7 (7)	1241	1147	1171
Amedisys Home Health Care	75064	Rutherford	17 (17)	1476	1431	1582
Amedisys Home Health Care	32102	Hamblen	13 (13)	3613	3675	3896
Amedisys Home Health Care	79246	Shelby	3 (3)	576	683	936
Amedisys Home Health of Tennessee	13022	Claiborne	5 (5)	1730	2074	1830
Amedisys Home Health Svcs.	19684	Davidson	10 (10)	756	388	23
Americare Home Health Agency, Inc.	79256	Shelby	2 (2)	1324	1727	1811

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Baptist Home Care and Hospice - Covington	84046	Tipton	5 (5)	326	361	353
Baptist Memorial Home Care	09065	Carroll	11 (11)	235	213	262
Baptist Trinity Home Care	79276	Shelby	3 (3)	3248	3367	3862
Baptist Trinity Home Care - Private Pay Division	79446	Shelby	1 (1)	1	1	1
Best Nurses, Inc.	79546	Shelby	3 (3)	311	366	364
Blount Memorial Hospital Home Health Services	05012	Blount	19 (19)	1357	1308	1224
C.M.C. Home C.A.R.E.	18054	Cumberland	1 (1)	536	409	407
Camellia Home Health of East Tennessee, LLC	47062	Knox	22 (22)	1448	1556	1716
CareAll	19724	Davidson	21 (21)	-	-	1562
Careall Home Care Services	89074	Warren	8 (8)	520	337	637
CareAll Home Care Services	47232	Knox	6 (6)	257	278	510
CareAll Homecare Services	84076	Tipton	14 (14)	1491	1103	1556
CareAll Home Care Services	92025	Weakley	12 (12)	1903	2668	2036
CareAll Homecare Services	60074	Maury	11 (11)	285	224	609
Caresouth HHA Holdings of Winchester, LLC	26024	Franklin	35 (35)	1395	1371	2030
Suncrest Home Health	13032	Claiborne	11 (11)	436	581	852
Clinich River Home Heath	01032	Anderson	7 (7)	473	468	461
Continucare Healthservices, Inc. - I	33213	Hamilton	8 (8)	1638	1494	1466
Continucare Healthservices, Inc. - II	33383	Hamilton	11 (11)	21	17	8
Continuous Care Services, LLC	19664	Davidson	6 (6)	905	671	407
Coram Specialty Infusion Services	19734	Davidson	37 (37)	-	-	11
Covenant Homecare	47402	Knox	16 (16)	3838	3946	3953
Cumberland River Homecare	14024	Clay	10 (10)	361	236	392
Deaconess Homecare II	36025	Hardin	11 (11)	1213	1244	1330
Deaconess Homecare	76032	Scott	5 (5)	406	352	394
Deaconess Homecare	52024	Lincoln	24 (24)	712	704	842
Deaconess Homecare	95034	Wilson	21 (21)	1237	1210	1222
East Tennessee Children's Hospital Home Health Care	47222	Knox	16 (16)	671	559	586
Extended Health Care, Inc.	79136	Shelby	6 (6)	780	341	79
Elk Valley Health Services, LLC	19494	Davidson	95 (95)	250	245	277
Lifeline of West Tenn., LLC	57095	Madison	20 (20)	962	993	1085
Extendicare Home Health Care of Union City, LLC	66035	Obion	5 (5)	398	347	302
Family Home Care, Cleveland	06043	Bradley	5 (5)	673	1023	598
Family Home Health Agency	79206	Shelby	1 (1)	375	863	379
Friendship Home Health, Inc.	89084	Warren	10 (10)	1025	1345	1724
Friendship Home Healthcare, Inc.	19614	Davidson	14 (14)	1040	1093	845

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Angel Private Duty and Home Health, Inc.	19714	Davidson	24 (24)	10	73	123
Functional Independence Home Care, Inc.	79496	Shelby	3 (3)	729	804	953
Gateway Home Health, Clarksville	63034	Montgomery	7 (7)	1050	1067	949
Gentiva Health Services	19084	Davidson	12 (12)	1239	1239	1003
Gentiva Health Services	47042	Knox	16 (16)	898	870	779
Gentiva Health Services	16024	Coffee	9 (9)	726	629	424
Gentiva Health Services	33093	Hamilton	12 (12)	487	268	328
Gentiva Health Services	82061	Sullivan	9 (9)	1286	979	936
Gentiva Health Services	95074	Wilson	15 (15)	1705	1482	1380
The Home Option by Harden Health Care	47372	Knox	8 (8)	0	1	29
Girling Health Care, Inc.	47182	Knox	18 (18)	1093	1031	1467
Guardian Home Care of Nashville, LLC	94074	Williamson	15 (15)	1265	1365	1370
Guardian Home Care, LLC	33083	Hamilton	9 (9)	2179	2116	1484
Hancock County Home Health Agency	34011	Hancock	4 (4)	297	323	463
Henry County Medical Center Home Health	40075	Henry	5 (5)	355	399	363
Heritage Home Health	02024	Bedford	6 (6)	282	280	241
Hickman Community Home Care, Inc.	41034	Hickman	7 (7)	146	134	214
Highland Rim Home Health Agency	71014	Putnam	7 (7)	555	495	574
HMC Home Health, LLC	36035	Hardin	5 (5)	252	274	341
Home Care of Chattanooga	33133	Hamilton	3 (3)	208	119	269
Home Health Care of East Tennessee, Inc.	06063	Bradley	17 (17)	4764	4755	3318
Home Health Care of Middle Tennessee, LLC	19584	Davidson	14 (14)	4246	3914	2963
Home Health Care of West Tennessee, Inc.	79486	Shelby	4 (4)	1308	1118	1010
Health at Home	94094	Williamson	1 (1)	63	50	58
Homechoice Health Services	79376	Shelby	6 (6)	2887	1788	861
Hometown Home Health Care, Inc.	37021	Hawkins	3 (3)	173	-	89
Innovative Senior Care Home Health	19504	Davidson	22 (22)	73	504	677
Interim Healthcare of Memphis, Inc.	79056	Shelby	3 (3)	720	889	769
Intrepid USA Healthcare Services	62052	Monroe	15 (15)	238	259	358
Intrepid USA Healthcare Services	71084	Putnam	8 (8)	244	341	327
Intrepid USA Healthcare Services	79226	Shelby	4 (4)	662	615	605
Intrepid USA Healthcare Services	57165	Madison	15 (15)	294	86	422
Intrepid USA Healthcare Services	19364	Davidson	11 (11)	644	920	766
Intrepid USA Healthcare Services	89064	Warren	11 (11)	650	159	822

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Johnson County Home Health	46031	Johnson	3 (3)	403	396	446
Laughlin Home Health Agency	30041	Greene	5 (5)	553	547	655
Home Care Solutions	19544	Davidson	46 (46)	2192	2080	1930
Home Care Solutions	33363	Hamilton	10 (10)	727	734	663
Life Care at Home of Tennessee	33303	Hamilton	10 (10)	616	989	956
Lifeline Home Health Care	74064	Robertson	5 (5)	289	336	428
Lincoln Medical Home Health and Hospice	52044	Lincoln	7 (7)	356	396	348
Magnolia Regional Health Center Home Health and Hospice Agency	96010	Unknown	2 (2)	1000	915	856
Maury Regional Home Services	60044	Maury	8 (8)	1188	1220	1151
Maxim Healthcare Services	33433	Hamilton	8 (8)	71	150	56
Maxim Healthcare Services, Inc.	47432	Knox	18 (18)	159	150	159
Maxim Healthcare Services, Inc.	79536	Shelby	6 (6)	103	197	155
Maxim Healthcare Services, Inc.	19704	Davidson	9 (9)	138	141	106
Medical Center Home Health, LLC	57055	Madison	14 (14)	1403	1617	1706
Medical Center Homecare Services	90091	Washington	5 (5)	2801	3118	3503
Medical Center Homecare, Kingsport	90081	Washington	7 (7)	1126	1628	1960
Memorial Hospital Home Health	33253	Hamilton	10 (10)	3469	3264	2439
Tennove Home Health	47092	Knox	14 (14)	3586	3188	3063
Methodist Alliance Home Care	79316	Shelby	3 (3)	3226	3180	3179
University of TN Medical Center Home Health Services	32122	Hamblen	10 (10)	986	1244	1327
NHC Homecare	60024	Maury	22 (22)	2212	2134	2408
NHC Homecare	27025	Gibson	12 (12)	479	625	569
NHC Homecare	54043	McMinn	8 (8)	221	183	239
NHC Homecare	24026	Fayette	8 (8)	254	217	226
NHC Homecare	75024	Rutherford	24 (24)	3007	3269	3776
NHC Homecare	90131	Washington	7 (7)	241	264	259
NHC Homecare	47012	Knox	15 (15)	575	567	613
NHC Homecare	33033	Hamilton	10 (10)	199	203	354
NHC Homecare	74054	Robertson	6 (6)	867	909	1332
No Place Like Home, Inc.	79506	Shelby	3 (3)	38	55	58
Premier Support Services	32132	Hamblen	16 (16)	972	900	1169
Premiere Home Health, Inc.	19374	Davidson	1 (1)	118	81	87
Procare Home Health Services	30051	Greene	6 (6)	418	384	433
Professional Case Management of Tennessee	01042	Anderson	11 (11)	127	182	164
Professional Home Health Care Agency, Inc.	96030	Unknown	2 (2)	3021	2985	2641
American National Home Health	95084	Wilson	9 (9)	217	358	311
Quality First Home Care	60084	Maury	5 (5)	906	855	923

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Quality Home Health	25044	Fentress	13 (13)	4540	4012	3404
Quality Private Duty Care	25034	Fentress	9 (9)	599	703	879
Regional Home Care Parkway	96020	Unknown	1 (1)	31	14	28
Regional Home Care, Jackson	57085	Madison	15 (15)	1206	1061	1164
Regional Home Care, Lexington	39035	Henderson	22 (22)	578	616	569
Regional Home Care, Dyersburg	23035	Dyer	6 (6)	744	814	707
Senior Services Home Health	79106	Shelby	1 (1)	642	697	609
Smoky Mountain Home Health and Hospice, Inc.	15032	Cocke	12 (12)	1622	1535	1296
Still Waters Home Health Agency	79526	Shelby	1 (1)	105	127	101
Highpoint Homecare	80064	Smith	8 (8)	312	280	377
Highpoint Homecare	83114	Sumner	6 (6)	978	738	855
Sunbelt Homecare	07032	Campbell	7 (7)	285	260	261
SunCrest Home Health	21024	DeKalb	7 (7)	1406	1501	1568
SunCrest Home Health	19324	Davidson	12 (12)	5428	6710	5490
SunCrest Home Health of Manchester, Inc.	16034	Coffee	15 (15)	988	1114	1588
SunCrest Home Health of Nashville, Inc.	63044	Montgomery	6 (6)	229	381	587
Sweetwater Hospital Home Health	62062	Monroe	5 (5)	462	569	613
Tennessee Quality Homecare – Northwest	03025	Benton	15 (15)	1129	1128	1164
Tennessee Quality Homecare - Southwest	20045	Decatur	15 (15)	1352	1082	1080
Unicoi County Home Health	86051	Unicoi	1 (1)	246	209	206
University of TN Medical Center Home Care Services - Home Health	47132	Knox	15 (15)	2530	3264	3439
Vanderbilt Community and Home Services	19394	Davidson	7 (7)	1179	1230	1879
Vanderbilt Home Care Services	19314	Davidson	7 (7)	1180	1268	1812
Volunteer Home Care, Inc.	27085	Gibson	13 (13)	2549	3027	3041
Volunteer Homecare of West Tennessee, Inc.	20055	Decatur	13 (13)	1598	1503	1534
Vanderbilt HC Affiliated Walgreens IV and RT Services	94084	Williamson	33 (33)	81	86	67
Where The Heart Is, Inc.	24036	Fayette	3 (3)	253	271	116
Willowbrook Home Health Care Agency, Inc.	19694	Davidson	36 (36)	3088	2149	1565
Willowbrook Visiting Nurse Association, Inc.	79236	Shelby	6 (6)	473	533	479
Woods Home Health, LLC	54083	McMinn	4 (4)	297	349	283

** Please highlight any HHA in bold font that offers intrathecal home infusion services, even if on a limited basis.*
*** Please show the # of all counties for each HHA. The # of counties in the applicant's service area should be shown separately in the bracket.*

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Please complete the Exhibit 2 below identifying the estimated need in each county of the applicant's proposed statewide service area. The response should incorporate the need estimate prepared by TDH that is attached with this questionnaire. A suggested template to be used for the response is noted in the table below.

Exhibit 2
Home Health Need Formula in the Applicant's 95-County Service Area

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Tennessee	1,619	1,457	175,924	6,528,014	0.0269	6,833,509	184,157	102,503	(81,654)
Anderson	22	19	2,893	76,182	0.0380	77,851	2,956	1,168	(1,789)
Bedford	20	19	1,120	46,700	0.0240	50,566	1,213	758	(454)
Benton	11	10	667	16,315	0.0409	16,104	658	242	(417)
Bledsoe	10	8	462	12,698	0.0364	12,599	458	189	(269)
Blount	18	18	2,507	126,809	0.0198	135,171	2,672	2,028	(645)
Bradley	16	14	2,021	102,235	0.0198	107,481	2,125	1,612	(512)
Campbell	21	18	1,715	41,163	0.0417	42,566	1,773	638	(1,135)
Cannon	19	16	423	14,013	0.0302	14,540	439	218	(221)
Carroll	13	13	1,246	28,213	0.0442	27,831	1,229	417	(812)
Carter	12	11	2,072	57,228	0.0362	57,680	2,088	865	(1,223)
Cheatham	24	25	772	39,603	0.0195	40,765	795	611	(183)
Chester	14	13	563	17,355	0.0324	17,999	584	270	(314)
Claiborne	19	15	2,002	32,457	0.0617	33,280	2,053	499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673	249	115	(133)
Cocke	16	14	1,467	36,330	0.0404	38,615	1,559	579	(980)
Coffee	20	16	1,874	53,784	0.0348	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0369	14,683	541	220	(321)
Cumberland	15	13	1,601	57,370	0.0279	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0230	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0542	12,080	655	181	(473)
DeKalb	21	16	469	18,918	0.0248	19,125	474	287	(187)
Dickson	25	24	1,617	50,596	0.0320	51,964	1,661	779	(881)
Dyer	11	10	1,671	38,205	0.0437	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0178	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0346	42,122	1,459	632	(828)
Gibson	15	14	1,924	50,748	0.0379	52,163	1,978	782	(1,195)
Giles	12	11	1,001	29,325	0.0341	29,285	1,000	439	(560)
Grainger	22	20	886	22,994	0.0385	23,675	912	355	(557)
Greene	20	17	2,454	69,888	0.0351	71,594	2,514	1,074	(1,440)
Grundy	18	16	529	13,396	0.0395	13,293	525	199	(326)
Hamblen	19	17	2,835	63,763	0.0445	65,570	2,915	984	(1,932)
Hamilton	16	16	8,038	345,447	0.0233	353,577	8,227	5,304	(2,924)
Hancock	14	11	682	6,652	0.1025	6,640	681	100	(581)
Hardeman	17	15	917	26,492	0.0346	26,067	902	391	(511)
Hardin	16	14	1,157	25,968	0.0446	26,244	1,169	394	(776)

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Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Hawkins	21	18	2,148	57,273	0.0375	58,164	2,181	872	(1,309)
Haywood	15	13	612	18,199	0.0336	18,009	606	270	(335)
Henderson	14	13	1,015	28,080	0.0361	28,631	1,035	429	(605)
Henry	10	10	1,283	32,595	0.0394	32,956	1,297	494	(803)
Hickman	18	17	725	24,393	0.0297	24,698	734	370	(364)
Houston	12	11	281	8,358	0.0336	8,447	284	127	(157)
Humphreys	16	14	803	18,488	0.0434	18,561	806	278	(528)
Jackson	12	11	402	11,355	0.0354	11,495	407	172	(235)
Jefferson	20	19	1,749	53,006	0.0330	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
Lake	6	5	325	9,795	0.0332	9,468	314	142	(172)
Lauderdale	14	11	857	27,465	0.0312	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0394	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0332	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0313	35,697	1,116	535	(580)
Loudon	23	21	1,572	50,356	0.0312	53,192	1,661	798	(863)
McMinn	17	17	1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315	101,001	3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256	28,992	743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomery	19	20	2,903	184,087	0.0158	200,561	3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216	22,004	476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	(141)
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256	16,588	425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)

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Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Stewart	10	10	339	13,436	0.0252	13,941	352	209	(143)
Sullivan	14	13	5,259	158,451	0.0332	161,136	5,348	2,417	(2,931)
Sumner	26	27	4,160	169,409	0.0246	183,406	4,504	2,751	(1,753)
Tipton	26	22	1,298	63,001	0.0206	67,545	1,392	1,013	(378)
Trousdale	16	14	431	8,046	0.0536	8,582	460	129	(331)
Unicoi	13	11	659	18,334	0.0359	18,511	665	278	(388)
Union	21	18	371	19,231	0.0193	19,605	378	294	(84)
Van Buren	12	11	240	5,456	0.0440	5,474	241	82	(159)
Warren	20	15	2,266	40,299	0.0562	41,155	2,314	617	(1,697)
Washington	16	14	4,181	128,537	0.0325	138,370	4,501	2,076	(2,425)
Wayne	11	9	640	16,887	0.0379	16,724	634	251	(383)
Weakley	13	11	1,180	38,255	0.0308	39,491	1,218	592	(626)
White	14	9	962	26,612	0.0361	27,974	1,011	420	(592)
Williamson	32	32	2,815	198,045	0.0142	223,333	3,174	3,350	176
Wilson	28	31	3,727	121,626	0.0306	133,357	4,086	2,000	(2,086)

*Most recent year of Joint Annual Report data for Home Health Agencies

Data is projected four years from the year the Home Health data was **finalized, not the actual year of Home Health data.

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8. **Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)**

   The applicant notes that letters of support will be provided. In addition to letters from physicians, written support from other referral sources such as hospitals and HHAs, and patients would be helpful. Please note the following:

   A. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

   Pentec's regional manager for Specialty Infusion with responsibility for Tennessee has called on physicians and other referral sources throughout Tennessee, and is in the process of obtaining the required letters. These will be provided as a supplement as soon as available.

   B. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

   As noted above, these will be provided as a supplement as soon as available.

9. **Section C. Need, Item 1 (Specific Criteria: Home Health Services - Items 6a and 6b)**

Based on the response, it appears that a billed cost for 39 intrathecal pump patients would amount to approximately $578,214.00 in Year 1 of the project ($2,471 per visit x average of 6 visits per patient x 39 patients). However, the Projected Data Chart on page 18 of the application identifies $304,573.00 in gross revenue. What accounts for the significant difference between these amounts?

The gross revenue amount of $304,573 in the Projected Data Chart is based on a Year 1 ***average*** patient census of 20.2 intrathecal pump patients, not 39 patients. Pentec projects that the intrathecal pump patient census would be 5 at the beginning of Year 1 and would increase to 39 by the ***end*** of Year 1.

The applicant intends to charge and file claims for IP services to commercial payors and managed care organizations. Given Pentec's existing pharmacy activities in TN, what is the applicant's experience with reimbursement for intrathecal pump and Ig-G covered services in Tennessee? How does this level of reimbursement compare to allowable charges covered by Medicare for Medicare patients who receive IP home infusion and/or Ig-G services?

Pentec's pharmacy operations in Tennessee are presently limited to Renal Nutrition. Pentec's pharmacy provides renal nutrition products (and limited DME) to patients in Tennessee. However, at present, Pentec has no intrathecal pump patients in Tennessee, and its pharmacy does not deliver intrathecal medications to Tennessee. Pentec also has no Ig-G replacement therapy patients in Tennessee. Consequently, Pentec does not have experience with reimbursement for medication used in connection with these therapies, or for the services themselves, in Tennessee.

However, Pentec is aware from its experience in other states that the levels of reimbursement by commercial insurers vs. the federal Medicare and state Medicaid programs are very different for infusion services. Currently, Medicare does not cover the administration of Ig-G replacement therapy in the home, and requires that a pump be used for administration (unless delivery is subcutaneous), but does not cover the pump equipment or the nursing services; only the drug is reimbursable. The same is applicable for to intrathecal pump refills, as only the drug and the administration kit (a syringe and other low-cost disposable items) are reimbursable by Medicare. Overall, reimbursement is approximately 25% of what commercial payors who recognize the HIPAA standard code sets allow.

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10. Section C, Need, Item 3

This question asks applicants to identify and justify the reasonableness of the proposed service area.

What is the source of the data supporting the applicant's estimate of 1,976 intrathecal pump patients and 1,020 Ig-G patients in Tennessee as noted on page C.II.2 of the application? Using this estimate, please justify the statewide service area by providing a breakout of patients by patient county of residence for the first year of the project.

Pentec has contracted with a commercial provider of health care market intelligence that is the source of the number of intrathecal pump patients (1,876) in Tennessee. The estimated number of Ig-G replacement therapy patients in Tennessee was calculated on the basis of population and national usage of immunoglobulin-G. This calculation assumes that Tennessee represents approximately 2% of national usage of 55 million grams of Ig-G per year. This amount would be 1.1 million grams per year, or 91,667 grams per month. Assuming use of 90 grams per month per patient, Pentec arrives at the estimate of 1,020 patients.

Per telephone conversation with Mr. Grimm on November 19, 2014, Pentec is providing an estimated breakout of intrathecal pump patients for the first year of the project by Grand Division. Because Ig-G replacement therapy would be offered as an ancillary service, Pentec has assumed for purposes of its projections that no Ig-G patients would be on service in Year 1.

Grand Division	# of Intrathecal Pump patients	# of Ig-G patients
East Tennessee	17	0
Middle Tennessee	14	0
West Tennessee	8	0
Total	39	0

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Using current and projected population data from the Department of Health; and the most recent enrollee data from the Bureau of TennCare and demographic information from the US Census Bureau, complete the following table and include data for each county in your proposed service area:

Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Tennessee	**6,588,698**	**6,649,438**	**0.9%**	**6,588,698**	**6,649,438**	**0.9%**	**100.0%**	**36.7**	**$44,140**	**1,241,028**	**18.8%**	**1,139,845**	**17.3%**
Anderson	76,579	76,949	0.5%	76,579	76,949	0.5%	1.2%	36.7	$44,154	14,289	18.7%	12,789	16.7%
Bedford	47,368	48,099	1.5%	47,368	48,099	1.5%	0.7%	36.7	$39,635	11,025	23.3%	8,953	18.9%
Benton	16,257	16,208	-0.3%	16,257	16,208	-0.3%	0.2%	36.7	$33,663	3,528	21.7%	3,316	20.4%
Bledsoe	12,641	12,610	-0.2%	12,641	12,610	-0.2%	0.2%	36.7	$31,388	2,890	22.9%	2,920	23.1%
Blount	128,368	129,973	1.3%	128,368	129,973	1.3%	2.0%	36.7	$46,347	19,380	15.1%	16,303	12.7%
Bradley	103,308	104,364	1.0%	103,308	104,364	1.0%	1.6%	36.7	$40,614	18,850	18.2%	18,389	17.8%
Campbell	41,474	41,783	0.7%	41,474	41,783	0.7%	0.6%	36.7	$31,312	11,805	28.5%	9,829	23.7%
Cannon	14,125	14,218	0.7%	14,125	14,218	0.7%	0.2%	36.7	$40,998	2,643	18.7%	2,317	16.4%
Carroll	28,119	28,012	-0.4%	28,119	28,012	-0.4%	0.4%	36.7	$35,595	6,895	24.5%	5,399	19.2%
Carter	57,284	57,359	0.1%	57,284	57,359	0.1%	0.9%	36.7	$32,908	11,564	20.2%	13,061	22.8%
Cheatham	39,853	40,088	0.6%	39,853	40,088	0.6%	0.6%	36.7	$53,363	6,453	16.2%	4,663	11.7%
Chester	17,472	17,593	0.7%	17,472	17,593	0.7%	0.3%	36.7	$42,097	3,463	19.8%	2,953	16.9%
Claiborne	32,604	32,765	0.5%	32,604	32,765	0.5%	0.5%	36.7	$33,568	8,121	24.9%	7,499	23.0%
Clay	7,702	7,681	-0.3%	7,702	7,681	-0.3%	0.1%	36.7	$30,184	1,965	25.5%	1,517	19.7%
Cocke	36,762	37,207	1.2%	36,762	37,207	1.2%	0.6%	36.7	$29,764	10,184	27.7%	9,558	26.0%
Coffee	54,273	54,817	1.0%	54,273	54,817	1.0%	0.8%	36.7	$38,151	11,343	20.9%	11,180	20.6%
Crockett	14,596	14,611	0.1%	14,596	14,611	0.1%	0.2%	36.7	$37,601	3,578	24.5%	2,802	19.2%
Cumberland	57,815	58,340	0.9%	57,815	58,340	0.9%	0.9%	36.7	$37,963	10,735	18.6%	9,482	16.4%
Davidson	656,385	663,151	1.0%	656,385	663,151	1.0%	10.0%	36.7	$46,676	124,103	18.9%	121,431	18.5%
Decatur	11,822	11,883	0.5%	11,822	11,883	0.5%	0.2%	36.7	$34,146	2,564	21.7%	2,471	20.9%
DeKalb	18,952	18,996	0.2%	18,952	18,996	0.2%	0.3%	36.7	$36,713	4,629	24.4%	3,601	19.0%
Dickson	50,860	51,127	0.5%	50,860	51,127	0.5%	0.8%	36.7	$45,109	9,368	18.4%	8,138	16.0%

Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Dyer	38,218	38,246	0.1%	38,218	38,246	0.1%	0.6%	36.7	$38,167	9,393	24.6%	7,338	19.2%
Fayette	40,930	41,835	2.2%	40,930	41,835	2.2%	0.6%	36.7	$56,297	6,089	14.9%	5,403	13.2%
Fentress	18,404	18,553	0.8%	18,404	18,553	0.8%	0.3%	36.7	$27,773	5,426	29.5%	4,675	25.4%
Franklin	41,230	41,391	0.4%	41,230	41,391	0.4%	0.6%	36.7	$41,625	6,675	16.2%	6,556	15.9%
Gibson	51,102	51,412	0.6%	51,102	51,412	0.6%	0.8%	36.7	$36,981	11,662	22.8%	9,505	18.6%
Giles	29,315	29,293	-0.1%	29,315	29,293	-0.1%	0.4%	36.7	$38,014	5,312	18.1%	5,453	18.6%
Grainger	23,111	23,236	0.5%	23,111	23,236	0.5%	0.3%	36.7	$33,185	5,118	22.1%	4,668	20.2%
Greene	70,187	70,520	0.5%	70,187	70,520	0.5%	1.1%	36.7	$35,613	13,214	18.8%	15,792	22.5%
Grundy	13,355	13,322	-0.2%	13,355	13,322	-0.2%	0.2%	36.7	$26,644	4,443	33.3%	3,873	29.0%
Hamblen	64,108	64,438	0.5%	64,108	64,438	0.5%	1.0%	36.7	$39,316	13,519	21.1%	11,924	18.6%
Hamilton	347,451	349,273	0.5%	347,451	349,273	0.5%	5.3%	36.7	$46,544	57,298	16.5%	56,287	16.2%
Hancock	6,652	6,645	-0.1%	6,652	6,645	-0.1%	0.1%	36.7	$22,205	2,209	33.2%	2,175	32.7%
Hardeman	26,359	26,231	-0.5%	26,359	26,231	-0.5%	0.4%	36.7	$31,963	6,309	23.9%	6,063	23.0%
Hardin	26,012	26,075	0.2%	26,012	26,075	0.2%	0.4%	36.7	$33,044	6,410	24.6%	5,775	22.2%
Hawkins	57,509	57,741	0.4%	57,509	57,741	0.4%	0.9%	36.7	$36,419	12,015	20.9%	9,431	16.4%
Haywood	18,117	18,044	-0.4%	18,117	18,044	-0.4%	0.3%	36.7	$32,827	5,355	29.6%	3,841	21.2%
Henderson	28,186	28,279	0.3%	28,186	28,279	0.3%	0.4%	36.7	$37,784	6,199	22.0%	4,933	17.5%
Henry	32,697	32,766	0.2%	32,697	32,766	0.2%	0.5%	36.7	$36,593	7,157	21.9%	5,689	17.4%
Hickman	24,422	24,465	0.2%	24,422	24,465	0.2%	0.4%	36.7	$42,330	5,462	22.4%	3,981	16.3%
Houston	8,388	8,413	0.3%	8,388	8,413	0.3%	0.1%	36.7	$34,595	1,692	20.2%	1,820	21.7%
Humphreys	18,498	18,519	0.1%	18,498	18,519	0.1%	0.3%	36.7	$41,943	3,605	19.5%	2,590	14.0%
Jackson	11,368	11,383	0.1%	11,368	11,383	0.1%	0.2%	36.7	$33,363	2,581	22.7%	2,740	24.1%
Jefferson	53,729	54,482	1.4%	53,729	54,482	1.4%	0.8%	36.7	$38,800	10,568	19.7%	10,316	19.2%
Johnson	18,094	18,090	0.0%	18,094	18,090	0.0%	0.3%	36.7	$30,063	4,009	22.2%	4,596	25.4%
Knox	453,629	459,124	1.2%	453,629	459,124	1.2%	6.9%	36.7	$47,270	65,007	14.3%	64,415	14.2%
Lake	9,732	9,676	-0.6%	9,732	9,676	-0.6%	0.1%	36.7	$26,212	2,012	20.7%	2,949	30.3%
Lauderdale	27,341	27,264	-0.3%	27,341	27,264	-0.3%	0.4%	36.7	$32,987	7,108	26.0%	7,136	26.1%

Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Lawrence	42,329	42,373	0.1%	42,329	42,373	0.1%	0.6%	36.7	$36,663	8,905	21.0%	7,619	18.0%
Lewis	12,112	12,112	0.0%	12,112	12,112	0.0%	0.2%	36.7	$33,956	2,567	21.2%	2,350	19.4%
Lincoln	34,281	34,624	1.0%	34,281	34,624	1.0%	0.5%	36.7	$40,904	6,405	18.7%	5,622	16.4%
Loudon	50,926	51,495	1.1%	50,926	51,495	1.1%	0.8%	36.7	$49,602	7,366	14.5%	7,435	14.6%
McMinn	53,233	53,476	0.5%	53,233	53,476	0.5%	0.8%	36.7	$38,944	10,660	20.0%	9,848	18.5%
McNairy	26,582	26,755	0.7%	26,582	26,755	0.7%	0.4%	36.7	$33,066	6,935	26.1%	6,247	23.5%
Macon	23,188	23,419	1.0%	23,188	23,419	1.0%	0.4%	36.7	$35,452	6,061	26.1%	5,449	23.5%
Madison	99,555	99,971	0.4%	99,555	99,971	0.4%	1.5%	36.7	$42,348	21,610	21.7%	18,219	18.3%
Marion	28,556	28,652	0.3%	28,556	28,652	0.3%	0.4%	36.7	$39,817	6,198	21.7%	5,483	19.2%
Marshall	31,286	31,413	0.4%	31,286	31,413	0.4%	0.5%	36.7	$40,687	5,575	17.8%	5,600	17.9%
Maury	82,280	82,526	0.3%	82,280	82,526	0.3%	1.2%	36.7	$45,603	15,237	18.5%	13,000	15.8%
Meigs	12,205	12,331	1.0%	12,205	12,331	1.0%	0.2%	36.7	$33,492	2,700	22.1%	2,844	23.3%
Monroe	46,092	46,563	1.0%	46,092	46,563	1.0%	0.7%	36.7	$36,430	10,221	22.2%	8,896	19.3%
Montgomery	187,649	191,068	1.8%	187,649	191,068	1.8%	2.9%	36.7	$49,459	25,741	13.7%	30,399	16.2%
Moore	6,350	6,364	0.2%	6,350	6,364	0.2%	0.1%	36.7	$44,977	781	12.3%	933	14.7%
Morgan	21,848	21,870	0.1%	21,848	21,870	0.1%	0.3%	36.7	$37,522	4,321	19.8%	4,173	19.1%
Obion	31,453	31,365	-0.3%	31,453	31,365	-0.3%	0.5%	36.7	$40,516	6,808	21.6%	5,378	17.1%
Overton	22,489	22,593	0.5%	22,489	22,593	0.5%	0.3%	36.7	$34,119	4,561	20.3%	4,970	22.1%
Perry	8,014	8,025	0.1%	8,014	8,025	0.1%	0.1%	36.7	$32,101	1,887	23.5%	1,939	24.2%
Pickett	5,019	4,998	-0.4%	5,019	4,998	-0.4%	0.1%	36.7	$34,255	1,034	20.6%	1,054	21.1%
Polk	16,604	16,570	-0.2%	16,604	16,570	-0.2%	0.2%	36.7	$37,235	3,529	21.3%	2,956	17.7%
Putnam	77,024	78,416	1.8%	77,024	78,416	1.8%	1.2%	36.7	$34,107	14,591	18.9%	18,563	24.1%
Rhea	33,392	33,767	1.1%	33,392	33,767	1.1%	0.5%	36.7	$36,470	8,090	24.2%	7,480	22.4%
Roane	54,006	54,079	0.1%	54,006	54,079	0.1%	0.8%	36.7	$43,017	10,013	18.5%	7,777	14.4%
Robertson	70,391	71,437	1.5%	70,391	71,437	1.5%	1.1%	36.7	$52,588	11,427	16.2%	9,151	13.0%
Rutherford	293,582	302,237	2.9%	293,582	302,237	2.9%	4.5%	36.7	$55,105	38,869	13.2%	38,166	13.0%
Scott	21,944	21,915	-0.1%	21,944	21,915	-0.1%	0.3%	36.7	$29,161	7,177	32.7%	5,662	25.8%

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Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Sequatchie	15,019	15,246	1.5%	15,019	15,246	1.5%	0.2%	36.7	$33,181	3,574	23.8%	2,899	19.3%
Sevier	94,833	96,116	1.4%	94,833	96,116	1.4%	1.4%	36.7	$43,300	16,139	17.0%	12,708	13.4%
Shelby	943,812	946,559	0.3%	943,812	946,559	0.3%	14.2%	36.7	$46,251	234,528	24.8%	190,650	20.2%
Smith	19,618	19,771	0.8%	19,618	19,771	0.8%	0.3%	36.7	$44,116	3,762	19.2%	3,472	17.7%
Stewart	13,549	13,659	0.8%	13,549	13,659	0.8%	0.2%	36.7	$40,200	2,596	19.2%	2,710	20.0%
Sullivan	158,975	159,494	0.3%	158,975	159,494	0.3%	2.4%	36.7	$40,025	28,715	18.1%	26,867	16.9%
Sumner	172,262	175,054	1.6%	172,262	175,054	1.6%	2.6%	36.7	$55,560	24,135	14.0%	16,882	9.8%
Tipton	63,865	64,759	1.4%	63,865	64,759	1.4%	1.0%	36.7	$51,847	11,941	18.7%	8,941	14.0%
Trousdale	8,167	8,275	1.3%	8,167	8,275	1.3%	0.1%	36.7	$43,613	1,761	21.6%	1,078	13.2%
Unicoi	18,376	18,419	0.2%	18,376	18,419	0.2%	0.3%	36.7	$35,415	3,644	19.8%	4,061	22.1%
Union	19,301	19,347	0.2%	19,301	19,347	0.2%	0.3%	36.7	$33,456	4,553	23.6%	4,362	22.6%
Van Buren	5,450	5,433	-0.3%	5,450	5,433	-0.3%	0.1%	36.7	$31,940	1,185	21.7%	1,221	22.4%
Warren	40,489	40,662	0.4%	40,489	40,662	0.4%	0.6%	36.7	$34,008	9,600	23.7%	9,272	22.9%
Washington	130,586	132,599	1.5%	130,586	132,599	1.5%	2.0%	36.7	$42,995	20,213	15.5%	22,591	17.3%
Wayne	16,854	16,815	-0.2%	16,854	16,815	-0.2%	0.3%	36.7	$35,377	2,972	17.6%	3,489	20.7%
Weakley	38,522	38,790	0.7%	38,522	38,790	0.7%	0.6%	36.7	$35,509	6,664	17.3%	7,897	20.5%
White	26,871	27,132	1.0%	26,871	27,132	1.0%	0.4%	36.7	$34,717	6,176	23.0%	5,401	20.1%
Williamson	202,923	207,872	2.4%	202,923	207,872	2.4%	3.1%	36.7	$91,146	9,214	4.5%	11,770	5.8%
Wilson	124,073	126,472	1.9%	124,073	126,472	1.9%	1.9%	36.7	$61,353	15,162	12.2%	11,539	9.3%

Note:
Pentec's target population equals the total population because Pentec serves patients in all age groups. At present, Pentec's nationwide patient census is broken down by age group as follows: 0-17 years, 4%; 18-64 years, 67%; 65 years and older, 29%.

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11. Section C, Need, Item 5

The applicant must address the utilization of all existing home health agencies in its proposed service area. Generally speaking, the metrics provided for this question should be very similar to the utilization information you were asked to provide for HHAs in the responses to the questions pertaining to the project specific criteria for home health services.

Pentec's proposed service area is all 95 counties in Tennessee. Utilization information for all currently-licensed home health agencies in the service area is included in the answer to Question 7 in the table at Exhibit 1.

12. Section C, Need, Item 6

Please summarize the methodology used to estimate utilization and gross revenue in Year 1 by identifying all variables that apply such as total patient visits, estimated payor mix, average charge, etc).

Pentec currently services intrathecal pump patients in many other states, and therefore based all Year 1 financial information on actual results in these other states. As such, Pentec based its average charge for Year 1 based on actual averages the Company currently recognizes. The Company also applied its actual average payor mix of 50% commercial reimbursement patients and 50% Medicare/Medicaid reimbursement patients to the Tennessee Year 1 financials. Utilization is estimated to be 100% every year as the Company hires according to its patient census in order to maintain its nurse to patient ratios.

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13. Section C, Economic Feasibility, Item 4 (Historical and Projected Data Charts)

Please identify the number of patients or visits in Line A of both charts.

Because revenues for Pentec Health, Inc. as a whole are derived from both its Renal Nutrition and Specialty Infusion divisions, it is not possible to specify a single unit of measure for purposes of the Historical Data Chart. However, the Projected Data Chart reflects Specialty Infusion only and uses average patient census as the unit of measure.

What is the estimated number of charity patients and/or visits to be provided in Year 1?

At present, "charity care" or "free care" patients comprise approximately 3% of Pentec's nationwide patient census, or 75 out of 2,492 intrathecal pump patients. Applying this percentage to the assumed year-end patient census of 39 for Year 1, one patient in Tennessee would be a charity care or free care patient.

Pentec receives less than full reimbursement for a significant percentage of its total patient census – currently approximately 61%. For purposes of the Projected Data Chart, Pentec assumed that at the end of Year 1, 20 patients would be full-pay commercially insured patients, and 19 would be partial-reimbursement patients.

Please explain why contractual adjustments from the applicant's charges are not budgeted in Line C.1 of the charts.

Pentec does not book revenue for free care. Therefore, no provision for free care is shown in Pentec's financial statements. Pentec's financial statements are reported at the net revenue line item. Therefore, gross revenue and contractual adjustments do occur, but are not reflected on Pentec's financial statements. Pentec provided financial information for the Historical Data Chart in the application in a manner consistent with its revenue recognition and presentation practices at the net revenue level, and as reflected in its audited financial statements.

Taxes are shown as negative numbers in the 2012 and 2013 columns of the Historical Data Chart. As a result, there appears to be a math error for the net operating income shown for these periods. Please revise and submit a replacement chart.

The reporting of negative numbers for Taxes at line D.4 of the Historical Data Chart is not an error. In 2012, Pentec took an extraordinary, one-time charge for impairment of goodwill in the amount of $46.5 million, which resulted in a net loss of $39.3 million for 2012. In addition, Pentec experienced reimbursement rate decreases in its Renal Nutrition operations in mid-2012, and the full-year impact of those decreases resulted in a net loss of $1.6 million in 2013. The negative numbers for Taxes shown in line D.4 reflect tax benefits relating to the net losses in 2012 and 2013.

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14. Section C. Economic Feasibility Item 1 (Project Cost Chart)

Your response is noted. In accordance with HSDA Rules, please confirm that the cost of the office space in line B.1 of the chart is based on the higher of the rental cost over the term of the rental agreement or the fair market value cost of the office space. The higher of the 2 amounts must be used for this chart.

As discussed in the answer to Question 2 of this Supplement, Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. The office itself contains 87 square feet, although Pentec and its visitors also have the use of office suite common areas, including a Business Lounge, Refreshment Bar and Videoconferencing Room, containing an additional area of approximately 1,200 square feet.

The annual rental for Pentec's 87 square foot office is $8,028, which equals an annual rate of $92.28 per square foot. This rate includes the use of office suite common areas, and also includes utilities, telephone lines, internet service, a shared receptionist, business and IT support, covered parking and secure 24-hour access.

Estimates of fair market rent for Class A office space in downtown Nashville vary. However, the average asking rent for 2014 has been reported at $23.10 per square foot by Colliers International / Nashville, a member company of Colliers International Property Consultants. The "Nashville Office Market Snapshot" report for Third Quarter 2014 by Cassidy Turley, published by the *Nashville Post* on October 1, 2014, states that quoted rates for new Class A office buildings in downtown Nashville are $33.00 - $35.00 per square foot.

Because of the amenities included in Pentec's annual rent, a direct comparison to fair market rental rates for Class A office space in downtown Nashville is difficult. However, based on current estimates of fair market rent for Class A office space in downtown Nashville it is reasonable to conclude that Pentec's actual rent expense as shown in the Project Costs Chart is higher than the FMV rate.

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15. Section C. Economic Feasibility Item 4

The applicant's charges are noted. It appears the charges may include the cost of the medications provided by Pentec's licensed pharmacy. Please clarify.

Medications provided by Pentec's pharmacy are coded separately and are not reflected on the Home Infusion Fee Schedule attached to the application as Attachment, Section C, Economic Feasibility, Item 6.A.

Please provide a comparison to allowable charges covered by commercial/managed care 3rd parties and Medicare.

Medicare does not cover home infusion nursing therapies, while typical reimbursement by commercial plans for nursing services is approximately $92 per visit of up to 2 hours. Similarly, Medicare does not cover per diem charges, while typical reimbursement by commercial plans is in the range of $50-70 dollars per day.

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16. Section C, Economic Feasibility, Item 9

Please complete the following chart for the proposed HHA.

Payor	Year One Gross Revenues	As a % of total Gross Revenue
Medicare	$21,545	7%
Medicaid/TennCare	$21,545	7%
Commercial insurance	$261,483	86%
Self-Pay	$0	0%
Charity	Not reported	NA
Total	$304,573	100%

Note: Self-Pay is reflected at $0. Pentec does collect self-pay in the form of co-pays from patients, but that revenue is originally recorded under the patients' primary payor, and therefore captured in the insurance categories in the lines above Self-Pay.

17. Section C, Contribution to Orderly Development, Items 1 and 2

Please explain how the applicant plans to address the geographic aspects of referral coordination and build a physician referral base of sufficient size to support the economic sustainability of the HHA's skilled nursing service for intrathecal pump patients and Ig-G patients statewide.

In each state in which Pentec operates, sales account executives solicit appropriate patient referrals from treating physicians. These account executives work closely with other companies operating in this specialized area of medicine to identify physician practices who have appropriate patients for this service. In addition, Pentec has commissioned proprietary market research and has a list of targeted physicians who have patients whom are potential candidates for this service in Tennessee. Once licensed, Pentec sales personnel will meet with appropriate potential referring physicians across Tennessee and solicit referrals for appropriate patients.

Please identify and discuss the reasons that a pain management physician in Memphis would want to refer patients to a home health agency in Nashville in lieu of continuing to provide care in his/her medical office.

A pain management physician in Memphis (or any other city) typically would refer patients to a home health agency for one of three reasons: 1) a patient is at great need for at-home service due to travel burden, overarching health status, mobility issues or the enormity of caregiver burden while transporting the patient to the treating physician's office; 2) a physician wishes to discontinue providing pump-refill procedures in their normal office due to declining of reimbursement, increased overhead required to perform the procedures or the desire to reallocate office staff time to perform more profitable procedures; or 3) the physician's practice has an acute staffing situation that diminishes or ends the offices ability to continue to perform pump refills and maintenance. Currently, there are no licensed home health agencies in Tennessee that exclusively provide intrathecal pump management services. Pentec, once licensed as a HHA, would be able to provide care for appropriate patients in Tennessee for any (and all) of the reasons physicians chose to refer their patients for intrathecal pump management.

Please describe how the applicant's plans to not participate in Medicare and TennCare contributes to orderly development in Tennessee.

At current, the TennCare and federal Medicare programs do not provide reimbursement for the type of in-home nursing services provided by Pentec, and, therefore, Pentec would not receive reimbursement for those services when rendered. However, just as in other states in which Pentec operates, Pentec is prepared and willing to provide free care or partially reimbursed care for residents of Tennessee under its Compassionate Care, No Insurance Coverage and Financial Assistance Policies, which are discussed in greater detail its application at Section C, Economic Feasibility, Item 9. Pentec's willingness to accept non-paying and partially paying patients is unique in the pump management industry. Without Pentec as a provider for intrathecal pump management, TennCare and federal Medicare plan patients may not have access to home care.

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18. Section C, Contribution to Orderly Development, Item 7.a.

The response is noted. What accreditation for home health agencies applies to this service?

Pentec is accredited by The Joint Commission. Pentec's accreditation certificate and letter, and related information from The Joint Commission, is attached to its application as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c

Home Health Agencies are required to have a process in place to assess and manage patient pain. In addition, agency regulations require physician supervision of patient care, including the plan of care (POC) developed for each patient and review by the MD at least once every 62 days or more often if severity of the patient's condition requires. Please describe how the applicant intends to comply with these patient care requirements as a condition of licensure in Tennessee.

Under Pentec's policies, the treating physician will review the patient's plan of care (developed by the assigned primary care nurse with physician input) at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

The plan of care is implemented at the patient's start of care, and upon any changes in the patient's status or prognosis. The patient's primary care nurse manages the plan of care by initiating at the start of care and identifying and reporting any changes to the physician that could change the patient's plan of care and treatment goals. If no change to the plan of treatment is noted by the primary care nurse, the plan of care will be maintained as signed and noted during previous certification period, with renewal submitted for physician signature. Patient pain is addressed in the plan of care by intrathecal pump medications and patient treatment goals, as appropriate.

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19. Proof of Publication

The copies of the Letter of Intent in the 15 newspapers of general circulation identified with your LOI appear to cover 92 of 95 Tennessee counties, the exception being Hancock, Perry and Van Buren Counties. Please identify the newspapers that include these counties and provide verification from the publisher that the newspaper serves as the newspaper of general circulation.

Pentec engaged the Tennessee Press Service ("TPS"), to place the legal notices containing the letter of intent in 15 Tennessee newspapers. According to Mr. Earl Goodman of TPS, Hancock and Van Buren Counties currently do not have TPA member newspapers serving those communities and could only be reached by publishing in neighboring counties, while Perry County is served by a county-wide newspaper which does not circulate outside its borders. However, two Tennessee state agencies that use TPS for publication of notices, the Department of Transportation and the Department of General Services/Department of Finance, have designated certain newspapers as region-wide publications, meaning those newspapers sufficiently cover a number of counties and satisfy the publication needs of those Tennessee agencies. Pentec placed legal notices with the letter of intent in the following papers covering the counties in question:

Hancock County: Knoxville *News Sentinel*
Van Buren County: Chattanooga *Times Free Press*
Perry County: Nashville *Tennessean*

Copies of the newspaper pages containing the legal notices are included in Pentec's application. TPS is in the process of receiving affidavits of publication from the 15 newspapers in question, and Pentec will provide those as a supplement once received.

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AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Joseph C. Cosgrove, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Joseph C. Cosgrove, President and CEO

Sworn to and subscribed before me, a Notary Public, this the 21st day of November, 2014 witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

Kathy L Sitler
NOTARY PUBLIC

My commission expires April 3, 2016

COMMONWEALTH OF PENNSYLVANIA
Notarial Seal
Kathy L. Sitler, Notary Public
City of Harrisburg, Dauphin County
My Commission Expires April 3, 2016
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

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ATTACHMENT TO QUESTION 3

SUPPLEMENT NO. 1

List of services covered by the per diem charge.

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D. Comprehensive 24 hour per day, seven days per week delivery and pick-up services. Includes mileage and the constant availability of a dedicated infusion team consisting of pharmacist(s), nurse(s), delivery team, and all other medical professionals responsible for clinical response, problem solving, trouble shooting, question answering, and other professional duties during evenings, weekends, holidays, and all other times.

E. **Clinical Coordination. Including:**
1. Development and monitoring of nursing care plans.
2. Coordination of benefits, care and services.
3. Development of Patient Assessment and Patient Education materials.
4. Coordination of non-Infusion related services.
5. Case Management services.
6. Measurement of Field Nursing competency with subsequent education and training.
7. Coordination, education, training and management of Field Nursing staff (or sub-contracted agencies).

F. **Inventories and accounts receivable. Including:**
1. Interest and opportunity costs associated with the carrying of large accounts receivable balances.
2. Depreciation expenses.
3. Equipment maintenance and repair.
4. Other applicable inventory and accounts receivable expenses.

G. **Costs associated with substantial insurance requirements.**
Includes costs associated with remaining in compliance with all state and federal regulatins related to minimal insurance coverage.

H. **Costs associated with accreditation requirements. Including:**
1. Outcomes assessments and analysis.
2. Ongoing staff development and competency assessment.
3. Continuous quality assessment and performance improvement programs.
4. All other policies and procedures necessary to remain in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Community Health Accreditation Program (CHAP), Accreditation Commission for HealthCare (ACHC), and other professional accreditation standards.
5. Certification fees and expenses.
6. Other applicable accreditation expenses.

I. **Costs associated with administrative requirements. Including:**
1. Insurance verification processes.
2. Prior authorization requirements.
3. Billing functions.
4. Account Posting functions.
5. Account collection activities.
6. Bad debt expense.
7. Certificate of medical necessity and other medical necessity documentation.
8. Internal and external auditing and other regulatory compliance activities.
9. Quality assessment and improvement activities.
10. Professional association and subsequent fees.
11. Other applicable administrative costs.

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SERVICES COVERED BY THE PER DIEM

A. Pharmacy Professional and Cognitive Services. Including:

1. Initial and ongoing patient assessment and clinical monitoring.
2. Development and implementation of pharmaceutical care plans.
3. Coordination of care with physicians, nurses, patients, patient's family, other providers, and other caregivers.
4. Sterile procedures, including intravenous admixtures, clean room upkeep, vertical and horizontal laminar flow hood certification, and all other biomedical procedures necessary for a safe environment.
5. Compounding of medications.
6. Pharmacokinetic dosing.
7. Medication profile set-up.
8. Drug utilization review.
9. Comprehensive knowledge of vascular access systems.
10. Patient educational activities.
11. Monitoring of potential drug interactions.
12. Review and interpretation of patient test results.
13. Recommendation of dosage or medication changes based on clinical findings.
14. Patient discharge services, including communication with other medical professionals and closing of the medical record. Other applicable professional and cognitive services.

B. Overhead and operational expenses. Including:

1. Wages, salaries, benefits, payroll taxes, FICA, unemployment insurance, and workers compensation premiums.
2. Office supplies.
3. Sales, advertising, and marketing.
4. Physical plant expenses.
5. Utilities and telephone.
6. Cell phones and pagers.
7. Postage and shipping.
8. Patient education materials.
9. Continuing education expenses.
10. Legal and accounting expenses.
11. Licensing fees.
12. Infectious waste storage and removal.
13. Medical records storage and retrieval.
14. Community commitment and charitable donations.
15. Property Taxes.
16. New product research and development.
17. Other applicable overhead and operational expenses.

C. Infusion therapy related supplies. Including:

1. Durable, reusable infusion pumps.
2. Elastomeric, disposable infusion pumps.
3. All other infusion therapy administration devices.
4. Short peripheral vascular access devices.
5. Needles, gauze, sterile tubing, catheters, dressing kits, and other supplies necessary for the safe and effective administration of infusion therapy.
6. Other applicable supply expenses.

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ATTACHMENT TO QUESTION 4.D

SUPPLEMENT NO. 1

1. Job Description – Administrator (Tennessee), Pentec Health, Inc.
2. Job Description – Primary Care Nurse, Pentec Health, Inc.

SUPPLEMENTAL #1
November 25, 2014
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Position Description

Position Title: Administrator (Tennessee) Employee Name: _____

Reports To: Vice President, Nursing

Department: Specialty Infusion Date Prepared: _____, 20___

Approved By: Board of Directors, Pentec Health, Inc. Date: _____, 20___

Overall Objective	The Administrator will be responsible for implementing and supervising the administrative, client care and personnel policies of the Home Health Agency ("HHA") and administratively supervising the provision of all services.
Duties and Responsibilities	1. Organize and direct the HHA's ongoing operations and provision of services. 2. Act as a liaison between the HHA and the senior management and board of directors of Pentec Health, Inc. 3. Employ and, if appropriate, contract with qualified personnel. 4. Ensure adequate staff education and performance evaluations. 5. Participate in developing qualifications for assignments of personnel. 6. Ensure the accuracy of public information materials and activities, including all information pertaining to patient rights required by applicable Tennessee law. 7. Implement an effective budgeting and accounting system that promotes the health and safety of clients. 8. Ensure that the HHA meets the requirements of and remains in compliance with all applicable Tennessee statutes, rules and regulations pertaining to licensure. 9. Maintain and make available upon request to the applicable regulatory authorities, all reports, records, minutes, files, documentation and other information pertaining to the HHA in accordance with the requirements of applicable Tennessee law. 10. Ensure that a qualified alternate Administrator or other person is authorized, in writing, to act in the absence of the Administrator. 11. Implement and administer an ongoing quality assurance program designed to objectively and systematically monitor and evaluate the quality and appropriateness of client care, resolve any identified problems, and improve client care. 12. Ensure that personnel records of HHA employees who provide services

	to clients are kept current and comply with the requirements of applicable Tennessee law, and ensure that personnel policies and job descriptions are made available to all employees. 13. Implement and participate in the development of policies and procedures consistent with standards of The Joint Commission, HIPAA and its implementing regulations, and applicable Tennessee law, and maintain copies of all applicable HHA policies and procedures. 14. Ensure that the documentation of services provided is accurate and timely. 15. Supervise and evaluate client satisfaction survey reports on all clients served, and ensure that all clients receive a copy of the patients' bill of rights in accordance with applicable Tennessee law. 16. Be available in person or by telephone during normal operating hours.
Authority and Accountability	Reports directly to the Vice President, Nursing. Directly supervises Nursing Supervisor (if a separate position). Supervises primary care nurses.
Skills and Competencies	The Administrator should demonstrate the following competencies to perform the essential functions of this position: 1. Have strong written and verbal communication skills along with excellent customer service skills. 2. Be a resourceful, proactive problem solver. 3. Possess strong organizational and process skills. 4. Demonstrate the ability to work well with all staff levels and with varied personalities. 5. Have the ability to work well under pressure and continually multi-task.
Education and Work Experience	1. Current licensure as a Registered Nurse in Tennessee (or a compact state). 2. Possess a Bachelor of Science in Nursing (BSN) degree from an accredited School of Nursing. 3. 2+ years of clinical nursing experience. 4. 1+ years of supervisory or administrative experience in health service. 5. Strong clinical background, preferably in neurology, physical rehabilitation, pain management and/or specialty infusion. 6. Demonstrated leadership and problem solving abilities associated with the intrathecal pump. 7. Familiarity with standards of The Joint Commission for home care and a thorough understanding of HIPAA requirements. 8. Intermediate computer skills with programs such as Microsoft Office Suite: Outlook, Word, Excel and Power Point.

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Physical Demands	The physical demands described here are representative of those that must be met to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this job, the employee is frequently required to travel via car, train or airplane; stand, sit, walk, see and hear; use hands and fingers regularly; handle or feel objects, tools, or controls; and reach with hands and arms. The employee must frequently lift and/or move up to 5 pounds and occasionally lift and/or move up to 40 pounds.

Signatures:

Employee **Date** **Manager** **Date**

Human Resources **Date**

SUPPLEMENTAL #1

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pentec health
Large Enough to Serve Small Enough to Care

Position/Title: Primary Care Nurse	Location: Field
Typical work hours:	Division:
Supervisor: Regional Nurse Manager	Department: Nursing
Employee:	Effective Date:
Wage Band:	Status: Exempt

Objective:

To administer safe infusion therapy in the home while providing quality patient care.

Critical features of this job are described under the headings below. They may be subject to change at any time due to reasonable accommodation or other reasons

Essential Duties & Responsibilities:

- Work flexible scheduled hours: days + call
- Manage all aspects of patient care including:
- Refill and reprogram intrathecal pumps
- Assess patients in all aspects of care
- Coordinate patient care with all departments
- Perform other infusion therapy as needed
- Understands and adheres to established company policies and procedures.
- Makes initial visits, processes orders, notifies physician of patient needs and changes in condition. Initiates care, completes certification/recertification orders, and discharge summaries, if required.
- Determines the amount and type of nursing needed by each individual patient.
- Regularly re-evaluates needs of the patients.
- Counsels with the patient and family/significant others on nursing, teaching and related needs.
- Inserts intravenous cannulas; administers prescribed intravenous solutions, medications, and blood products; monitors and maintains infusion sites and systems; evaluates response to prescribed therapy.
- Complies statistics as requested to quantify, qualify, and justify.
- Informs the physician and personnel of changes in the condition and needs of the patient.
- Initiates appropriate preventive and rehabilitative nursing procedures.
- Provides those services requiring substantial specialized nursing skills.
- Refers to Physical Therapist, Speech Language Pathologist, Occupational Therapist, and Medical Social Worker, Nutritionist those patients requiring their specialized skills.
- Prepares clinical records, care plans, progress notes for each patient visit and summaries of care conferences on his/her patients in a timely manner per company policy.
- Participates in in-service programs and presents in-service programs.
- Conducts patient care conferences on patients assigned to his/her care.
- Attends all patient care conferences as scheduled.
- Participates in peer review and performance improvement as assigned.
  Participates in review of clinical records as assigned.
- Takes on-call duty nights, weekends, and holidays as assigned.

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Non Essential Duties and Responsibilities

- Perform other duties, special projects as assigned

Skills, Competencies and Experience:

Required

- Have strong written and verbal communication skills along with excellent customer service skills
- Be a resourceful, proactive problem solver
- Possess strong organizational and process skills
- Demonstrate the ability to work well with all staff levels and with varied personalities
- Strong clinical background.
- 2 years med/surg experience required.
- Have the ability to work well under pressure and continually multi-task

Preferred

- ICU/ER and home care experience preferred.

Education, Certifications, Trainings:

Required

- Current licensure as a Registered Nurse and the ability to become licensed in another state if needed
- CPR certification- active

Preferred

Equipment:

Required

- Telemetry equipment
- Intermediate computer skills with programs such as Microsoft Office Suite: Outlook, Word, Excel and Power Point

Physical requirements:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is frequently required to travel via car, train or plane, stand, sit, walk, see, hear, use hands and fingers regularly, handle, or feel objects, tools, or controls, and reach with hands and arms.

The employee must frequently lift and/or move up to 5 pounds and occasionally lift and/or move up to 40 pounds.

Nothing in this job description restricts management's right to assign or reassign duties and responsibilities to this job at any time.

This job description reflects management's assignment of essential functions; it does not prescribe or restrict the tasks that may be assigned.

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Pentec Health, Inc. is committed to maintaining workplaces that are free from illegal drugs, controlled substances, and/or alcohol.

By signing below I acknowledge that I have reviewed this job description with the associate listed above:

Manager/Supervisor Signature:_____ Date:_____

Employee Signature:_____ Date:_____

Human Resources Signature:_____ Date:_____

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ATTACHMENT TO QUESTION 5.B

SUPPLEMENT NO. 1

Nurse Training Program Policy and Procedure, Pentec Health, Inc.

SUPPLEMENTAL #1
November 25, 2014
9:50 am

PENTEC HEALTH, INC. AND AFFILIATED COMPANIES

INFUSION

POLICY AND PROCEDURE

1.8 NURSE TRAINING PROGRAM

PURPOSE:

To ensure proper training for each nurse hired to maintain consistent, high quality care in the provision of services to high tech patients served by Pentec Health, Inc.. To provide each newly trained nurse with a mentor to support them through their orientation, training and professional development.

POLICY:

1. Primary Care Nurses are interviewed and selected by a Regional Nurse Manager, a member of the Training Team, and/or the Vice President, Nursing Services.

2. All Primary Care Nurses are oriented to Pentec policies and procedures by a member of the Training Team and a Regional Nurse Manager as part of their orientation. This is provided during a two week intensive classroom presentation. The first week of classroom is presented by the Regional Nurse Manager and includes general orientation to the company (see New Associate Orientation Checklist Specialty Infusion-Nursing) as well as beginning introduction to the EMR, Programmer, Refills, etc.

3. The second week of classroom presentation is given by a member of the training team. The new Primary Care Nurse is given hands on practice with the N'Vision Programmer and practice with accessing Synchromed pumps as well as practice with the EMR system. The new PCN is introduced to the clientele serviced by Pentec Health along with the theory behind administration of intrathecal medications via an implanted pump. All trainers have completed a preceptor training program focused on adult learning.

4. Following completion of the classroom session, the new Primary Care Nurse will either spend two weeks in a high volume area (Pennsylvania or other high volume area) to do intensive access training or will return to his/her home area to start training with a Preceptor. Preceptors are experienced Primary Care Nurses who have completed the one day Preceptor Workshop. At the end of training in the high volume area, an Orientation Progress Report will be initiated via conference call.

5. The training in the home area will encompass all aspects of care including but not limited to new admissions, pump refills, pump adjustments, patient assessments, physician contact and documentation. This training will be guided by a Preceptor (if in an existing

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area with an established patient base) or a Traveler/Trainer (in an expansion area without established patients). At the end of each week, a report will be given to the Regional Nurse Manager and the Director of Education outlining the weekly progress and goals for the coming week.

6. At the completion of three months, the nurse will take a knowledge exam proctored by the Trainer or Regional Nurse Manager. The nurse must obtain a passing grade of 80%. (See Measurements of Success policy.) Remedial instruction will be given for all incorrect answers.

7. Orientation is not completed until the Preceptor/Traveler Trainer, the Director of Nursing Education and the Regional Nurse Manager are in agreement that the new Primary Care Nurse has successfully completed all areas of the "Initial Competency Tool for Nurses." Another conference call will be done at this time and an Orientation Progress Final Report will be completed. At this time a mentor will be assigned to the new PCN.

8. In the event that the Primary Care Nurse is unable to complete all aspects of the initial competency tool due to lack of exposure to those patients with the specified competency (Synchromed EL refill/programming, advanced flex programming, medication change with bridge bolus, reservoir rinse) the skill can be demonstrated in demo mode/simulation and can be marked as a demonstrated competency from that. When the nurse then encounters the actual situation she will notify the Regional Nurse Manager and discuss the procedure prior to seeing the patient.

9. Primary Care Nurses shall follow the job description for the Primary Care Nurse as outlined by Pentec Health.

10. The Regional Nurse Manager will attempt to visit onsite a minimum of once yearly for the purpose of performance evaluations. When possible, the Regional Nurse Manager will "ride along" and observe the Primary Care Nurse while she performs her duties. The "Annual Competency Tool for Nurses, Intrathecal Pump" will be filled out yearly for all Primary Care Nurses, either by their Regional Nurse Manager, or through a peer to peer review, showing that they are competent to perform the necessary procedures and will be kept in their employee files.

Compensation for pool nurses during the classroom period and high stick orientation will be as follows. Please note orientation in the comments section of the expense sheet:

0-4 hours/day = Partial day/$160
4+hours/day = Full day/$320

Effective: 10/09
Revised: 4/10
Reviewed: 7/10
Revised: 6/11
Revised: 9/11
Revised: 4/12
Revised: 8/12

SUPPLEMENTAL #2

SUPPLEMENTAL #2
December 10, 2014
10:13 am

PENTEC HEALTH, INC.

SUPPLEMENT NO. 2

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

DECEMBER 2014

SUPPLEMENTAL #2
December 10, 2014
10:13 am

1. **Section A, Item 4**

Review of the Annual Report of Pentec Health, Inc. filed 1/2012 with the TN Secretary of State's Office (page 99 of revised application) identified the names of the parent company's Board of Directors. What are the qualifications of the members as it relates to the responsibilities of the Board for oversight of the proposed home health organization? What changes to the responsibilities of the Board will be made to incorporate oversight responsibilities for operations of the proposed HHA to be added to the Board's responsibilities for Pentec Health's existing pharmacy operations in Tennessee.

The information on file with the Tennessee Secretary of State is not completely up to date, as several Directors of Pentec Health, Inc. have changed. A current list of Directors follows:

Name	Position/Title	Occupation	Employer	Business Address
Joseph Cosgrove	Director; President/CEO; Secretary; Treasurer	Healthcare Executive	Pentec Health, Inc.	4 Creek Parkway Boothwyn, PA 19061
Brian Morfitt	Director	Private Equity Executive	Frazier Healthcare Partners	601 Union Square Suite 3200 Seattle, WA 98101
Andrew Carragher	Director	Private Equity Executive	DW Healthcare Partners	1413 Center Drive Suite 220 Park City, UT 84098
Rod Boone	Director	Private Equity Executive	DW Healthcare Partners	1413 Center Drive Suite 220 Park City, UT 84098
Tim Kuehl	Director	Private Equity Executive	Norwest Equity Partners	80 South 8th Street Suite 3600 Minneapolis, MN 55402
John Lindahl	Director	Private Equity Executive	Norwest Equity Partners	80 South 8th Street Suite 3600 Minneapolis, MN 55402
Carter Balfour	Director	Private Equity Executive	Norwest Mezzanine Partners	80 South 8th Street Suite 3600 Minneapolis, MN 55402

Joseph Cosgrove is the Chairman of the Board of Directors. He has served as President and CEO, Secretary and Treasurer of Pentec since 2008. Mr. Cosgrove has more than 20 years of diversified life sciences industry experience in both the public and private sectors. Prior to joining Pentec, he served as Vice President and General Manager for several operating units of Cardinal Health Inc., including Nuclear Pharmacy Services from 2002 to 2006, and Global Pharmaceutical Services from 2006 to 2008. Prior to Cardinal Health, Mr. Cosgrove worked for DuPont Pharmaceuticals Company as Senior Director of sales, marketing and strategic planning, and Senior Director of national accounts.

The other Directors represent Pentec's principal shareholders. Brian Morfitt is a General Partner of Frazier Healthcare Partners, a private equity firm that invests exclusively in healthcare companies. In addition to Pentec's Board, Mr. Morfitt serves on the boards of TridentUSA Health Services, Correct Care Solutions, Informed Medical Communications and Orthotic Holdings Inc. Andrew Carragher is the founder and Managing Director of DW

Healthcare Partners, a private equity firm that invests solely in healthcare companies. In addition to serving as a Pentec Director, Mr. Carragher is a director of Genesis Technology Partners, Verathon, Tandem Labs, Reliant Renal Care, Reliant Rehabilitation, Career Step, Z-Medica Corporation, Health & Safety Institute, ABC Home Medical Supply and Aerosol Science Laboratories Inc. Rod Boone is a Managing Director of DW Healthcare Partners, and has over 20 years of experience building and operating healthcare companies. In addition to Pentec's Board, Mr. Boone serves on the boards of ABC Home Medical Supply, Aerosol Science Laboratories Inc., Career Step, Emphusion, Health & Safety Institute, Hill Top Research and Tandem Labs, Inc. John Lindahl is the founder and Chairman of Norwest Equity Partners, a private equity firm, and is an investment and financial professional with more than 40 years of experience. Tim Kuehl is a Partner at Norwest Equity Partners, and is a financial and investment professional. Carter Balfour is a Partner at Norwest Mezzanine Partners, and is also a financial and investment professional.

The Board of Directors of Pentec has all of the responsibilities of a board of directors of a Pennsylvania business corporation as provided in the Pennsylvania Business Corporation Law of 1988. As such, the Board is responsible for oversight of all aspects of Pentec's operations, including its Specialty Infusion and Renal Nutrition divisions, and its closed-door pharmacy, which supports both of the foregoing divisions. Therefore, the Board is already responsible for oversight of Pentec's home health care operations and its pharmacy operations in all states in which Pentec is active. The only change to the Board's area of responsibility would be the addition of Tennessee to the jurisdictions for which it oversees home health care operations.

Specific Board responsibilities for oversight of home health care operations include, but are not limited to, the following:

- Appointment of the HHA administrator
- Adoption and approval of comprehensive policies and procedures for the HHA
- Adoption and approval of quality assurance and performance improvement policies and programs and review of program results
- Appointment of an advisory board for the HHA, when required by applicable law
- Ongoing review of HHA operations, including financial performance

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2. **Section A, Applicant Profile, Item 13**

It appears that the certification status of the existing pharmacy (limited to renal nutrition services) is provided in this item and will not apply to the proposed HHA. HSDA staff is under the impression that the applicant does not plan to seek Medicare/Medicaid certification for the proposed home health agency. In addition, it appears that the applicant may provide services to enrollees of these programs on a limited basis and only under the terms of the Compassionate Care policy noted in the response. Is this a fair summary of the applicant's plans in this regard? Please explain.

Although Pentec's pharmacy presently supplies renal nutrition products for use by Tennessee residents, its state certification is not limited to renal nutrition. As stated in Pentec's most recent pharmacy license renewal application, submitted to the Tennessee Board of Pharmacy in March 2014, the pharmacy supplies IV, Intrathecal, TPN, Parenteral and Intraperitoneal compounded products. As such, the pharmacy would supply compounded products for administration to patients of the proposed HHA. As stated correctly above, Pentec would not seek Medicare/Medicaid certification for home health care. Nevertheless, and also as stated above, it would provide services to enrollees of these programs on a limited basis, under its Compassionate Care Policy, No Insurance Policy, or Financial Assistance Policy, as applicable.

In your response, please also describe what arrangements will be made to lift the existing pharmacy restriction (limited to renal nutrition services) and expand to specialty infusion services support for the proposed HHA.

As noted immediately above, Pentec's pharmacy is not restricted or limited to the provision of renal nutrition products. Under its current non-resident Tennessee pharmacy license (No. 4108; valid until March 31, 2016), Pentec may supply compounded medication for administration to patients of the proposed HHA. No further action is required.

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In a recent application, Coram Specialty Infusion services, CN1406-017, the applicant provided a service area study that included a comparison of a typical Medicare-certified home health agency patient to an infusion therapy patient. The comparison was illustrated in the table below from the HSDA staff summary for the project.

Variable	*Medicare Home Health Agency*	*Infusion Nursing Agency*	**Pentec – Intrathecal Pump Services**
Average Visit Duration	*One to two hours*	*Up to six hours*	Typically, one to two hours
Equipment	*Generally not involved*	*Typically includes infusion equipment*	Administration kit (syringes and other disposable items); pump programmer
Payor	*87% Medicare and TennCare patients*	*Private Insurance mainly*	Mostly private insurance
Age	*Approximately 73% over age 65*	*Predominantly under age 65*	Approximately 71% under age 65
Service Provided	*46% is skilled nursing. Balance of service includes therapy, home health aide, and medical social services.*	*100% specialized skilled nursing*	100% specialized skilled nursing
Patient Status	*Homebound*	*Patient may or may not be homebound*	Patient may or may not be homebound

What observations or suggestions can the applicant provide by contrasting its IP intrathecal infusion services program with the categories in the table above? Please feel free to revise the table as appropriate to illustrate the comparison.

The services to intrathecal pump patients that Pentec provides are different from those provided by the traditional, full-service home health agency or by agencies that provide primarily other types of infusion services such as IV infusion. Pentec has the following observations, which are summarized in the right-hand column above.

- The typical visit to an intrathecal pump patient lasts only 1-2 hours (vs. up to 6 hours, e.g., in the case of an Ig-G replacement therapy patient). Although the duration of visits to intrathecal pump patients is comparable to the traditional HHA visit, visits to intrathecal pump patients occur much less frequently than traditional HHA visits – usually one time every 30-60 days.

- In contrast to IV infusion, intrathecal pump refills do not require an infusion pump or other durable infusion equipment. The refill itself requires only a low-cost administration kit consisting of disposable items. If the pump also requires reprogramming, then the nurse will use an external programming device to reprogram the pump.

- As with IV infusion, reimbursement is typically through private insurance plans. This is because the skilled nursing services provided to intrathecal pump patients and the per diem charge typically are not covered under traditional Medicare and Medicaid coverage guidelines.

- Also like the IV infusion patient population, the overwhelming majority of Pentec's intrathecal pump patients (71%) are under the age of 65. This contrasts sharply with the predominantly geriatric population served by the traditional HHA.

- As with IV infusion, the services provided to intrathecal pump patients consist entirely of skilled nursing (which itself requires completion of a highly specialized training regimen to be performed proficiently). Pentec's proposed HHA would not provide any of the other services offered by traditional HHAs.

- Finally, as with IV infusion patients but unlike the traditional HHA patient, the intrathecal pump patient is not necessarily homebound. In fact, in many cases, intrathecal pump therapy allows patients who might otherwise be homebound or suffer from limited mobility to resume many normal activities including ambulation.

Item 4.A – *Process planned for compounding/preparation, shipping, delivery and safeguard of medications.* It appears that the shipping process involves shipping in advance to a Pentec nurse and, in some cases, shipment direct to the patient at his/her home. Please address what flexibility the applicant may have, if any, in changing the model to a 100% patient delivery mode as it pertains to compliance with federal and state requirements.

For a variety of reasons, including minimization of the risk of diversion or abuse of controlled substances, minimization of the risk of loss, and maintenance of proper storage conditions, Pentec's model entails shipment by its pharmacy, pursuant to the order of the prescribing physician, of intrathecal medications to the appropriate primary care nurse. It should be noted that Pentec Health, Inc. is the pharmacy license holder in all 50 states and the District of Columbia; the federal Drug Enforcement Agency ("DEA") registrant (No. BP9684627); and the license holder in those jurisdictions in which a home health or similar agency license is required. Therefore, shipment of intrathecal medications to the primary care nurse in advance of administration to the patient constitutes shipment by the pharmacy to an employee. Pentec notes that the DEA defines "employees" as persons "who are directly paid by the registrant; who are subject to direct oversight by the registrant; who are required, as a condition of employment, to follow the registrant's procedures and guidelines pertaining to the handling of controlled substances; who receive a performance rating or performance evaluation on a regular/routine basis from the registrant; [and] who are subject to disciplinary action by the registrant". 79 Fed. Reg. 53,527 (Sept. 9, 2014). All of the foregoing factors apply directly to Pentec's nurses.

Pentec further notes that its pharmacy shipped approx. 63,000 packages in 2013, and approx. 68,000 packages between January 1 and October 31, 2014, in each case with a 99.99% accuracy rate. Pentec strongly believes that its proven model for handling intrathecal medication is superior to any alternative, and provides the best protection against diversion, abuse, loss and spoilage.

The process appears to apply only to refills and not the initial dosage administration following implant by a physician in a hospital or other appropriate health care facility. Please confirm.

The physician always does the initial dosage administration. If a patient needs to have an intrathecal pump or catheter replaced, the physician usually also does the initial dosage administration immediately after that surgery is completed. Further, the patient typically needs a follow-up appointment with the physician for clearance to have a Pentec nurse administer new medication or perform a refill following such surgery. Thereafter, the process for compounding/preparation, shipping, delivery and safeguard of medications would apply.

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Item 4.C – *Examples of patient services.* Please also provide examples of the types of clinical classifications that apply to patents served by the proposed HHA such as patients with multiple sclerosis, chronic cancer pain, etc. If possible, please identify diagnostic related group (DRG) codes or the equivalent for IP intrathecal infusion services (note: these would be used by HSDA staff to seek assistance from the Department of Health in identifying the incidence of IP procedures in TN hospitals using data from the Hospital Discharge Data Base).

Typical diagnoses for intrathecal pump patients include:

1. Chronic Pain Syndrome
2. Complex Regional Pain Syndrome
3. Multiple Sclerosis
4. Traumatic Brain Injury
5. Cerebral Palsy
6. Abnormal Involuntary Movement (Spasticity)

Applicable ICD-9-CM diagnosis codes for intrathecal pump patients include the following:

Chronic Pain Disorders

338.0	Central pain syndrome
338.29	Other chronic pain
338.3	Neoplasm-related pain (cancer pain)
338.4	Chronic pain syndrome

Reflex Sympathetic Dystrophy and Causalgia

337.22	Reflex sympathetic dystrophy of the lower limb (complex regional pain syndrome type I of lower limb)
355.71	Causalgia of the lower limb (complex regional pain syndrome type II of lower limb)

Spasticity of Spinal Origin: Multiple Sclerosis

340	Multiple sclerosis

Spasticity of Cerebral Origin: Cerebral Palsy

343.0	Infantile cerebral palsy, diplegic (congenital diplegia, congenital paraplegia)
343.1	Infantile cerebral palsy, hemiplegic (congenital hemiplegia)
343.2	Infantile cerebral palsy, quadriplegic (tetraplegic)
343.3	Infantile cerebral palsy, monoplegic
343.4	Infantile cerebral palsy, infantile hemiplegia (postnatal)
343.8	Other specified infantile cerebral palsy
343.9	Infantile cerebral palsy, unspecified
344.89	Spastic cerebral palsy, not congenital or infantile

Other Spasticity of Spinal or Cerebral Origin

342.1X	Spastic hemiplegia
344.0X	Spastic quadriplegia
344.1	Spastic paraplegia, non-infantile or congenital
344.2	Spastic diplegia of upper limbs
344.3X	Spastic monoplegia of lower limb
344.4X	Spastic monoplegia of upper limb

344.5 Spastic monoplegia, unspecified
344.9 Spastic paralysis, unspecified

Intrathecal Injection
03.91 Injection of anesthetic into spinal canal for analgesia
03.92 Injection of other agent into spinal canal

Typical diagnoses for Ig-G replacement therapy patients include:

1. Primary Immune Deficiency
2. Auto Immune Disorder

Item 4.E – *Collaboration with existing HHAs and state professional HHA association(s) to identify and assess the need for its specialty IP and Ig-G services.* Input from the TN Association of Home Care and the TN Hospital Association is important to a better understanding of the proposed HHA, especially in light of recent HSDA approval of Coram Specialty Infusion Services, CN1406-017A (includes provision of Ig-G replacement therapy services) and a pending application from Implanted Pump Management, Inc. of Wayne, N.J., that is presently being reviewed by the Department of Health for the establishment of a home health organization limited to implanted pump intrathecal infusion therapy (IP) services serving all 95 counties of Tennessee (CN1407-017). In light of these recent developments, support for the applicant's proposed project from these parties may be helpful to HSDA and TDH in the review of the application. Please contact these parties for information related to the need for an additional HHA offering IP and Ig-G services in TN at this time.

Pentec's National Sales Director for Specialty Infusion, Doug Wynd, has contacted the Tennessee Association of Home Care regarding whether intrathecal pump management services are available from licensed home health agencies in Tennessee. The Association advised Mr. Wynd that it is not aware of any licensed Tennessee HHA that provides these services. There are a number of licensed agencies that provide other types of home infusion services, including Ig-G replacement therapy, but they do not provide intrathecal pump management services.

Pentec is aware of the Tennessee CON application submitted by Intrathecal Pump Management, LLC ("IPM"). Pentec is also aware, from testimony provided by IPM's Director of Nursing at an administrative hearing conducted by the Kentucky Cabinet for Health and Family Services on October 15, 2014, that IPM's parent, Basic Home Infusion, Inc. ("BHI"), presently serves intrathecal pump patients in Tennessee by independently contracting with a nurse licensed to practice in Tennessee to perform the services. (Transcript of testimony of Melissa Hill, R.N., In re: Implanted Pump Management, LLC, CON #000-00-5591(1), Oct. 15, 2014, volume I, pages 39-40.) Pentec believes that its model of patient care, involving the use of registered nurses who are Pentec employees, who have completed Pentec's comprehensive, ANCC-accredited primary care nurse training program, and who are subject to ongoing performance and competency evaluation, is superior, particularly in light of the risks inherent in intrathecal pump therapy.

What source(s) of information did the applicant have at its disposal in identifying the 2 organizations as current or possible providers of IP intrathecal in-home services? Is the applicant aware of their IP intrathecal infusion utilization for the most recent 12 month period available? Please clarify. (Note: applies to names provided - Professional Home Health (license # 96030) and Basic Home Infusion (not an existing licensed HHA in Tennessee).

Pentec had contact with Professional Home Health in connection with Pentec's application for a Certificate of Need for a mobile health service in Kentucky, and is aware from those contacts that Professional is active in Tennessee as well as Kentucky. Pentec cannot provide information regarding Professional's intrathecal services utilization. The 2013 Joint Annual Report does not include specific data regarding intrathecal services provided. However, the 2013 Joint Annual Report does indicate that for the agency as a whole, 20.0% of total reported nursing visits were "skilled nursing care" visits, and intrathecal pump services would fall into this category. Of the agency's 2,641 reported patients, 13 were from

2 counties in Tennessee. Even if all of these were intrathecal pump patients, the data indicate that the service provided by Professional in Tennessee is very limited.

Pentec has been aware for many years of BHI's operations in many jurisdictions. As noted above, Pentec is also aware of the application by BHI's wholly-owned subsidiary, IPM, for a Certificate of Need to establish a limited HHA in Tennessee and of BHI's present operations in Tennessee conducted through the use of an independent contractor nurse.

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Item 4.F – *Patient services provided by staff RNs.* Are there instances where RN staff might be present with physicians and their patients for initial IP medication administration? Please briefly describe.

The initial administration of medication is done by the treating physician immediately after surgical implantation of the intrathecal pump. During the entire surgery, a pump representative from the pump manufacturer is present to assist the surgeon as needed. A Pentec primary care nurse is not present. On rare occasions, a patient does not receive the initial dose immediately after the surgery and saline is instilled in lieu of medication. In those instances, the patient instead receives the initial dose administration in the physician's office at a follow-up visit. Pentec's nurse may be present during that follow-up visit, but does not assist with or perform the procedure unless the guidelines set forth in Pentec's post-surgical policies have been met.

Please also briefly describe the process that will be followed to ensure cross checking when pumps need to be reprogrammed for changes in medication dosage.

Pentec's process includes the following:

1. Following Pentec's Safety Checklist: reviewing pump telemetry with the patient and/or caregiver immediately following programming of the pump of any kind.
2. Uploading pump telemetry on the day of the visit.
3. Using demo mode prior to complex programming and prior to patient visit.
4. Reviewing demo mode telemetry prior to, and telemetry reviewed after, patient visit with a Pentec Regional Nurse Manager or nurse trainer to verify accuracy of any complex programming.

Copies of Pentec's "Patient Safety Checklist" Policy and the "Patient Safety Checklist" used by its primary care nurses are attached to this Supplement as Attachment to Question 3, Item 4.F.

4. **Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services, Items 1 through 4)**

Alecia Craighead, Statistical Analyst, HSDA staff, reviewed the response and noted a few minor changes to Exhibit 1. Please revise Exhibit 1 with the entries included in the table below.

Existing Licensed HHAS & Their Utilization serving the 95 County Declared Service Area

Agency Name (license #)*	County of Parent Office	Total Counties authorized in license (# counties in service area) **	2010 JAR Total patients served	2011 JAR Total patients served	2012 JAR Total patients served
Amedisys Home Health	Davidson	22 (22)	1,538	1,598	2,008
CareAll Homecare Services	Davidson (formerly in Wilson County)	21 (21)	1,473	1,292	1,562

The revised Exhibit 1, reflecting the foregoing changes, is set forth below:

Exhibit 1

Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Accredo Health Group, Inc.	79456	Shelby	6 (6)	9	14	20
Advanced Home Care, Inc.	82051	Sullivan	8 (8)	2825	2583	2245
Advanced Home Care, Inc.	30021	Greene	4 (4)	385	526	762
Alere Women's and Children's Health, LLC	33423	Hamilton	13 (13)	18	52	74
Alere Women's and Children's Health	79466	Shelby	7 (7)	357	401	417
Alere Women's and Children's Health, LLC	19654	Davidson	14 (14)	140	196	202
Amedisys Home Health	67024	Overton	11 (11)	1325	1277	1453
Amedisys Home Care	26054	Franklin	15 (15)	1015	1074	1150
Amedisys Home Care	79146	Shelby	3 (3)	882	938	1060
Amedisys Home Health	19674	Davidson	22 (22)	1538	1598	2008
Amedisys Home Health	90121	Washington	6 (6)	2496	2384	1821
Amedisys Home Health	33103	Hamilton	19 (19)	3358	3342	2878
Amedisys Home Health	79386	Shelby	4 (4)	2411	1806	1934
Amedisys Home Health	75054	Rutherford	7 (7)	543	554	661
Amedisys Home Health Care	47202	Knox	27 (27)	5267	5420	5354
Amedisys Home Health Care	57075	Madison	19 (19)	2489	2586	2741

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Amedisys Home Health Care	10031	Carter	7 (7)	1241	1147	1171
Amedisys Home Health Care	75064	Rutherford	17 (17)	1476	1431	1582
Amedisys Home Health Care	32102	Hamblen	13 (13)	3613	3675	3896
Amedisys Home Health Care	79246	Shelby	3 (3)	576	683	936
Amedisys Home Health of Tennessee	13022	Claiborne	5 (5)	1730	2074	1830
Amedisys Home Health Svcs.	19684	Davidson	10 (10)	756	388	23
Americare Home Health Agency, Inc.	79256	Shelby	2 (2)	1324	1727	1811
Baptist Home Care and Hospice - Covington	84046	Tipton	5 (5)	326	361	353
Baptist Memorial Home Care	09065	Carroll	11 (11)	235	213	262
Baptist Trinity Home Care	79276	Shelby	3 (3)	3248	3367	3862
Baptist Trinity Home Care - Private Pay Division	79446	Shelby	1 (1)	1	1	1
Best Nurses, Inc.	79546	Shelby	3 (3)	311	366	364
Blount Memorial Hospital Home Health Services	05012	Blount	19 (19)	1357	1308	1224
C.M.C. Home C.A.R.E.	18054	Cumberland	1 (1)	536	409	407
Camellia Home Health of East Tennessee, LLC	47062	Knox	22 (22)	1448	1556	1716
CareAll Homecare Services	19724	Davidson (formerly Wilson)	21 (21)	1473	1292	1562
Careall Home Care Services	89074	Warren	8 (8)	520	337	637
CareAll Home Care Services	47232	Knox	6 (6)	257	278	510
CareAll Homecare Services	84076	Tipton	14 (14)	1491	1103	1556
CareAll Home Care Services	92025	Weakley	12 (12)	1903	2668	2036
CareAll Homecare Services	60074	Maury	11 (11)	285	224	609
Caresouth HHA Holdings of Winchester, LLC	26024	Franklin	35 (35)	1395	1371	2030
Suncrest Home Health	13032	Claiborne	11 (11)	436	581	852
Clinch River Home Heath	01032	Anderson	7 (7)	473	468	461
Continucare Healthservices, Inc. - I	33213	Hamilton	8 (8)	1638	1494	1466
Continucare Healthservices, Inc. - II	33383	Hamilton	11 (11)	21	17	8
Continuous Care Services, LLC	19664	Davidson	6 (6)	905	671	407
Coram Specialty Infusion Services	19734	Davidson	37 (37)	-	-	11
Covenant Homecare	47402	Knox	16 (16)	3838	3946	3953
Cumberland River Homecare	14024	Clay	10 (10)	361	236	392
Deaconess Homecare II	36025	Hardin	11 (11)	1213	1244	1330
Deaconess Homecare	76032	Scott	5 (5)	406	352	394
Deaconess Homecare	52024	Lincoln	24 (24)	712	704	842
Deaconess Homecare	95034	Wilson	21 (21)	1237	1210	1222
East Tennessee Children's	47222	Knox	16 (16)	671	559	586

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Hospital Home Health Care						
Extended Health Care, Inc.	79136	Shelby	6 (6)	780	341	79
Elk Valley Health Services, LLC	19494	Davidson	95 (95)	250	245	277
Lifeline of West Tenn., LLC	57095	Madison	20 (20)	962	993	1085
Extendicare Home Health Care of Union City, LLC	66035	Obion	5 (5)	398	347	302
Family Home Care, Cleveland	06043	Bradley	5 (5)	673	1023	598
Family Home Health Agency	79206	Shelby	1 (1)	375	863	379
Friendship Home Health, Inc.	89084	Warren	10 (10)	1025	1345	1724
Friendship Home Healthcare, Inc.	19614	Davidson	14 (14)	1040	1093	845
Angel Private Duty and Home Health, Inc.	19714	Davidson	24 (24)	10	73	123
Functional Independence Home Care, Inc.	79496	Shelby	3 (3)	729	804	953
Gateway Home Health, Clarksville	63034	Montgomery	7 (7)	1050	1067	949
Gentiva Health Services	19084	Davidson	12 (12)	1239	1239	1003
Gentiva Health Services	47042	Knox	16 (16)	898	870	779
Gentiva Health Services	16024	Coffee	9 (9)	726	629	424
Gentiva Health Services	33093	Hamilton	12 (12)	487	268	328
Gentiva Health Services	82061	Sullivan	9 (9)	1286	979	936
Gentiva Health Services	95074	Wilson	15 (15)	1705	1482	1380
The Home Option by Harden Health Care	47372	Knox	8 (8)	0	1	29
Girling Health Care, Inc.	47182	Knox	18 (18)	1093	1031	1467
Guardian Home Care of Nashville, LLC	94074	Williamson	15 (15)	1265	1365	1370
Guardian Home Care, LLC	33083	Hamilton	9 (9)	2179	2116	1484
Hancock County Home Health Agency	34011	Hancock	4 (4)	297	323	463
Henry County Medical Center Home Health	40075	Henry	5 (5)	355	399	363
Heritage Home Health	02024	Bedford	6 (6)	282	280	241
Hickman Community Home Care, Inc.	41034	Hickman	7 (7)	146	134	214
Highland Rim Home Health Agency	71014	Putnam	7 (7)	555	495	574
HMC Home Health, LLC	36035	Hardin	5 (5)	252	274	341
Home Care of Chattanooga	33133	Hamilton	3 (3)	208	119	269
Home Health Care of East Tennessee, Inc.	06063	Bradley	17 (17)	4764	4755	3318
Home Health Care of Middle Tennessee, LLC	19584	Davidson	14 (14)	4246	3914	2963
Home Health Care of West Tennessee, Inc.	79486	Shelby	4 (4)	1308	1118	1010
Health at Home	94094	Williamson	1 (1)	63	50	58
Homechoice Health Services	79376	Shelby	6 (6)	2887	1788	861
Hometown Home Health Care, Inc.	37021	Hawkins	3 (3)	173	-	89

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Innovative Senior Care Home Health	19504	Davidson	22 (22)	73	504	677
Interim Healthcare of Memphis, Inc.	79056	Shelby	3 (3)	720	889	769
Intrepid USA Healthcare Services	62052	Monroe	15 (15)	238	259	358
Intrepid USA Healthcare Services	71084	Putnam	8 (8)	244	341	327
Intrepid USA Healthcare Services	79226	Shelby	4 (4)	662	615	605
Intrepid USA Healthcare Services	57165	Madison	15 (15)	294	86	422
Intrepid USA Healthcare Services	19364	Davidson	11 (11)	644	920	766
Intrepid USA Healthcare Services	89064	Warren	11 (11)	650	159	822
Johnson County Home Health	46031	Johnson	3 (3)	403	396	446
Laughlin Home Health Agency	30041	Greene	5 (5)	553	547	655
Home Care Solutions	19544	Davidson	46 (46)	2192	2080	1930
Home Care Solutions	33363	Hamilton	10 (10)	727	734	663
Life Care at Home of Tennessee	33303	Hamilton	10 (10)	616	989	956
Lifeline Home Health Care	74064	Robertson	5 (5)	289	336	428
Lincoln Medical Home Health and Hospice	52044	Lincoln	7 (7)	356	396	348
Magnolia Regional Health Center Home Health and Hospice Agency	96010	Unknown	2 (2)	1000	915	856
Maury Regional Home Services	60044	Maury	8 (8)	1188	1220	1151
Maxim Healthcare Services	33433	Hamilton	8 (8)	71	150	56
Maxim Healthcare Services, Inc.	47432	Knox	18 (18)	159	150	159
Maxim Healthcare Services, Inc.	79536	Shelby	6 (6)	103	197	155
Maxim Healthcare Services, Inc.	19704	Davidson	9 (9)	138	141	106
Medical Center Home Health, LLC	57055	Madison	14 (14)	1403	1617	1706
Medical Center Homecare Services	90091	Washington	5 (5)	2801	3118	3503
Medical Center Homecare, Kingsport	90081	Washington	7 (7)	1126	1628	1960
Memorial Hospital Home Health	33253	Hamilton	10 (10)	3469	3264	2439
Tennove Home Health	47092	Knox	14 (14)	3586	3188	3063
Methodist Alliance Home Care	79316	Shelby	3 (3)	3226	3180	3179
University of TN Medical Center Home Health Services	32122	Hamblen	10 (10)	986	1244	1327
NHC Homecare	60024	Maury	22 (22)	2212	2134	2408
NHC Homecare	27025	Gibson	12 (12)	479	625	569
NHC Homecare	54043	McMinn	8 (8)	221	183	239
NHC Homecare	24026	Fayette	8 (8)	254	217	226
NHC Homecare	75024	Rutherford	24 (24)	3007	3269	3776
NHC Homecare	90131	Washington	7 (7)	241	264	259
NHC Homecare	47012	Knox	15 (15)	575	567	613
NHC Homecare	33033	Hamilton	10 (10)	199	203	354
NHC Homecare	74054	Robertson	6 (6)	867	909	1332

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
No Place Like Home, Inc.	79506	Shelby	3 (3)	38	55	58
Premier Support Services	32132	Hamblen	16 (16)	972	900	1169
Premiere Home Health, Inc.	19374	Davidson	1 (1)	118	81	87
Procare Home Health Services	30051	Greene	6 (6)	418	384	433
Professional Case Management of Tennessee	01042	Anderson	11 (11)	127	182	164
Professional Home Health Care Agency, Inc.	96030	Unknown	2 (2)	3021	2985	2641
American National Home Health	95084	Wilson	9 (9)	217	358	311
Quality First Home Care	60084	Maury	5 (5)	906	855	923
Quality Home Health	25044	Fentress	13 (13)	4540	4012	3404
Quality Private Duty Care	25034	Fentress	9 (9)	599	703	879
Regional Home Care Parkway	96020	Unknown	1 (1)	31	14	28
Regional Home Care, Jackson	57085	Madison	15 (15)	1206	1061	1164
Regional Home Care, Lexington	39035	Henderson	22 (22)	578	616	569
Regional Home Care, Dyersburg	23035	Dyer	6 (6)	744	814	707
Senior Services Home Health	79106	Shelby	1 (1)	642	697	609
Smoky Mountain Home Health and Hospice, Inc.	15032	Cocke	12 (12)	1622	1535	1296
Still Waters Home Health Agency	79526	Shelby	1 (1)	105	127	101
Highpoint Homecare	80064	Smith	8 (8)	312	280	377
Highpoint Homecare	83114	Sumner	6 (6)	978	738	855
Sunbelt Homecare	07032	Campbell	7 (7)	285	260	261
SunCrest Home Health	21024	DeKalb	7 (7)	1406	1501	1568
SunCrest Home Health	19324	Davidson	12 (12)	5428	6710	5490
SunCrest Home Health of Manchester, Inc.	16034	Coffee	15 (15)	988	1114	1588
SunCrest Home Health of Nashville, Inc.	63044	Montgomery	6 (6)	229	381	587
Sweetwater Hospital Home Health	62062	Monroe	5 (5)	462	569	613
Tennessee Quality Homecare – Northwest	03025	Benton	15 (15)	1129	1128	1164
Tennessee Quality Homecare - Southwest	20045	Decatur	15 (15)	1352	1082	1080
Unicoi County Home Health	86051	Unicoi	1 (1)	246	209	206
University of TN Medical Center Home Care Services - Home Health	47132	Knox	15 (15)	2530	3264	3439
Vanderbilt Community and Home Services	19394	Davidson	7 (7)	1179	1230	1879
Vanderbilt Home Care Services	19314	Davidson	7 (7)	1180	1268	1812
Volunteer Home Care, Inc.	27085	Gibson	13 (13)	2549	3027	3041
Volunteer Homecare of West Tennessee, Inc.	20055	Decatur	13 (13)	1598	1503	1534
Vanderbilt HC Affiliated Walgreens IV and RT Services	94084	Williamson	33 (33)	81	86	67

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Where The Heart Is, Inc.	24036	Fayette	3 (3)	253	271	116
Willowbrook Home Health Care Agency, Inc.	19694	Davidson	36 (36)	3088	2149	1565
Willowbrook Visiting Nurse Association, Inc.	79236	Shelby	6 (6)	473	533	479
Woods Home Health, LLC	54083	McMinn	4 (4)	297	349	283

** Please highlight any HHA in bold font that offers intrathecal home infusion services, even if on a limited basis.*
*** Please show the # of all counties for each HHA. The # of counties in the applicant's service area should be shown separately in the bracket.*

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5. **Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)**

   The applicant notes that letters of support will be provided in a future supplemental response. In addition to letters from physicians, written support from other referral sources such as hospitals and HHAs, and patients would be helpful. Please note the following:

   A. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

   Pentec's regional manager for Specialty Infusion with responsibility for Tennessee has called on physicians and other referral sources throughout Tennessee and continues to do so. Pentec has received one letter of support, from Comprehensive Pain Specialists of Hendersonville, Tennessee (Richard Muench, M.D.), which is attached to this Supplement as Attachment to Question 5, Item A, Pentec will provide additional letters of support as a further supplement to its CON application as soon as they are available.

   B. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

   Please see the answer to Question 5, Item A, above.

6. **Section C. Need, Item 1 (Specific Criteria: Items 6a and 6b)**

Based on the response, it appears that the average billed cost per visit would amount to approximately $2,513 per visit in lieu of $2,471 per visit noted on page 30 of the revised application. In addition, it appears that the average cost per patient may change to $15,078 in lieu of $14,826 per patient noted on page 31. Please clarify.

The higher numbers shown above ($15,078 average annual cost per patient and $2,513 average cost per visit) are more accurate. They were calculated as follows: (1) the $15,078 average annual cost per patient = estimated Year 1 total revenue of $304,573 divided by 20.2, the average Year 1 patient census; (2) the $2,513 average per visit cost per patient = the average annual cost per patient of $15,078 divided by 6, the assumed number of visits. The lower numbers previously reported reflected rounding errors and an approximation of blended revenue for full-pay and partial-pay patients, and should be disregarded.

A better approach may be to provide separate data for full-pay and partial-pay patients for Year 1, as follows:

Full-pay (third-party insurance) – Year 1 average patient census = 10.4167

Cost ($)	Per diem	Nursing	Drugs	Supplies	Total
Total	218,284	3,455	38,969	776	261,483
Annual per patient	20,955	332	3,741	75	25,102
Per visit	3,493	55	623	12	4,184

Partial-pay (Medicare/Medicaid) – Year 1 average patient census = 9.75

Cost ($)	Per diem	Nursing	Drugs	Supplies	Total
Total	2,656	3,234	36,474	727	43,090
Annual per patient	272	332	3,741	75	4,419
Per visit	45	55	623	12	737

All patients – Year 1 average patient census = 20.1667

Cost ($)	Per diem	Nursing	Drugs	Supplies	Total
Total	220,940	6,689	75,423	1,503	304,573
Annual per patient	10,956	332	3,740	75	15,103
Per visit	1,826	55	623	12	2,517

The foregoing projections are based on actual 2013 charges in connection with Specialty Infusion services provided in the other states in Pentec's service area. Pentec is reimbursed for services provided by national and local insurance plans, and it bills in accordance with the insurers' charge schedules. In addition, some state Medicaid plans provide limited reimbursement for nursing and per diem charges, in addition to drugs and supplies, and that is reflected in the estimates above. For these reasons, actual Tennessee results could vary from the projections. However, Pentec believes that the Projected Data Chart (set forth on page 46 of its revised CON application) presents reasonable estimates for Years 1 and 2.

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7. **Section C, Economic Feasibility, Item 4 – Historical and Projected Data Chart and Item 5**

   Item 4 – Based on the response provided in Item 13 on page 39 of the 11/25/14 Supplemental Response, the $304,573.00 revenue entry in line B.2 of the Projected Data Chart appears to pertain to net operating revenue only. If so, the amount would need to be shown as Net Operating Revenue in a revised chart.

   There is a difference in the treatment of "Provisions for Bad Debt" between the Projected Data Chart (on page 46 of Pentec's revised CON application) and Pentec's audited financial statements (on page 133 of Pentec's revised CON application). In the Projected Data Chart, "Provisions for Bad Debt" (line item C.3) is shown as a deduction from Gross Operating Revenue and appears *above* the Net Operating Revenue line. In Pentec's audited financial statements, this item is shown as an Operating Expense, which is *below* the Net Operating Revenue line. This means that the Gross Operating Revenue line item on the Projected Data Chart is the equivalent of the "Net Patient Services Operating Revenue" line item in Pentec's audited financial statements. Therefore, unless "Provisions for Bad Debt" is shown as "0" and the projected number is moved to Other Expenses (line item D.8), it is appropriate to show total projected Year 1 revenue of $304,573 in the Gross Operating Revenue line of the Projected Data Chart.

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Are there management fees to affiliates or non-affiliates associated with this project? Are there any Other Expenses in amounts of $50,000 or more? If so, please enter the information in the templates provided in the exhibit at the end of this questionnaire and submit as a replacement chart for the application (please number the pages 44-R and 46-R, as appropriate).

There are no management fees to either affiliates or non-affiliates associated with the project.

There are Other Expenses in amounts of $50,000 or more for each of the three historical periods reported in the Historical Data Chart and for Year 2 (2016) in the Projected Data Chart. Per telephone conversation with Mr. Grimm of the Tennessee Health Services and Development Agency on December 3, 2014, historical and projected information regarding the composition of Other Expenses is set forth in the tables below:

HISTORICAL DATA CHART – OTHER EXPENSES

Other Expenses Categories	**Year 2011**	**Year 2012**	**Year 2013**
Sales and Marketing Expense	$2,605,000	$3,259,000	$2,667,000
General And Administrative Expenses	$2,646,000	$3,259,000	$2,934,000
One-time charges	$1,271,000	$6,474,000	$3,111,000
Goodwill Impairment	$0	$46,482,000	$0
Amortization	$145,000	$4,909,000	$8,326,400
Interest Expense (Income)	($18,000)	($19,000)	($24,000)
Gain / Loss on Disposal	$12,000	$16,000	$14,000
Total Other Expenses	**$6,661,000**	**$64,380,000**	**$17,028,400**

PROJECTED DATA CHART – OTHER EXPENSES

Other Expenses Categories	**Year 2015**	**Year 2016**
Sales and Marketing Expense	$18,884	$52,943
General And Administrative Expenses	$45,686	$128,088
One-time charges	$0	$0
Goodwill Impairment	$0	$0
Amortization	$0	$0
Interest Expense (Income)	$0	$0
Gain / Loss on Disposal	$0	$0
Total Other Expenses	**$64,569**	**$181,032**

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Item 5 – Based on the applicant's accounting convention of reporting at the net revenue line item, it appears that the information below for Year 1 may apply. Please confirm.

Average gross operating revenue = 0
Average contractual adjustments = 0
Average Net Operating revenue= $14,098 per patient or $2,350 per visit

As discussed in the answer to Question 7, Item 4 of this Supplement, the "net revenue line item" reported by Pentec in its audited financial statements, entitled "Net Patient Services Operating Revenue" (please see page 133 of Pentec's CON application), is the equivalent of the "Gross Operating Revenue" line item on the Projected Data Chart due to the difference in treatment of "Provisions for Bad Debt" between the Projected Data Chart and Pentec's audited financial statements.

It is correct to state that average contractual adjustments per patient = $0 for Year 1. However, as discussed in the answer to Question 6 of this Supplement, Pentec's projected Year 1 total revenue (i.e., Gross Operating Revenue) = $15,103 per patient and $2,517 per visit. Total projected Provisions for Bad Debt for Year 1 = $19,797, as shown in the Projected Data Chart at line item C.3. Based on the average Year 1 patient census of 20.1667, projected Gross Operating Revenue should be reduced as follows:

($)	Total	Annual per patient	Per visit
Gross Operating Revenue	304,573	15,103	2,517
Provisions for Bad Debt	(19,797)	(982)	(164)
Net Operating Revenue	284,775	14,121	2,354

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8. **Section C, Economic Feasibility, Item 9**

The completed chart is noted. It appears that Medicare and Medicaid revenue would not be the case absent certification of the proposed HHA. Shouldn't the combined amount incurred by non-covered enrollees of these programs be reported as "Compassionate Care" in the table below (Charity has been removed per the applicant)? If so, please revise the response by using the table below.

Payor	Year One Gross Revenues	As a % of total Gross Revenue
Medicare		
Medicaid/TennCare		
Commercial insurance		
Self-Pay		
Compassionate Care		
Total		

The chart as provided in the answer to Question 16 at page 42 of Supplement No. 1 is correct. This is because Pentec, as a licensed non-resident Tennessee pharmacy that is a Medicare and Medicaid provider, would be able to bill these programs for drugs and supplies, at a minimum. The chart provided in Supplement No. 1 is presented again below for reference.

Payor	Year One Gross Revenues	As a % of total Gross Revenue
Medicare	$21,545	7%
Medicaid/TennCare	$21,545	7%
Commercial insurance	$261,483	86%
Self-Pay	$0	0%
Charity	Not reported	NA
Total	$304,573	100%

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9. **Additional information for future review by Tennessee Department of Health**

   Following notification by the HSDA Executive Director that initial review of the proposal by HSDA staff is complete, the applicant will undergo a 60-day review period by TDH and possibly the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS). To facilitate their review (at least initially), please provide a response for the questions that are included in Exhibit 2 at the end of this questionnaire.

   Answers have been provided in Exhibit 2 of this Supplement.

10. Proof of Publication

Clarification to follow by the applicant in a future supplement is noted as to the status for the 3 counties – Hancock, Perry and Van Buren Counties. Thank you for following up on this item.

An affidavit of publication from the Tennessee Press Service, which is in addition to the proofs of publication already provided, is attached to this Supplement at Attachment to Question 10.

Pentec has contacted the applicable newspapers regarding circulation in Hancock, Perry and Van Buren counties, and is awaiting responses.

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Exhibit 1 – Historical & Projected Data Charts

The HSDA is utilizing more detailed Historical and Projected Data Charts. Please complete the revised Projected Data Chart provided at the end of this request for supplemental information. Please note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should also include any management fees paid by agreement to third party entities not having common ownership with the applicant. Management fees should not include expense allocations for support services, e.g., finance, human resources, information technology, legal, managed care, planning marketing, quality assurance, etc. that have been consolidated/centralized for the subsidiaries of a parent company.

As noted in the answer to Question 7 of this Supplement, there are no management fees to either affiliates or non-affiliates associated with the project.

Also as noted in the answer to Question 7 of this Supplement, per telephone conversation with Mr. Grimm of the Tennessee Health Services and Development Agency on December 3, 2014, historical and projected information regarding the composition of Other Expenses is presented in the answer to Question 7, rather than in revised Historical and Projected Data Charts.

EXHIBIT 2 – Reviewing Agency Questions

Issue: Administration of Home Service – Licensure Requirements

1. **To the best knowledge of TDH, intrathecal medication administration is not generally taught in nursing school. Is any certification required or available for performing IP services?**

   State certification is not available, but Pentec has developed a comprehensive program of classroom and field training for its primary care nurses is accredited through the American Nurses Credentialing Center ("ANCC"). Pentec believes that its nurse training program is unique, and stands in sharp contrast to the limited nurse training provided by many other agencies offering intrathecal pump services (e.g., reliance on training provided by pump manufacturers).

   Pentec's nurse training program is discussed in its revised CON application at Section C, Contribution to the Orderly Development of Health Care, Item 5, under the heading "Staff Education" (pages 62-63), and in the answer to Question 5, Item B at page 18 of Supplement No. 1. In addition, a copy of Pentec's Nurse Training Program Policy and Procedure is attached at pages 60-62 of Supplement No. 1 as Attachment to Question 5.B.

2. **If approved, the CON should be limited to IP management; no other home health services should be permitted.**

   In its CON application, Pentec has requested authority to establish a specialized home health agency to provide Ig-G replacement therapy services in addition to intrathecal pump services. However, if it is a necessary condition of approval, Pentec would agree to limit its CON to intrathecal pump services.

Issue: Administration of Home Service – Impact of Existing Regulations

1. **What participation by physicians will be involved/required in the overall supervision of patient care in addition to implanting of IPs?**

   The initial administration of medication is done by the treating physician immediately after surgical implantation of the intrathecal pump. On rare occasions, a patient does not receive the initial dose immediately after the surgery and saline is instilled in lieu of medication. In those instances, the patient instead receives the initial dose administration in the physician's office at a follow-up visit.

   If a patient needs to have an intrathecal pump or catheter replaced, the physician usually also does the initial dosage administration immediately after that surgery is completed. Further, the patient typically needs a follow-up appointment with the physician for clearance to have a Pentec nurse administer new medication or perform a refill following such surgery.

   The patient's physician will refer the patient to Pentec for treatment, order the patient's plan of care (developed by the primary care nurse with physician assistance), and prescribe all medication to be provided to the patient. In addition, the physician will review the patient's plan of care at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

   The patient's primary care nurse reports to the physician any changes that could change the patient's plan of care and treatment goals, which may result in a modified plan of care. If no change to the plan of care is noted by the primary care nurse, the plan will be maintained as signed and noted during the previous certification period, with renewal submitted for physician signature.

   Treating physicians have 24/7 access to patient records and real-time updates following patient visits through use of Pentec's proprietary Physician Portal, located on its website, which provides physicians with secure access to patients' medical information and also allows secure, HIPAA-compliant secure, two-way video-conferencing capability ("eVisit") that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the in-home visit.

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Issue: Administration of Home Service – Risks Involved

1. **There are risks of infection, diversion, overdose, and equipment malfunction/ troubleshooting. How can patient issues be resolved before it transitions into an emergent situation? How does a patient or caregiver know if there is an emergent situation? The applicant's small staff and large service area increase risk of harm. Additionally, how are workforce sick days and capacity issues to be handled?**

The risk of infection is addressed by the requirement of strict adherence to Pentec's infection control policies. A copy of Pentec's Infection Control Policy and Procedure is attached to this Supplement as Attachment to Exhibit 2, Issue: Administration of Home Service – Risks Involved.

The risk of diversion is addressed in detail in the answer to Question 4, Item G at page 13 of Supplement No. 1.

To the extent reasonably possible, Pentec's contingency planning allows problems such as missed appointments, overdose, and equipment malfunction to be identified and addressed, or avoided entirely, before they result in an emergent situation.

Missed appointments: Intrathecal pump patients must have their pumps refilled and reprogrammed at regular intervals. Because consequences of a pump running dry are serious and sometimes life-threatening, this cannot be allowed to happen, and Pentec has implemented procedures to ensure that it does not happen. Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances. In addition, each Pentec primary care nurse (the nurse assigned to a particular patient) is backed up by one or more other nurses who are available to provide care to the primary care nurse's assigned patient if the need arises. Pentec has a sufficient number of nurses licensed to practice in Tennessee to ensure that full coverage is always available.

Overdose; pump malfunction: All Pentec patients (and/or their representatives, if applicable) are educated on the signs and symptoms of medication withdrawal and overdose and the need to seek medical attention in such an event. In addition, Pentec nurses monitor pump battery life and advise patients in advance of the need to have the batteries replaced. (Intrathecal pumps are implanted surgically and batteries must be replaced in a surgical procedure.) However, a malfunction of an intrathecal pump is not an event that can be addressed by a Pentec contingency plan. As with any medical emergency, a patient with a malfunctioning intrathecal pump will need to seek immediate medical attention.

Pentec's ability to cover a large, statewide service area with a relatively small staff is addressed in detail in the answer to Question 4, Item G at page 12 of Supplement No. 1.

Staff capacity and workforce sick days are discussed in the answer to Question 4, Item G at page 12 of Supplement No. 1, and Question 6 at page 20 of Supplement No. 1.

SUPPLEMENTAL #2
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Issue: Administration of Home Service – Workforce Qualifications and Training

1. **The Board of Nursing Rules require that the RN be licensed and be competent (have the education and training) to perform any anticipated services; the applicant therefore must document how the RN is trained to be competent and how the RN will retain those competencies.**

   In addition to having and maintaining in good standing a license to practice professional nursing in Tennessee, each Pentec nurse must complete Pentec's in-house, ANCC-accredited primary care nurse training program. This program, which is the only such program of its kind in the United States, includes both classroom and field training and evaluation, and also includes regular refresher training and competency evaluation. Pentec's nurse training program is described in detail at Exhibit 2, Issue: Administration of Home Service – Licensure Requirement, Question 1 of this Supplement.

2. **It is TDH's understanding that the Joint Commission doesn't require nurses to be certified to perform critical care services in, e.g., a hospital.**

   The Joint Commission does not provide certification, but ongoing continuing education provides Pentec's nurses with the means to obtain clinical excellence and competencies.

SUPPLEMENTAL #2
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Issue: Administration of Home Service – Payment for Service Including Participation in TennCare

1. **TDH understands that TennCare covers IP services performed in a physician's office, but not in the home setting.**

   This is correct. TennCare covers the skilled nursing services required to treat intrathecal pump patients when performed in a physician's office, but not when performed in the patient's place of residence.

2. **No economic impact to TennCare.**

   This is correct. Because Pentec's services would be performed in the patient's place of residence, the nursing and per diem components of Pentec's charges would not be covered. Because Pentec is also a non-resident Tennessee pharmacy that is a Medicare and Medicaid provider, it would be able to bill for drugs and the administration kit (low-cost disposable supplies), but TennCare would be billed for these items whether the services are performed in a physician's office setting or in the patient's place of residence.

SUPPLEMENTAL #2
December 10, 2014
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Issue: Administration of Home Service – Health Plan Consistency: Access, Economic Efficiency, Quality

1. **The CON would provide greater access to IP services, however greater access must be balanced by the increased risk to patients.**

   Pentec believes that the benefits of treatment of patients in their places of residences outweigh any increased risk, and, in some respects, treatment in the home may actually reduce risk. For example, many patients with intrathecal pumps suffer from limited mobility; for these patients, travel to a physician's office for treatment can be burdensome and increases the risk of a missed appointment and the pump running dry – an emergency that can be life-threatening. Furthermore, Pentec has developed and implemented comprehensive policies and procedures that are designed to minimize risk. The risks to patients with intrathecal pumps and the measures taken by Pentec to minimize them are discussed in the answer to Exhibit 2, Issue: Administration of Home Service – Risks Involved, Question 1 of this Supplement.

2. **There may be a lower cost to the patient in providing this service in the home setting.**

   Pentec believes, and research has indicated, that in-home treatment of intrathecal pump patients has the potential to reduce patient use of inpatient and outpatient services as well as ancillary services such as ambulance transport and EMS. The potential for reduction of costs to the patient and to the healthcare system generally are discussed in the answer to Section C, Need, Question 1, under the heading "Principle 3: Economic Efficiencies" at pages 25-26 of Pentec's revised CON application.

3. **Quality of Care issues:**

   a. **An IP patient already has a provider team in place; why fracture the continuity of care? Based on the existence of a provider team, applicant should explain further the need for the service.**

      Pentec notes that the proposed services would not entirely replace physician office visits; instead, they become an extension of the physician's care. Pentec's primary care nurses provide services pursuant to a plan of care ordered by and developed in conjunction with the treating physician, and they are in frequent contact with the physician: plans of care is reviewed at least every 60 days, and physicians receive a report immediately following each visit by a Pentec nurse. Treating physicians have 24/7 access to their patients' medical records through Pentec's electronic medical records system, and 24/7 contact with the assigned primary care nurse.

      Providing services to intrathecal pump patients in the home can address and mitigate problems caused patient mobility restrictions, burdensome travel to the physician's office for treatment (especially for patients outside urban areas, where travel times and distances can be great due to the limited number of physicians practicing in the area of intrathecal medicine), and long waiting periods in physician offices when the patient is experiencing pain or episodes of spasticity.

b. Describe the process for dosage adjustments – coordination between applicant's staff and patients' personal physicians

The dose adjustment typically begins with a patient's request to the assigned primary care nurse. The nurse will send an order to the physician's office after discussion with the physician and/or qualified staff on whether and what dose adjustment is appropriate. Confirmation of the physician's order for the adjustment with the physician's signature will be documented in the patient's chart.

The Pentec primary care nurse can also receive a signed physician's order to perform a dose adjustment. Confirmation of the order will be completed by communication with the physician and/or qualified staff and with the patient and/or the patient's caregiver prior to scheduling the patient for the dose adjustment.

The plan of treatment for each intrathecal pump patient includes the patient's medication profile containing all medications ordered by all physicians. It gives the physicians opportunity for medication reconciliation noting all the medications the patient is receiving.

c. Describe the process for monitoring IP maintenance, including troubleshooting of the intrathecal pump.

Intrathecal pump maintenance involves patient and/or caregiver awareness and education. The nurse's assessment of the patient, performed at each visit, always includes visual inspection of the intrathecal pump and catheter areas for signs and symptoms of fluid accumulation, signs and symptoms of infection, possible signs and symptoms of dislodgement or displacement; and the nurse reports any concerns to the treating physician immediately. The patient's intrathecal pump refill interval is always noted along with the alarm date (the date on which the pump *must* be refilled). The patient is scheduled for a refill visit in advance of the alarm date to ensure that the patient's refill is completed in a timely manner. The nurse will also monitor pump battery life and advise patients in advance of the need to have the batteries replaced (a surgical procedure).

An intrathecal pump malfunction cannot be treated by the Pentec nurse. As with any medical emergency, a patient with a malfunctioning intrathecal pump will need to seek immediate medical attention, and will be directed to the nearest hospital emergency department.

Intrathecal pump maintenance also involves patient and caregiver awareness and education. All Pentec patients (and their representatives or caregivers, if applicable) are educated on the signs and symptoms of medication withdrawal and overdose and the need to seek medical attention in such an event.

d. Since physician review of patient condition is dependent upon report by RN, what are provisions for face-to-face assessment by physicians?

Provisions for a face-to-face physician assessment will depend on the patient's diagnosis, prognosis, current status and any changes in status, as well as applicable state laws governing minimum required frequency of physician examination of patients. The patient will be instructed to follow up with his or her physician in the event of any changes in the patient's assessment, both objective and subjective, by the Pentec primary care nurse. In addition, the nurse will enter notes into Pentec's electronic medical records system immediately after each visit, and these will be provided to the treating physician for review. Frequency of physician face-to-face assessment of intrathecal pump patients can vary greatly depending on the foregoing factors.

Any changes in the status of a patient possibly related to the intrathecal pump or catheter requires urgent or emergent physician assessment and follow-up. These can include sudden changes in pain and/or spasticity levels, sudden neurological, respiratory, or cardiac changes, any signs or symptoms of an infection, any signs or symptoms of fluid accumulation around the intrathecal pump or catheter areas, and signs or symptoms of dislodgement or displacement of the pump or catheter.

Issue: Administration of Home Service – Other Laws, Regulation or Guidelines that the Service/Facility Would Impact

1. **TDH draft Chronic Pain Guidelines don't address IP services specifically. Morphine equivalents, however, have specific delivery requirements (see 4.c, below).**

   Pentec has reviewed the draft Tennessee Chronic Pain Guidelines and notes that the focus of the Guidelines appears to be on the prescribing and control of orally-administered opioids. As noted above, the Guidelines do not address intrathecal delivery of controlled substances by means of a surgically-implanted intrathecal pump. However, as discussed in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1, Pentec is cognizant of the risks posed by diversion of controlled substances, and in response has developed a protocol for shipping, storage and delivery of all intrathecal medication (including opioids/ controlled substances) that is designed to ensure continuous Pentec custody of all medication until the time it is administered to the patient.

2. **The Professional Boards are not yet in position to provide recommendations.**

   Pentec strongly believes that its proven model for handling intrathecal medication (including opioids/controlled substances), which entails delivery by Pentec's pharmacy to a Pentec employee for ultimate delivery and administration to the patient, is superior to available alternatives and provides the best protection against diversion, abuse, loss and spoilage.

3. **How would existing Home Health Agencies that provide infusion services be impacted?**

   The impact of the proposed HHA on existing Tennessee agencies that provide home infusion services would be minimal. This is because the proposed services would be limited almost exclusively to patients with intrathecal pumps (although Pentec would offer Ig-G replacement therapy as an ancillary service).

   Effective care of intrathecal pump patients requires both the ability to refill medications, which requires a pharmacy license, and the ability to administer medications, which requires very specialized skilled nursing services. Pentec is already licensed in Tennessee as a non-resident pharmacy. Its pharmacy staff is specially trained in the preparation of intrathecal drugs and required packaging and delivery systems, and the medication compounding occurs in an absolutely clean, controlled environment. Pentec presently employs registered nurses licensed in Tennessee or a compact state who would staff the proposed HHA. The nursing skills necessary to administer a patient's medications and effectively monitor the operation of the delivery system are highly specialized. To ensure that its nurses have and maintain the required skills, Pentec has instituted a rigorous in-house program of classroom instruction, field training and proficiency evaluation. All Pentec nurses must successfully complete this program, which is the only such program certified by the American Nursing Credentialing Center ("ANCC"), and maintain required proficiency on an ongoing basis.

   Although there are large providers of infusion therapy services with affiliated pharmacies such as Coram Specialty Infusion, these home infusion agencies typically do not provide

services to patients with intrathecal pumps. The impact on agencies such as these would be small to non-existent, since they serve different patient populations. Other agencies, such as Professional Home Health, do treat intrathecal pump patients, but on a very limited basis. While the approval of Pentec's proposal could affect agencies that provide intrathecal pump services, no presently-licensed HHA is a specialty provider of intrathecal pump services, so the impact would be most likely be small.

4. **TDH Rules do not prohibit physician or pharmacist ownership of the applicant and prescribing. However, there are the following issues:**

   a. **Administering: Inside the physician office, prescribing is a permitted "administration" act.**

      The proposed HHA would not be owned by a physician or a pharmacist, so the foregoing concern would not apply. The applicant, Pentec Health, Inc., is a Pennsylvania business corporation that would be the holder of the certificate of need and the HHA license, and it is also the holder of a Tennessee non-resident pharmacy license. Under the Pentec model, all prescribing of intrathecal medication would be by the treating physician. Pentec's pharmacy would fill the prescription and deliver the medication to a Pentec employee in Tennessee for ultimate administration to the patient by a Pentec registered nurse.

   b. **Dispensing: Outside of the physician office, it is a "dispensing" act, which falls under the Pain Clinic Guidelines. Physicians cannot "dispense" opioids.**

      Again, the proposed HHA would not be owned by a physician or a pharmacist, so the foregoing concern would not apply. As noted above, treating physicians will prescribe intrathecal medications (including controlled substances), Pentec's pharmacy will fill the prescriptions, and a Pentec nurse will administer the prescribed medication to the patient.

   c. **Delivery: The draft Chronic Pain Guidelines require that morphine equivalents be "delivered" directly to the ultimate user by an "agent" of a pharmacist. Are there other Pharmacy guideline requirements?**

      Under Pentec's model of care for intrathecal pump patients, all medication, including scheduled controlled substances, are delivered by Pentec's pharmacy to a Pentec employee, i.e., the Pentec primary care nurse. The primary care nurse then performs the administration of the medication to the patient.

      Pentec has developed a shipping, storage and delivery protocol that is designed to ensure continuous Pentec custody of all medication until the time it is administered to the patient. This protocol is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

   d. **Transport:**

      i. **There is a risk of opioid diversion. TDH is waiting on Drug Enforcement Agency input.**

         As noted immediately above, Pentec has developed a shipping, storage and delivery protocol designed to ensure continuous Pentec custody of all medication until the time of administration to the patient, thereby keeping the risk of diversion to an absolute minimum. This is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

ii. Transport of Medications – Licensure; how will the medications be obtained? By the RN from the pharmacy delivered to the patient, by the RN from the physician's office delivered to the patient, by the patient to pick-up directly from the pharmacy?

For reasons including minimization of the risk of diversion or abuse of controlled substances, minimization of the risk of loss, and maintenance of proper storage conditions, Pentec's model entails shipment by its pharmacy, pursuant to the order of the prescribing physician, of intrathecal medications to the appropriate primary care nurse. Pentec Health, Inc. is the pharmacy license holder in all 50 states and the District of Columbia; the federal Drug Enforcement Agency ("DEA") registrant (No. BP9684627); and the license holder in those jurisdictions in which a home health or similar agency license is required. Therefore, Pentec's pharmacy ships intrathecal medications to an employee, who is also the primary care nurse that administers the medication to the patient. Pentec's shipment, delivery and administration process is described in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

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Issue: Follow-up Care – Licensure Requirements

1. **TDH is concerned about the level of follow-up care and how often the RN visits each patient.**

   Patient follow-up care is determined on a case-by-case basis depending on the patient's diagnosis, intrathecal pump refill interval, prognosis, and any changes in status. The patient would receive, at a minimum, the same level of follow-up care that would be provided if care were being performed by the physician directly. For example, if a patient is otherwise stable in his or her status and diagnosis, and the patient's refill interval is every 60 days, then the patient most likely would not have contact with the treating physician until his or her next appointment for a pump refill. Pentec's primary care nurses actually have *more* contact with patients then when patients are being cared for by their physician only. In the example mentioned above, the Pentec nurse would contact the patient not less than every 30 days, either by telephone call or by visit, depending on the particular needs of the patient.

2. **TDH is concerned about the applicant's patient care plans for physician follow-up of patient.**

   As a matter of Pentec policy, documentation of patient visits is always provided to the treating physician immediately following the visit. Also, Pentec's primary care nurses communicate continually with the physician and/or their qualified staff on any changes in the patient's status or any patient needs, whether identified by the nurse or the patient.

Issue: Follow-up Care – Risks Involved

1. **The continuity of care should lie with the implanting physician or the primary care provider following the patient's release from surgical care, who should order the appropriate medication dosage.**

   The intrathecal pump physician is the primary care provider with respect to a patient's intrathecal pump care. The family physician addresses other medical needs. The intrathecal pump physician coordinates the patient's care with the surgeon who implants the pump, including any appropriate medication dosage needed post-operatively. Thereafter, the intrathecal pump physician is the prescribing physician for the patient's intrathecal medication.

2. **Who is responsible if the patient is admitted to a hospital? In an emergent situation, what if the treating physician does not have admitting privileges at the nearest hospital?**

   The patient's admitting diagnosis will determine what physician directs the patient's care. If there are concerns involving the patient's intrathecal pump, the attending physician will consult an appropriate physician with privileges to that particular facility. If the intrathecal pump needs addressed, our nurse can enter the facility and care for the patient following the hospital's credentialing process.

3. **High risk of overdose due to high conversion ratio requires adequate experience with IPs and with interventional pain medication.**

   Pentec nurses attend an intense, in-house classroom and field training program that is ANCC-certified to assure adequate experience and the ability to identify factors in the prevention of and the risks of potential for overdose.

   Pentec's pharmacy has more than 30 years' experience in the compounding and preparation of intrathecal medications. It uses various reliable literature sources such as the Polyanalgesic Consensus guidelines to assist prescribing physicians when requested to do so.

4. **Will patient satisfaction and the quality of delivered services equal the current models for delivery of this care?**

   Pentec patient satisfaction surveys are conducted annually. The survey asks patients to assign a rating, on a scale of 1 (lowest) to 5 (highest), in 12 different areas. For each of the past 3 years (2011-2013), the average overall rating has been 4.8 out of 5.0. Survey results are reviewed by Pentec management each year, and unfavorable surveys are investigated by the Vice President of Nursing Services immediately, to ensure that patient concerns are being addressed. Survey results are shared with Pentec's nursing staff, and they are taken into consideration as part of the primary care nurses' performance evaluation process.

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5. **In addition to the proposed Nashville home office, does Pentec plan to maintain a 24 hour call center through its parent office in PA or other existing location? If so, please identify the address, the amount of time the center has operated, its staffing plan, the number of home health agencies covered by state and its "call" volume over the most recent 12-month period.**

   Pentec maintains centralized communications at its headquarters, which is located at 4 Creek Parkway, Boothwyn, Pennsylvania 19061. Pentec has a registered nurse on call 24 hours a day, 7 days a week, to handle patient calls. When a patient call is received, the on-call nurse responds by contacting the appropriate Regional Nurse Manager for the state in which the patient resides, who will then assess and respond appropriately to the patient's needs. (The on-call nurse does not assess or advise patients because he or she may not be licensed to practice in the patient's state of residence. However, the Regional Nurse Manager is licensed to practice professional nursing in each state for which he or she is responsible.) Pentec's Regional Nurse Managers have 24-hour accountability for responding to patient calls.

   For the 11-month period from January 1 to November 30, 2014, Pentec responded to 741 total patient calls, of which 445 calls were from Specialty Infusion patients. As of November 30, 2014, Pentec's Specialty Infusion division offered services in 32 states, although the patient census in several of these states is presently very small.

SUPPLEMENTAL #2
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Issue: Secure Medications – Risks Involved

1. **Potential for preparation of medication in a non-sterile environment, diversion risks, and risk of impinging sterility of the medications. Is there information on infection rates in the home with IP services?**

   The process of sterile compounding and preparation of intrathecal drugs by Pentec's pharmacy is described in detail in the answer to Question 4, Item A at page 6 of Supplement No. 1 and in the Attachment to Question 4.A at pages 49-52 of Supplement No. 1.

   Pentec has experienced a zero nosocomial infection rate.

2. **There may be compounding of drugs. How or where are drugs mixed or are only FDA-approved, commercially available products used?**

   Pentec Health utilizes commercially available products to prepare prescriptions except in instances where the physician is prescribing higher concentrations of ingredients or multiple ingredients which will not allow Pentec to achieve the desired final concentrations from utilizing commercially available products.

   If mixed, is manipulation or diversion of the product possible once mixed? A physician can mix drugs, and there is nothing in the nursing regulations that prohibits nurses from doing so. TDH has not considered the issue of a nurse mixing drugs in a home.

   Every prescription filled by Pentec's pharmacy is reviewed, compounded and verified by experienced pharmacy personnel at various stages of processing, including both before and after compounding. Pentec's nurses have no involvement in the compounding of intrathecal drugs.

   Pentec has developed a shipping, storage and delivery protocol designed to ensure continuous Pentec custody of all medication until the time of administration to the patient, thereby keeping the risk of diversion to an absolute minimum. This is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

   Dosage is changed based on laboratory values. How will these values be taken and reported?

   IT medications do not require laboratory monitoring. Ig-G replacement therapy does include some lab work but any changes to therapy will occur at the next scheduled dosage administration, after being reviewed by Pentec's nursing and pharmacy staff and reported to the treating physician.

   When ordered by the physician, blood specimens can be collected by Pentec nurses. In such cases, the nurse would send the specimens to the laboratory (Quest) for analysis, and the laboratory would report the values to Pentec. Once the laboratory values are received, the results are then reported and faxed to the treating physician.

Home health agency nurses are permitted to draw blood and deliver it to laboratories, adding time and costs as compared to performing this service in the physician's office where there is a laboratory.

Many physicians that do not have an in-office laboratory. If a physician does have a laboratory and the patient visits the physician only for the purpose of laboratory specimen collection and analysis, it may result in additional cost. In comparison, by having Pentec collect and send the specimen while in the patient's home performing other services, a cost saving may arise.

3. **What safeguards are in place to ensure security of medications during transport to the home?**

As noted above, Pentec has developed a shipping, storage and delivery protocol designed to ensure continuous Pentec custody of all medication until the time of administration to the patient, thereby keeping the risk of diversion to an absolute minimum. This is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

SUPPLEMENTAL #2
December 10, 2014
10:13 am

Other Questions:

1. **How does a typical IP services home health agency contract read?**

   Copies of the relevant agreements are attached to this Supplement as Attachment to Exhibit 2, Other Questions, Item 1. These agreements include the following:

   1. "Consent to Treat, Insurance Assignments, Financial Agreement, Authorization to Release Information, & Privacy Notice Acknowledgement"

   2. "Addendum to: Consent to Treat, Insurance Assignments, Financial Agreement, Authorization to Release Information, & Privacy Notice Acknowledgement"

2. **In what other states does the applicant operate as a licensed pharmacy, home health organization or other type of licensed provider classification?**

   Pentec operates physical pharmacy facilities in Pennsylvania and Massachusetts, and it is licensed as a resident or non-resident pharmacy, as applicable, in all 50 states and the District of Columbia. Pentec is also licensed as a home health agency or other applicable agency in 13 states.

   A table listing Pentec's HHA and pharmacy licensure status nationwide is provided in the answer to Question 4, Item I at pages 16-17 of Supplement No. 1.

3. **Does the applicant have any licensure or certification citations and/or enforcement actions within the past three years?**

   Pentec has not had any licensure or certification citations or enforcement actions within the three-year period ending December 10, 2014.

SUPPLEMENTAL #2
December 10, 2014
10:13 am

ATTACHMENT TO QUESTION 3

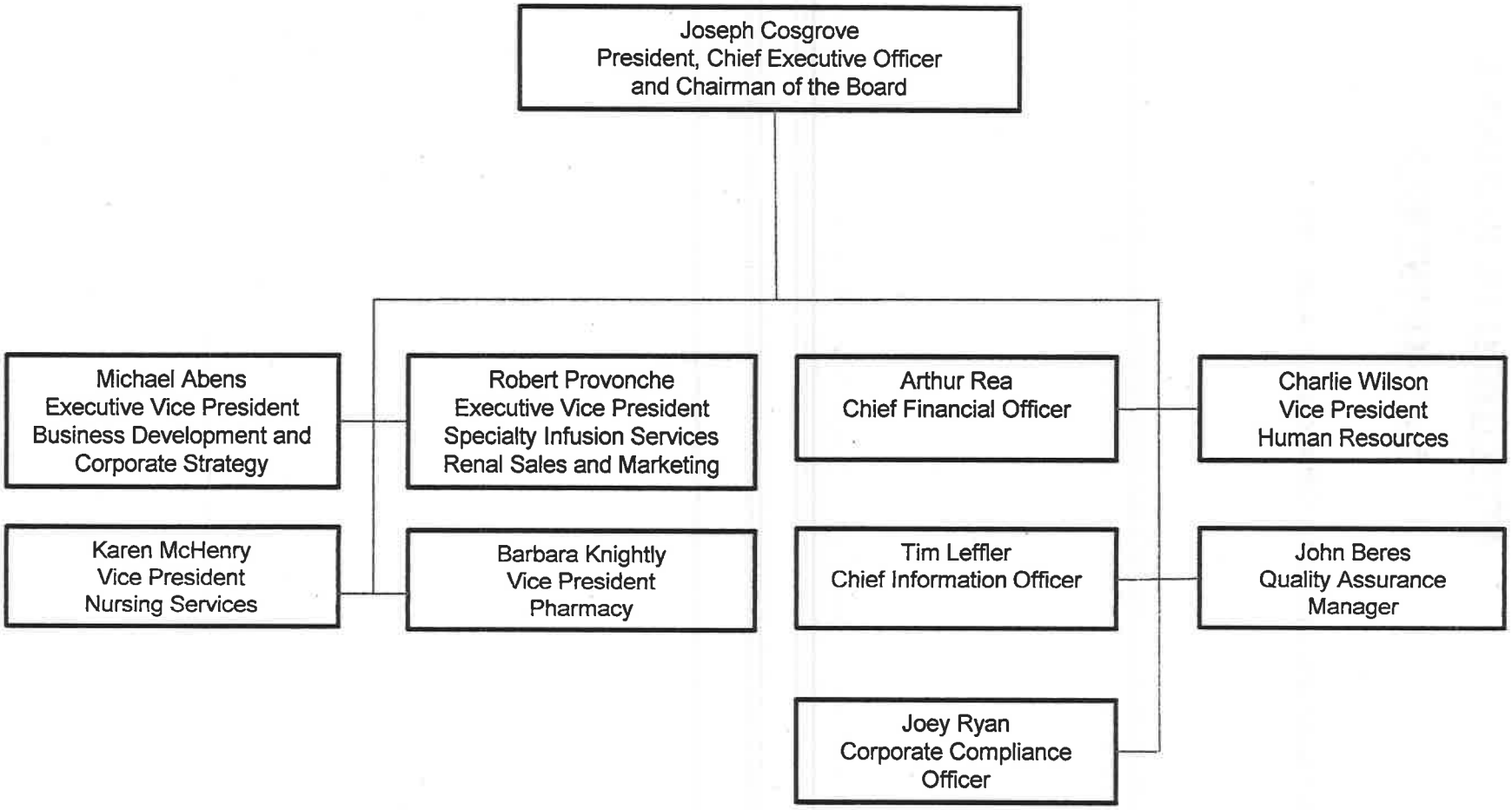
SUPPLEMENT NO. 2

Pentec Health, Inc. – Executive Office organizational chart.

Pentec Health, Inc.

Executive Office

As of November 30, 2014



SUPPLEMENTAL #2
December 10, 2014
10:13 am

48

SUPPLEMENTAL #2
December 10, 2014
10:13 am

ATTACHMENT TO QUESTION 3, ITEM 4.F

SUPPLEMENT NO. 2

1. Copy of Pentec Specialty Infusion Policy and Procedure No. 9.12 – Patient Safety Checklist.
2. Copy of Pentec "Patient Safety Checklist".

SUPPLEMENTAL #2
December 10, 2014
10:13 am

PENTEC HEALTH POLICY/PROCEDURE

DOCUMENTATION

S.I. POLICY AND PROCEDURE

9.12 Patient Safety Checklist

Policy:

To promote patient safety in refill of intrathecal pumps by implementing check points to confirm the accuracy of medication delivered to the nurse for administration to the patient, confirming the accuracy of medication prior to pump access, and reviewing all changes with the patient or caregiver.

Procedure:

1. Upon receipt of medication delivery (Medication Check In):
   a) Check all applicable boxes
   b) If no DOB on script, contact pharmacy to confirm and document accordingly

2. Before Pump Access (for refills and/or adjustments):
   a) Check all applicable boxes, reviewing out loud with the patient
   b) Confirm the label of syringe while you read the order
   c) If data on interrogation is not expected: STOP, CLARIFY, TAKE APPROPRIATE ACTION AND DOCUMENT IN EMR

3. After Pump refill and/or Adjustment:
   a) Review telemetry with the patient/caregiver or Pentec nurse as appropriate
   b) Record volume of medication in mLs and alarm date per current telemetry. Alarm date may vary based on medication stability, or physician/patient preferences

4. Pentec nurse sign form acknowledging accuracy of above information

5. Patient/Caregiver to sign form acknowledging above information reviewed with them by the Pentec nurse

6. Scan form and attach in message center with the title "SAFETY CHECKLIST"

Effective: 12/2013 Revised: 07/2014

SUPPLEMENTAL #2
December 10, 2014
10:13 am

Patient Safety Checklist

Patient Name:_____ DOB: _____

Medication check-in:

- ☐ N/A-adjustment only
- ☐ Patient's name and DOB verified
- ☐ No change in medication and/or concentration
- ☐ Change noted in medication and/or concentration
- ☐ Patient has a PTM
- ☐ Last telemetry reviewed
- ☐ Dose will remain the same
- ☐ Bridge bolus will be programmed
- ☐ New dose is ordered
- ☐ Last telemetry not available
- ☐ Non-programmable pump
- ☐ Program is simple continuous
- ☐ Program is flex mode
- ☐ Discard after date:_____

Medication and concentration on label:_____

_____

To be reviewed with the patient prior to performing a refill or adjustment:

- ☐ Patient's name and DOB verified
- ☐ Data on interrogation is different than last tele. STOP, REVIEW, CLARIFY
- ☐ Medication on syringe label read out loud
- ☐ Verbally confirm: changes ARE ordered
- ☐ Allergies reviewed
- ☐ Data on interrogation is the same as last tele.
- ☐ Non-programmable pump
- ☐ Verbally confirm: changes ARE NOT ordered

After pump refill and/or adjustment:

- ☐ Telemetry reviewed with patient/caregiver/ facility
- ☐ Telemetry reviewed with Pentec RN
- ☐ Non-programmable pump-refill information reviewed with patient/caregiver/facility

☐ Total volume is: _____mLs ☐ Alarm date is: _____

I have ensured the above information is accurate:

_____ **Date:** _____

The Pentec nurse has reviewed the above information with me:

_____ **Date:**_____

Revised: May, 2014

SUPPLEMENTAL #2
December 10, 2014
10:13 am

ATTACHMENT TO QUESTION 5, ITEM A

SUPPLEMENT NO. 2

Copy of letter of support from Comprehensive Pain Specialists (Richard Muench, M.D.), Hendersonville, Tennessee.

SUPPLEMENTAL #2
December 10, 2014
10:13 am

CPS
COMPREHENSIVE PAIN SPECIALISTS

131 SAUNDERSVILLE ROAD SUITE 160, HENDERSONVILLE, TN 37075 | WWW.CPSPAIN.COM

December 1, 2014

Dear ,

I am writing in support of Pentec Health, Inc. being granted their certificate of need by the state of Tennessee to become licensed as a home health agency so that patients with intrathecal pumps can be efficiently serviced in their homes.

Intrathecal pumps allow highly concentrated medications for pain and spasticity to be administered through the intrathecal space surrounding the spinal cord. This form of drug administration is very different from the delivery of medication intravenously or subcutaneously and requires highly specialized nursing and pharmaceutical services. Several of my patients have an intrathecal pump because they have not been able to obtain proper relief from traditional treatments for conditions such as chronic pain and/or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer.

Currently, these patients must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of few providers in Tennessee that treat patients with intrathecal pumps. We have patients coming from all areas of the state.

Sincerely,

Physician

SUPPLEMENTAL #2
December 10, 2014
10:13 am

ATTACHMENT TO QUESTION 10

SUPPLEMENT NO. 2

Copy of affidavit of publication from Tennessee Press Service regarding publication of Pentec's Letter of Intent in Tennessee newspapers of general circulation.

SUPPLEMENTAL #2
December 10, 2014
10:13 am

TENNESSEE PRESS SERVICE
433 Moontrace Lane
Knoxville, TN 37919
Voice (865) 584-5781 Fax [illegible] or (865) 584-6513 (Acctg)

AFFIDAVIT

Saul Ewing, LLP
2 North Second Street, 7th Floor
Harrisburg, PA 17101

To Whom It May Concern:

The enclosed itemized statement is for publication of **"Notification of Intent To Apply For a Certificate of Need"** in the list of newspaper (s) on invoice **$14.3671** on the date (s) stated therein as authorized by your office.

As requested, tearsheets are submitted herewith as further proof of publication.

I, *Laurie Alford*, Business Controller of Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Fifth day of November 2014

Laurie Alford – Business Controller

Sworn before me this 25th day of November 2014

Robyn Gentile, Notary Public
My commission expires September 11, 2016

ROBYN N. GENTILE
STATE OF TENNESSEE NOTARY PUBLIC
KNOX COUNTY

SUPPLEMENTAL #2

December 10, 2014

Tennessee Press Service, Inc.
Your Print & Digital Connection
Representing Tennessee Newspapers
435 Montbrook Lane
Knoxville,TN 37919-2704
Voice (865) 584-5761 Fax (865) 558-8687

Wednesday, November 19, 2014 09:49 AM

Invoice

	Maronetta F. Miller	**Invoice Date**	11/19/2014
Agency	Saul Ewing, LLP	**PO Number**	
	2 North Second Street 7th Floor Harrisburg, PA 17101-	**Order**	S14.3671

Client Pentec Health, Inc.

Reps State Earl Goodman

Newspaper

Caption	Run Date	Ad Size	Rate	Rate Name	Color	Disc.	Total
Bristol - Bristol Herald Courier							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 3.5	$66.40	Public Notice Classified	$0.00	0.0000%	$464.80
Chattanooga - Chattanooga Times Free Press							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	$44.96	Public Notice Classified	$0.00	0.0000%	$449.60
Clarksville - The Leaf-Chronicle							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	$693.18	Public Notice Classified	$0.00	0.0000%	$693.18
Cookeville - Herald-Citizen							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 4.5	$12.73	Classified National	$0.00	0.0000%	$114.57
Dyersburg - State Gazette							
Notification Of Intent To Apply For A Certificate Of Need (AD RAN INCORRECTLY~Rescheduled 11/11/14)	11/09/2014	2 x 7	$12.45	Classified National	$0.00	0.0000%	DNR
Notification Of Intent To Apply For A Certificate Of Need	11/11/2014	2 x 7	$12.45	Classified National	$0.00	0.0000%	$174.30
Greeneville - Greeneville Sun							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	$28.75	Classified National	$0.00	0.0000%	$287.50
Jackson - The Jackson Sun							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	$396.00	Public Notice Classified	$0.00	0.0000%	$396.00
Johnson City - Johnson City Press							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 6	$21.39	Classified National	$0.00	0.0000%	$256.68

We appreciate your business! TERMS: Due Net 30 Days

Ad-Vantage™ version 7.52 by Customware, Inc. Copyright 2001-2012

Registered To: Tennessee Press Association

SUPPLEMENTAL #2

December 10, 2014

TENNESSEE PRESS SERVICE
tnadvertising.biz

Tennessee Press Service, Inc.
Your Print & Digital Connection
Representing Tennessee Newspapers
435 Montbrook Lane
Knoxville,TN 37919-2704
Voice (865) 584-5761 Fax (865) 558-8687

Wednesday, November 19, 2014 09:49 AM

Invoice

	Maronetta F. Miller	**Invoice Date**	11/19/2014
Agency	Saul Ewing, LLP	**PO Number**	
	2 North Second Street 7th Floor Harrisburg, PA 17101-	**Order**	S14.3671
Client	Pentec Health, Inc.		
Reps	State	Earl Goodman	

Newspaper

Caption	Run Date	Ad Size	Rate	Rate Name	Color	Disc.	Total
Kingsport - The Kingsport Times-News							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 6	$32.90	Classified National	$0.00	0.0000%	$394.80
Knoxville - Knoxville News Sentinel							
Notification Of Intent To Apply For A Certificate Of Need	11/09/2014	2 x 9	$45.64	Public Notice Classified	$10.00	0.0000%	$831.52
Memphis - The Commercial Appeal							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 8.5	$149.00	Public Notice Classified	$30.00	0.0000%	$2,563.00
Murfreesboro - The Daily News Journal							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	$386.46	Public Notice Classified	$0.00	0.0000%	$386.46
Nashville - The Tennessean							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	$2,083.14	Public Notice Classified	$0.00	0.0000%	$2,083.14
Paris - The Paris Post-Intelligencer							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 7	$8.85	Classified National	$0.00	0.0000%	$123.90
Union City - Union City Daily Messenger							
Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 7	$8.75	Classified National	$0.00	0.0000%	$122.50

We appreciate your business! TERMS: Due Net 30 Days

58

SUPPLEMENTAL #2

December 10, 2014

Tennessee Press Service, Inc.
Your Print & Digital Connection
Representing Tennessee Newspapers
435 Montbrook Lane
Knoxville,TN 37919-2704
Voice (865) 584-5761 Fax (865) 558-8687

Wednesday, November 19, 2014 09:49 AM

Invoice

	Maronetta F. Miller	**Invoice Date**	11/19/2014
Agency	Saul Ewing, LLP	**PO Number**	
	2 North Second Street 7th Floor Harrisburg, PA 17101-	**Order**	S14.3671
Client	Pentec Health, Inc.		
Reps	State	Earl Goodman	

Newspaper Caption	Run Date	Ad Size	Rate	Rate Name	Color	Disc.	Total
				Total Advertising			$9,341.95
				Discounts			$0.00
				Tax: USA			$0.00
				Total Invoice			$9,341.95
				Payments			$5,000.00
				Adjustments			$0.00
				Balance Due			$4,341.95

We appreciate your business! TERMS: Due Net 30 Days

59

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Registered To: Tennessee Press Association

SUPPLEMENTAL #2
December 10, 2014
10:13 am

DEC 10 2014

AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 5 day of December, 2014, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

Christine Britton
NOTARY PUBLIC

My commission expires 11-4-18

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Christine Britton, Notary Public
Upper Chichester Twp., Delaware County
My Commission Expires Nov. 4, 2018
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

HF-0043
Revised 7/02

COPY-
Clarification
SUPPLEMENTAL-2

Pentec Health Inc.
CN1411-046

Saul Ewing LLP

COPY

SUPPLEMENTAL

Richard D. Leigh
Phone: (717) 257-7501
Fax: (717) 257-7599
rleigh@saul.com
www.saul.com

December 20, 2014

VIA FEDERAL EXPRESS (Tel. 615-741-2364)

State of Tennessee
Health Services and Development Agency
Attention: Jeff Grimm
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Pentec Health, Inc. / Certificate of Need Application CN1411-046 / Additional Clarification to Supplement No. 2

Dear Mr. Grimm:

In response to your letter to Doug Wynd of December 19, 2014, we are submitting for review one original and two copies of Pentec's Additional Clarification to Supplement No. 2 to Certificate of Need Application CN1411-046, together with the appropriate affidavit.

If you have any questions about the Certificate of Need application, please feel free to contact me (contact information provided above), or contact Doug Wynd at 636-751-6481 or dwynd@pentechealth.com. Again, we look forward to working with the Agency in connection with Pentec's application.

Sincerely,

Richard D. Leigh

Enclosure
cc: Doug Wynd, Pentec Health, Inc.
Robert A. Provonche, Pentec Health, Inc.
Karen McHenry, R.N., Pentec Health, Inc.

SUPPLEMENTAL

PENTEC HEALTH, INC.

ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

DECEMBER 2014

SUPPLEMENTAL

1. **Section C, Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)**

   The applicant notes that letters of support will be provided in a future supplemental response. An update was provided by e-mail on 12/16/14. Please provide a response for the following items:

   A. ***The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.***

   As in other states, Pentec expects that physicians practicing in the areas of pain management and spasticity would be its most likely referral sources in Tennessee. Pentec will continue to seek letters of support from Tennessee physicians who are possible referral sources, and will provide copies of these letters as they are received.

   B. ***The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.***

   Because Pentec is not presently licensed to provide home health services, it does not have Tennessee intrathecal pump patients who can offer letters indicating their need for in-home services.

   However, Pentec notes that the letter provided by Dr. Richard Muench of Comprehensive Pain Specialists (Attachment to Question 5, Item A, in Supplement No. 2 to the CON application) states that intrathecal pump patients "must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of the few providers in Tennessee that treat patients with intrathecal pumps. We have patients coming from all areas of the state."

2. **Proof of Publication**

   As noted previously, confirmation of newspapers of general circulation in 3 counties remains an open item under review (Hancock, Perry and Van Buren Counties). Please document the status update provided in your 12/16/14 e-mail, including any additional clarification from Mr. Goodman of the Tennessee Press Association that may have been provided since 12/16/14.

   Pentec believes that there are differences of opinion with respect to newspaper coverage of Hancock, Perry and Van Buren Counties. Pentec has relied primarily on the Tennessee Press Service ("TPS") of the Tennessee Press Association ("TPA") to ensure that proper coverage was achieved. On November 19, 2014, Pentec's counsel received the following statement by email from Mr. Earl Goodman of the TPS in response to its inquiry about these three counties:

   "Hancock and Van Buren counties currently do not have TPA member newspapers serving those communities and could only be reached by publishing in neighboring counties; Perry County is served by a county-wide newspaper which does not circulate

outside its borders. However, two of our largest public notices customers, the Tennessee Department of Transportation and the Tennessee Department of General Services/Department of Finance, have designated certain papers as region-wide publications, meaning those papers sufficiently cover a number of counties and satisfy the publication needs of their offices. In the case of the Pentec advertisements, the following papers in which you placed notices would cover the counties in question:

Hancock - Knoxville News Sentinel (the Greeneville Sun also extends into that county)
Van Buren - Chattanooga Times Free Press (the Cookeville Herald-Citizen also extends into that county)
Perry - Nashville's Tennessean"

A letter from Mr. Goodman dated December 19, 2014, affirming the foregoing and providing further clarification as to the adequacy of Pentec's publication of its Letter of Intent is attached to this Additional Clarification to Supplement No. 2 as Attachment to Question 2.

We have also been advised by the *Knoxville News Sentinel* that it distributes to subscribers in Hancock County by US Mail; by *The Tennessean* that it does not have a defined coverage area and that it occasionally covers news within Perry County; and by the Cookeville *Herald-Citizen* that it distributes to subscribers in Van Buren County by US Mail. Further, all three newspapers offer online editions. In addition, Pentec's Letter of Intent was placed on the Tennessee Press Service statewide website on November 9 and 10, 2014, in accordance with the requirements of the Tennessee Public Notice Law, Tenn. Code Ann. Section 1-3-120 (2013), effective April 1, 2014. This notice was still online as of December 19, 2014, and may be found at http://www.publicnoticeads.com/tn/search/results.asp?T=PN.

Pentec believes that it has satisfied the publication requirement with respect to all 95 counties in Tennessee. However, Pentec would consider a modification of its CON application to exclude Hancock, Perry and Van Buren Counties in the event that the Tennessee Department of Health determines otherwise. Pentec notes that according to U.S. Census Bureau 2010 census data for Tennessee, these three counties had a total of 20,282 residents, out of a statewide population of 6,346,105. Because these three counties represent only 0.32% of Tennessee's population, Pentec believes that such a modification to its CON application would not constitute a substantive change.

SUPPLEMENTAL

ATTACHMENT TO QUESTION 2

ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2

Copy of letter dated December 19, 2014, from Mr. Earl Goodman of the Tennessee Press Service regarding publication of notices in Hancock, Perry and Van Buren Counties.

SUPPLEMENTAL

December 19, 2014

Ladies and Gentlemen:

Tennessee Press Service would like to address the issue of placements in metropolitan newspapers throughout the state as it relates to the counties of Hancock, Van Buren and Perry.

Hancock and Van Buren counties currently do not have Tennessee Press Association member newspapers serving those communities and could only be reached by publishing in newspapers printed and distributed in neighboring counties. Perry County is served by a county-wide newspaper which does not circulate outside its borders. However, two of our largest public notice customers, the Tennessee Department of Transportation and the Tennessee Department of Finance, have designated certain metropolitan papers as region-wide publications, meaning those papers sufficiently cover a number of counties and satisfy the publication needs of their offices. Using this same criteria followed by TPS for several decades, the following papers would cover the counties in question:

Hancock - Knoxville News Sentinel
Van Buren - Chattanooga Times Free Press and Nashville's The Tennessean
Perry - Nashville's The Tennessean

As examples, a TDOT Multimodal notice published in 2013 mentioned Hancock County specifically and was published in the Knoxville News Sentinel as well as the Chattanooga Times Free Press and the Tennessean. A construction project for Lobelville's Tennessee National Guard Armory in Perry County was featured in an ad published in the Tennessean by the Department of Finance and Administration in 2010; Spencer's Fall Creek Falls State Park, Van Buren County, was the subject of a construction notice in the Tennessean in 2013. The Tennessee Department of Transportation, until changes in state laws were made two years ago, published all construction projects notices for the Eastern region in the Chattanooga Times Free Press after switching from the Knoxville News Sentinel; for the Middle region, the state changed from the Tennessean to the Leaf-Chronicle in Clarksville. Both changes were made only due to lower advertising costs involved.

Also, in accordance with the requirements of the Tennessee Public Notice Law (Tennessee Code Annotated Section 1-3-120, effective April 1, 2014), all public notices published by TPS member newspapers post their notices online to a statewide website. Notices are kept online and may be found by visiting the following website: http://www.publicnoticeads.com/tn/search/results.asp?T=PN.

By following the above outlined criteria, any agency--state or otherwise--would satisfy publishing commitments for public notices according to Tennessee state law and standards.

Earl Goodman

Earl Goodman
Senior Media Buyer • Tennessee Press Service

435 Montbrook Lane, Knoxville TN 37919 tnadvertising.biz egoodman@tnpress.com 865.584.5761

SUPPLEMENTAL

DEC 26 '14 AM 9:58

AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 19 day of December, 2014, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

Christine Britton

NOTARY PUBLIC

My commission expires November 4, 2018

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Christine Britton, Notary Public
Upper Chichester Twp., Delaware County
My Commission Expires Nov. 4, 2018
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

HF-0043
Revised 7/02

6

Copy

ADDITIONAL INFORMATION

Supplemental -2

PENTEC Health, INC

CN1411-046

SUPPLEMENTAL #2
December 30, 2014
10:00 am

Saul Ewing LLP

Richard D. Leigh
Phone: (717) 257-7501
Fax: (717) 257-7599
rleigh@saul.com
www.saul.com

December 29, 2014

VIA FEDERAL EXPRESS (Tel. 615-741-2364)

State of Tennessee
Health Services and Development Agency
Attention: Jeff Grimm
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Pentec Health, Inc. / Certificate of Need Application CN1411-046 / Additional Clarification to Supplement No. 2 (Revised)

Dear Mr. Grimm:

In response to your letter to Doug Wynd of December 19, 2014, and pursuant to our telephone conversation this afternoon, we are submitting for review one original and two copies of Pentec's Additional Clarification to Supplement No. 2 (Revised) to Certificate of Need Application CN1411-046, together with the appropriate affidavit.

If you have any questions about the Certificate of Need application, please feel free to contact me (contact information provided above), or contact Doug Wynd at 636-751-6481 or dwynd@pentechealth.com. Again, we look forward to working with the Agency in connection with Pentec's application.

Sincerely,

Richard D. Leigh

Enclosure

SUPPLEMENTAL #2
December 30, 2014
10:00 am

PENTEC HEALTH, INC.

ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

DECEMBER 2014

SUPPLEMENTAL #2
December 30, 2014
10:00 am

1. **Section C, Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)**

   The applicant notes that letters of support will be provided in a future supplemental response. An update was provided by e-mail on 12/16/14. Please provide a response for the following items:

   A. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

   As in other states, Pentec expects that physicians practicing in the areas of pain management and spasticity would be its most likely referral sources in Tennessee. Pentec will continue to seek letters of support from Tennessee physicians who are possible referral sources, and will provide copies of these letters as they are received.

   B. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

   Because Pentec is not presently licensed to provide home health services, it does not have Tennessee intrathecal pump patients who can offer letters indicating their need for in-home services.

   However, Pentec notes that the letter provided by Dr. Richard Muench of Comprehensive Pain Specialists (Attachment to Question 5, Item A, in Supplement No. 2 to the CON application) states that intrathecal pump patients "must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of the few providers in Tennessee that treat patients with intrathecal pumps. We have patients coming from all areas of the state."

2. **Proof of Publication**

   As noted previously, confirmation of newspapers of general circulation in 3 counties remains an open item under review (Hancock, Perry and Van Buren Counties). Please document the status update provided in your 12/16/14 e-mail, including any additional clarification from Mr. Goodman of the Tennessee Press Association that may have been provided since 12/16/14.

   Pentec believes that there are differences of opinion with respect to newspaper coverage of Hancock, Perry and Van Buren Counties. Pentec has relied primarily on the Tennessee Press Service ("TPS") of the Tennessee Press Association ("TPA") to ensure that proper coverage was achieved. On November 19, 2014, Pentec's counsel received the following statement by email from Mr. Earl Goodman of the TPS in response to its inquiry about these three counties:

   "Hancock and Van Buren counties currently do not have TPA member newspapers serving those communities and could only be reached by publishing in neighboring counties; Perry County is served by a county-wide newspaper which does not circulate

outside its borders. However, two of our largest public notices customers, the Tennessee Department of Transportation and the Tennessee Department of General Services/Department of Finance, have designated certain papers as region-wide publications, meaning those papers sufficiently cover a number of counties and satisfy the publication needs of their offices. In the case of the Pentec advertisements, the following papers in which you placed notices would cover the counties in question:

Hancock - Knoxville News Sentinel (the Greeneville Sun also extends into that county)
Van Buren - Chattanooga Times Free Press (the Cookeville Herald-Citizen also extends into that county)
Perry - Nashville's Tennessean"

A letter from Mr. Goodman dated December 19, 2014, affirming the foregoing and providing further clarification as to the adequacy of Pentec's publication of its Letter of Intent is attached to this Additional Clarification to Supplement No. 2 as Attachment to Question 2.

In addition, Pentec's legal counsel has made written and telephonic inquiries to the publications referenced above regarding the geographic areas in which they are distributed. It has been advised (1) by the *Knoxville News Sentinel* that although it does not "distribute" to Hancock County, *News Sentinel* publications distributed to Hancock County are subscriptions delivered by US Mail; (2) by *The Tennessean* that it does not have a defined coverage area and that it occasionally covers news within Perry County; and (3) by the Cookeville *Herald-Citizen* that it distributes to subscribers in Van Buren County by US Mail. Copies of email correspondence from the foregoing newspapers to Saul Ewing LLP, counsel for Pentec, are also attached to this Additional Clarification to Supplement No. 2 as Attachment to Question 2.

Further, all three newspapers offer online editions. In addition, Pentec's Letter of Intent was placed on the Tennessee Press Service statewide website on November 9 and 10, 2014, in accordance with the requirements of the Tennessee Public Notice Law, Tenn. Code Ann. Section 1-3-120 (2013), effective April 1, 2014. This notice was still online as of December 19, 2014, and may be found at http://www.publicnoticeads.com/tn/search/results.asp?T=PN.

Pentec believes that it has satisfied the publication requirement with respect to all 95 counties in Tennessee. However, Pentec would consider a modification of its CON application to exclude Hancock, Perry and Van Buren Counties in the event that the Tennessee Department of Health determines otherwise. Pentec notes that according to U.S. Census Bureau 2010 census data for Tennessee, these three counties had a total of 20,282 residents, out of a statewide population of 6,346,105. Because these three counties represent only 0.32% of Tennessee's population, Pentec believes that such a modification to its CON application would not constitute a substantive change.

SUPPLEMENTAL #2
December 30, 2014
10:00 am

ATTACHMENT TO QUESTION 2

ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2

1. Copy of letter dated December 19, 2014, from Mr. Earl Goodman of the Tennessee Press Service regarding publication of notices in Hancock, Perry and Van Buren Counties.

2. Copy of email dated December 5, 2014, from *Knoxville News Sentinel* (Louise Watkins) to Maronetta Miller (Paralegal, Saul Ewing LLP, counsel to Pentec) regarding distribution in Hancock County.

3. Copy of email dated December 10, 2014, from *The Tennessean* (Dan E.) to Maronetta Miller (Paralegal, Saul Ewing LLP, counsel to Pentec) regarding distribution in Perry County.

4. Copy of email dated December 5, 2014, from the Cookeville *Herald-Citizen* (Keith McCormick) to Maronetta Miller (Paralegal, Saul Ewing LLP, counsel to Pentec) regarding distribution in Van Buren County.

SUPPLEMENTAL #2
December 30, 2014
10:00 am

December 19, 2014

Ladies and Gentlemen:

Tennessee Press Service would like to address the issue of placements in metropolitan newspapers throughout the state as it relates to the counties of Hancock, Van Buren and Perry.

Hancock and Van Buren counties currently do not have Tennessee Press Association member newspapers serving those communities and could only be reached by publishing in newspapers printed and distributed in neighboring counties. Perry County is served by a county-wide newspaper which does not circulate outside its borders. However, two of our largest public notice customers, the Tennessee Department of Transportation and the Tennessee Department of Finance, have designated certain metropolitan papers as region-wide publications, meaning those papers sufficiently cover a number of counties and satisfy the publication needs of their offices. Using this same criteria followed by TPS for several decades, the following papers would cover the counties in question:

Hancock - Knoxville News Sentinel
Van Buren - Chattanooga Times Free Press and Nashville's The Tennessean
Perry - Nashville's The Tennessean

As examples, a TDOT Multimodal notice published in 2013 mentioned Hancock County specifically and was published in the Knoxville News Sentinel as well as the Chattanooga Times Free Press and the Tennessean. A construction project for Lobelville's Tennessee National Guard Armory in Perry County was featured in an ad published in the Tennessean by the Department of Finance and Administration in 2010; Spencer's Fall Creek Falls State Park, Van Buren County, was the subject of a construction notice in the Tennessean in 2013. The Tennessee Department of Transportation, until changes in state laws were made two years ago, published all construction projects notices for the Eastern region in the Chattanooga Times Free Press after switching from the Knoxville News Sentinel; for the Middle region, the state changed from the Tennessean to the Leaf-Chronicle in Clarksville. Both changes were made only due to lower advertising costs involved.

Also, in accordance with the requirements of the Tennessee Public Notice Law (Tennessee Code Annotated Section 1-3-120, effective April 1, 2014), all public notices published by TPS member newspapers post their notices online to a statewide website. Notices are kept online and may be found by visiting the following website: http://www.publicnoticeads.com/tn/search/results.asp?T=PN.

By following the above outlined criteria, any agency--state or otherwise--would satisfy publishing commitments for public notices according to Tennessee state law and standards.

Earl Goodman

Earl Goodman
Senior Media Buyer • Tennessee Press Service

435 Montbrook Lane, Knoxville TN 37919 tnadvertising.biz egoodman@tnpress.com 865.584.5761

SUPPLEMENTAL #2
December 30, 2014
10:00 am

Leigh, Richard D.

From: Miller, Maronetta F.
Sent: Friday, December 05, 2014 3:11 PM
Subject: RE: Hancock County is not in our coverage area

Follow Up Flag: Follow up
Flag Status: Completed

PcgIgnoreMessage: 0

PLEASE NOTE: You were BCC'd

To: Watkins, Louise

Thank you.

Maronetta F. Miller, Legal Assistant
Saul Ewing LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101
717.257.7524 (phone)
717.257.7588 (fax)
mmiller@saul.com
SaulEwing

From: Watkins, Louise [mailto:WatkinsL@knoxnews.com]
Sent: Friday, December 05, 2014 3:09 PM
To: Miller, Maronetta F.
Subject: RE: Hancock County is not in our coverage area

I have checked on this county before - we do not distribute to Hancock County. If there are any News Sentinel publications distributed to that area, it is just mailed subscriptions.

Louise Watkins
Account Manager
KNS Media Group
2332 News Sentinel Drive
Knoxville, TN 37921
(P): 865.342.6515
(F): 865.342.6508
E-mail: WATKINSL@KNOXNEWS.COM
www.knoxnews.com

From: Miller, Maronetta F. [mailto:MMiller@saul.com]
Sent: Friday, December 05, 2014 2:58 PM
To: Watkins, Louise
Cc: Miller, Maronetta F.
Subject: Hancock County is not in our coverage area

6

SUPPLEMENTAL #2

December 30, 2014
10:00 am

Ms. Watkins, I just left you a vmm. I would like some clarification please. . . If I place a legal advertisement in the Knoxville News does your distribution cover Hancock County?

Maronetta F. Miller, Legal Assistant
Saul Ewing LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101
717.257.7524 (phone)
717.257.7588 (fax)
mmiller@saul.com
Saul Ewing

From: Watkins, Louise [mailto:WatkinsL@knoxnews.com]
Sent: Friday, December 05, 2014 2:41 PM
To: Davis, Bonnie Lee
Subject: Hancock County is not in our coverage area

Thank you for your inquiry.

Louise Watkins
Account Manager
KNS Media Group
2332 News Sentinel Drive
Knoxville, TN 37921
(P): 865.342.6515
(F): 865.342.6508
E-mail: WATKINSL@KNOXNEWS.COM
www.knoxnews.com

"Saul Ewing LLP <saul.com>" made the following annotations:
+~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~+
This e-mail may contain privileged, confidential, copyrighted, or other legally protected information. If you are not the intended recipient (even if the e-mail address is yours), you may not use, copy, or retransmit it. If you have received this by mistake please notify us by return e-mail, then delete.
+~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~+

SUPPLEMENTAL #2
December 30, 2014
10:00 am

Leigh, Richard D.

From: Miller, Maronetta F.
Sent: Thursday, December 11, 2014 9:27 AM
To: Leigh, Richard D.
Subject: Perry County - Tennessee

Follow Up Flag: Follow up
Flag Status: Completed

FYI

Maronetta F. Miller, Legal Assistant
Saul Ewing LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101
717.257.7524 (phone)
717.257.7588 (fax)
mmiller@saul.com
Saul Ewing

From: 'customer@tennessean.com' [mailto:customer@tennessean.com]
Sent: Wednesday, December 10, 2014 7:00 PM
Subject: RE: Perry County

Thank you for contacting The Tennessean. Where every day matters!

I apologize in advance for not being able to provide you with an exact answer. We cover the Greater Nashville area, but do not have a defined coverage area. We due occasionally cover news within the county. If you have any more specific questions, please let me know.

Sincerely,

Dan E.
Account Specialist
The Tennessean
www.MyNewspaperService.com
www.Tennessean.com
1-800-342-8237

P.S. Our customer service agents can assist you via telephone from 8:00 AM - 7:00 PM Monday through Friday and Sunday from 7:30 AM - 1:00 PM. We are also available by e-mail and Live Chat via our website.

On Fri, Dec 05, 2014 at 12:24 PM, bdavis@saul.com wrote:

SUPPLEMENTAL #2
December 30, 2014
10:00 am

Good afternoon, and please pardon my interruption.

I am writing to confirm that the Nashville's Tennessean covers Perry County? I was on the newspaper's website and was unable to locate that information. I believe the case on which we are working needs clarification as to your publication's area of coverage.

I would very much appreciate your response via email. Or, if this email has reached you in error, and you could direct me to whom I should speak, that would be appreciated as well. If you have any questions, please do not hesitate to contact our office.

Thank you.

SUPPLEMENTAL #2
December 30, 2014
10:00 am

Leigh, Richard D.

From: Miller, Maronetta F.
Sent: Monday, December 08, 2014 10:07 AM
To: Leigh, Richard D.
Subject: FW: Van Buren County

Follow Up Flag: Follow up
Flag Status: Completed

See below email chain.

Maronetta F. Miller, Legal Assistant
Saul Ewing LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101
717.257.7524 (phone)
717.257.7588 (fax)
mmiller@saul.com
Saul Ewing

From: Keith McCormick [mailto:keith.mccormick@herald-citizen.com]
Sent: Friday, December 05, 2014 5:38 PM
To: Davis, Bonnie Lee
Subject: RE: Van Buren County

12-14-2014

To: Bonnie Lee Davis
RE: Circulation in Van Buren County

The Herald-Citizen is a general circulation newspaper. Most of our deliveries are done by our independent contract carrier force in Putnam and some in surrounding counties. If not delivered by our carriers ; it will be delivered by the postal service (which means anywhere).

As of today ,we currently have people who subscribe to the print version of the H-C and are being delivered thru the postal service. We also have an e-edition available on-line. One version is free and one is paid available to anyone anywhere.

Sincerely

Keith McCormick
Circulation Manager

From: Davis, Bonnie Lee [mailto:bdavis@saul.com]
Sent: Friday, December 05, 2014 11:23 AM

10

SUPPLEMENTAL #2
December 30, 2014
10:00 am

To: 'circulation@herald-citizen.com'
Subject: Van Buren County

Good afternoon, and please pardon my interruption.

I am writing to confirm that the Cookeville Herald-Citizen covers Van Buren County? I was on the newspaper's website and was unable to locate that information. I believe the case on which we are working needs clarification as to your publication's area of coverage.

I would very much appreciate your response via email. Or, if this email has reached you in error, and you could direct me to whom I should speak, that would be appreciated as well. If you have any questions, please do not hesitate to contact our office.

Thank you.

Bonnie Lee Davis
Practice Assistant to:
Eric L. Brossman, Esquire
Catherine E. Walters, Esquire
Nailah I. Rogers, Esquire
==========================
Saul Ewing LLP
2 North 2nd Street, 7th Floor
Harrisburg, PA 17101
Direct: 717.257.7568

"Saul Ewing LLP <saul.com>" made the following annotations:
+~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~+
This e-mail may contain privileged, confidential, copyrighted, or other legally protected information. If you are not the intended recipient (even if the e-mail address is yours), you may not use, copy, or retransmit it. If you have received this by mistake please notify us by return e-mail, then delete.
+~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~+

11

SUPPLEMENTAL #2
December 30, 2014
10:00 am

DEC 30 '14 PM 1:00

AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 29 day of December, 2014, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

Christine Britton
NOTARY PUBLIC

My commission expires 11-4-18

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
Christine Britton, Notary Public
Upper Chichester Twp., Delaware County
My Commission Expires Nov. 4, 2018
MEMBER, PENNSYLVANIA ASSOCIATION OF NOTARIES

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

January 2, 2015

Doug Wynd, National Sales Director, Specialty Infusion
Pentec Health, Inc.
4 Creek Parkway
Boothwyn, PA 19061

RE: **Certificate of Need Application -- Pentec Health, Inc. - CN1411-046**
The establishment of a home care organization and the initiation of home health services limited to intrathecal pump infusion and Ig-G replacement therapy services. The parent office will be located in leased space at 424 Church Street, Suite 200, Nashville, TN. No branch offices are proposed. The applicant plans to utilize Pentec Health's existing pharmacy whose compounding branch site is located at the parent office at 4 Creek Parkway in Boothwyn, PA. The pharmacy has an active Tennessee license. The project cost is estimated to be $142,028.00.

Dear Mr. Wynd:

This is to acknowledge the receipt of supplemental information to your application for a Certificate of Need. Please be advised your application is now considered complete by this office. Your application is being forwarded to the Tennessee Department of Health for review.

Please note that since the letter of intent was not published in a newspaper of general circulation in 3 of the proposed 95 counties, **Hancock, Perry and VanBuren Counties will be excluded from the proposed service area.**

In accordance with Tennessee Code Annotated, §68-11-1601, et seq., as amended by Public Chapter 780, the 60-day review cycle for this project will begin on January 1, 2015. The first sixty (60) days of the cycle are assigned to the Department of Health, during which time a public hearing may be held on your application. You will be contacted by a representative from this Agency to establish the date, time and place of the hearing should one be requested. At the end of the sixty (60) day period, a written report from the Department of Health or its representative will be forwarded to this office for Agency review within the thirty (30)-day period immediately following. You will receive a copy of their findings. The Health Services and Development Agency will review your application on March 25, 2015.

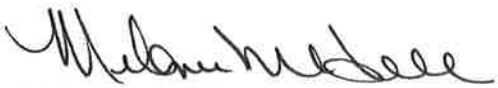
Any communication regarding projects under consideration by the Health Services and Development Agency shall be in accordance with T.C.A. § 68-11-1607(d):

(1) No communications are permitted with the members of the agency once the Letter of Intent initiating the application process is filed with the agency. Communications between agency members and agency staff shall not be prohibited. Any communication received by an agency member from a person unrelated to the applicant or party opposing the application shall be reported to the Executive Director and a written summary of such communication shall be made part of the certificate of need file.

(2) All communications between the contact person or legal counsel for the applicant and the Executive Director or agency staff after an application is deemed complete and placed in the review cycle are prohibited unless submitted in writing or confirmed in writing and made part of the certificate of need application file. Communications for the purposes of clarification of facts and issues that may arise after an application has been deemed complete and initiated by the Executive Director or agency staff are not prohibited.

Should you have questions or require additional information, please contact me.

Sincerely,



Melanie M. Hill
Executive Director

cc: Trent Sansing, CON Director, Division of Health Statistics

State of Tennessee
Health Services and Development Agency
Andrew Jackson, 9th Floor, 502 Deaderick Street, Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

MEMORANDUM

TO: Trent Sansing, CON Director
Office of Policy, Planning and Assessment
Division of Health Statistics
Andrew Johnson Tower, 2nd Floor
710 James Robertson Parkway
Nashville, Tennessee 37243

FROM: Melanie M. Hill
Executive Director

DATE: January 2, 2015

RE: Certificate of Need Application
Pentec Health, Inc. - CN1411-046

Please find enclosed an application for a Certificate of Need for the above-referenced project.

This application has undergone initial review by this office and has been deemed complete. It is being forwarded to your agency for a sixty (60) day review period to begin on January 1, 2015 and end on March 1, 2015.

Should there be any questions regarding this application or the review cycle, please contact this office.

Enclosure

cc: Doug Wynd, National Sales Director, Specialty Infusion

HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
MARCH 25, 2015
APPLICATION SUMMARY

NAME OF PROJECT: Pentec Health, Inc.

PROJECT NUMBER: CN1411-046

ADDRESS: 424 Church Street, Suite 2000
Nashville, (Davidson County), Tennessee 37219

LEGAL OWNER: Pentec Holdings, Inc.
4 Creek Parkway
Boothwyn, Pennsylvania 19061

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Doug Wynd
Pentec Health, Inc.
4 Creek Parkway
Boothwyn, Pennsylvania 19061
(800) 223-4376

DATE FILED: November 14, 2014

PROJECT COST: $142,028

FINANCING: Cash Reserves

PURPOSE FOR FILING: Establishment of a home care organization and the initiation of specialized home health services related to home infusion for patients with implanted intrathecal infusion pumps and patients receiving immunoglobulin-G replacement therapy in all counties of Tennessee except Hancock, Perry and VanBuren Counties.

DESCRIPTION:

Pentec Health, Inc. is requesting approval to establish a home care organization and provide specialized skilled nursing services for patients with surgically implanted intrathecal pumps under physician's orders. The applicant also

proposes providing skilled nursing for patients receiving immunoglobulin (Ig-G) replacement therapy through intravenous or subcutaneous infusion (as an ancillary service). The applicant's proposed specialized home health service will receive pharmacy support for the preparation, packaging and distribution of intrathecal medications from Pentec's pharmacy in Boothwyn, Pennsylvania, a specialty closed door compounding pharmacy that is licensed in Tennessee and other states. An overview of the nature and scope of Pentec nursing and pharmacy responsibilities for the proposed service is summarized on pages 6 and 7 of the 11/25/14 supplemental response.
The applicant initially proposed serving all 95 Tennessee Counties. However, due to HSDA requirements pertaining to publication of the Letter of Intent in a newspaper of general distribution, the service area was changed to a statewide service area that contains 92 Tennessee counties and excludes Hancock, Perry and VanBuren Counties. The applicant's proposed home health organization will operate from a main office located at 424 Church Street, Suite 2000 in Nashville (Davidson County), Tennessee.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

   The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

3. Using recognized population sources, projections for four years into the future will be used.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

   Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

The applicant states that the specialized nature of the proposed skilled nursing

service and the lack of comparable utilization data from existing agencies impacts the ability to provide an estimate of need for specialty infusion therapy services. Following Steps 1-4 above, the Department of Health report that is based on 2013 data indicates that residents of the applicant's proposed 92 county service area will need home health care in 2018; however approximately 182,973 patients are projected to be served in 2018 by existing home health organizations resulting in a net excess or surplus of (80,773).

It appears that this application does not meet the criterion.

5. Documentation from referral sources:

   a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

   During initial staff review, the applicant states that it had been in contact with a number of practitioners in Tennessee. Their names are noted on page 58 of the application. At HSDA request, the applicant provided a December 1, 2014 letter from a physician of Comprehensive Pain Specialists located in Hendersonville (Sumner County) as an attachment to Question 5, Supplemental 2. The physician states that the medical practice is one of few providers in Tennessee that treats patients with intrathecal pumps. Although the physician mentions that his practice treats patients from all over the state, no indication is given regarding the potential number of referrals.

   Since the applicant is requesting a 92 county service area, it appears that this criterion has not been met.

   b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

   According to the applicant's research, there were approximately 1,976 intrathecal pump patients and 1,020 Ig-G patients in Tennessee in calendar year 2014. The applicant notes that patients requiring skilled nursing services for assistance with infusion pump medication refills, titrations, and changes in medical condition would be candidates for referrals by physicians, primarily those practicing in the areas of pain management and spasticity. Approximately 100% of the total projected utilization in Year One amounts to approximately 121 total visits consisting solely of visits Pentec will provide to implanted pump infusion

therapy patients. However, as previously noted, the 1 physician referral letter did not specify the number of potential referrals.

It appears this criterion has been met.

c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided no letters from potential patients during review of the application. However, there was a 12/1/14 letter from a physician of Comprehensive Pain Specialists in Hendersonville (Sumner County) that described the nature of the drug administration service requiring highly specialized nursing and pharmaceutical services.

Since the applicant is requesting a 92-county service area, it appears that this criterion has not been met.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant states that the proposed services are substantially different from those provided by a traditional home health agency that may offer a variety of skilled nursing, home health aide or other clinical services such as physical therapy. By contrast, the applicant proposes limiting its services to home infusion related services for intrathecal pump infusion pump therapy and Ig-G replacement therapy patients. In response to supplemental staff questions, the applicant remarked that it was unable to confirm the extent, if any, to which other existing agencies treated intrathecal pump patients (please see page 11 of Supplemental 1 and page 11 of Supplemental 2 for further detail). Pentec's proposed specialty infusion services would be provided by trained nursing staff that are required to complete a corporate nurse training program that is approved by the American Nurses Credentialing Center. As such, the applicant maintains that these services and credentials are unique and are not typical of the average Medicare certified home health agency (a comparison of key differences is shown in the table on page 5 of Supplemental 2).

It appears this criterion has been met.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

   a. The average cost per visit by service category shall be listed.

      An average gross charge of $2,517 per skilled nursing visit and an average cost of $2,343 per visit is projected in Year One as reflected in the Projected Data Chart of the application and clarified in the table on page 24 of Supplemental 2. Although there are no known agencies with similar services for comparison, the applicant notes that typical reimbursement by commercial plans is approximately $92 per visit for nursing and $50 - $70 for per diem charges (page 41, Supplemental 1). A Table in the attachment on page 156 of the revised application provides a summary of the applicant's fee schedule for the proposed service.

      It appears this criterion has been met.

   b. The average cost per patient based upon the projected number of visits per patient shall be listed.

      The applicant projects an average daily census of approximately 20 patients per day in Year One. Based on 6 visits per intrathecal pump patient per year, the applicant's projected average charge and cost for these types of patients will be approximately $14,826.00/patient and $13,500.00/patient, respectively, in the first year of the project.

      It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

Pentec Health Inc., an existing, unique provider of specialty infusion therapy services in 30 states accredited by the Joint Commission in both home care and pharmacy, is seeking approval to establish a home health organization and provide skilled nursing services limited to patients with surgically implanted intrathecal infusion therapy pumps or patients receiving immunoglobulin-G (Ig-G) replacement therapy through intravenous or subcutaneous infusion. All nursing services will be provided to patients in their residence statewide (excluding Hancock, Perry and VanBuren Counties), under physician ordered

plans of care. The proposed home health agency will be located in approximately 87 square feet of leased office space at 424 Church Street, Suite 2000 in Nashville, Tennessee.

The applicant's nursing team will be on call to serve patients in the 92 county service area on a 24/7 basis. Patients will have direct contact with his/her assigned nurse through a toll free number or after office hours through a Pentec Health, Inc. central call center that will contact the appropriate nursing team member. Initial staff will consist of current licensed registered nurse employees, including individuals appointed as the proposed agency's administrator and alternate administrator. Additional licensed nursing staff will be assigned in accordance with Pentec Health Inc.'s staffing ratio of one nurse to 40 patients.

Pentec's non-resident licensed Tennessee pharmacy (#4108) will support the applicant's proposed home health operations in Tennessee. The pharmacy is licensed by the State of Tennessee (license # 4108) and is Joint Commission Accredited. The pharmacy is one of two pharmacies owned by Pentec Health, Inc. It is a specialty closed door compounding pharmacy located at Pentec's corporate headquarters in Boothwyn, Pennsylvania (the other Pentec pharmacy is located in Mansfield, Massachusetts). The pharmacy is licensed in all 50 states and the District of Columbia (*note: please see additional clarifying information on page 5 of Supplemental 1 and page 4 of Supplemental 2*). Pentec's Tennessee licensed pharmacy is actively certified for participation in Medicare and TennCare.

The payor types of home health patients to be served by the applicant will be privately insured, self-pay, or medically indigent patients. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid. The applicant will on occasion provide skilled nursing in-home services to Medicare and TennCare infusion patients on a limited basis under its Compassionate Care, No Insurance or Financial Assistance policies, as appropriate. Some financial assistance for these patients will be available on the basis of Pentec's pharmacy certification in both Medicare and TennCare.

The infusion-related in-home skilled nursing service activities required in connection with the target implanted pump infusion therapy or Ig-G replacement therapy patients are listed in detail on page 9 of Supplemental 1. Key activities include medication administration for pump refills in accordance with physician orders; assessment for side effects, adverse reactions, patient and caregiver education, assessment of pump equipment function in accordance with pump manufacturer requirements, assessing intrathecal and IV access sites and surrounding areas for possible complications, recording vital signs and collecting blood specimens when ordered by a physician. These services will be provided

by the applicant's registered nurse employees who are trained through Pentec's certified nursing education program (*a copy of the program was provided in the attachment for Question 5.B of Supplemental 1*).

As noted, the infusion product will be compounded, packaged and shipped from the applicant's licensed pharmacy in Boothwyn, Pennsylvania and delivered by a Pentec driver or Federal Express to the assigned Pentec nurse. In some instances the product may be shipped to the patient's home where it will be received, inspected and authenticated by Pentec's nurse employee prior to administration. Types of infusion products to be administered include refills of intrathecal pump pain medications under physician orders for patients with cancer pain, multiple sclerosis or cerebral palsy and medications for patients receiving Ig-G replacement therapy.

Note to Agency Members: the above is a brief summary of the nature and scope of the proposed in-home skilled nursing service for infusion therapy patients. For more detailed descriptions about the nature and scope of services, including measures taken to reduce the risks associated with these types of patients, please see the HSDA staff questions for Item 4.A – 4.H on pages 6-15 of Supplemental 1 and the TDH questions in Exhibit 2 on pages 29-46 of Supplemental 2.

A description of the types of patients with demonstrated needs for infusion nursing services in the home that may otherwise be unavailable from other home health agencies include the following:

- **Implanted Intrathecal Pump Infusion Therapy** – this highly specialized service is given to a very narrow and complex range of patients who have failed traditional therapy for severe or chronic pain and now rely on implanted drug delivery systems for their treatment. Types of patient conditions include pain secondary to cancer, multiple sclerosis, traumatic brain injury, head trauma, paralysis or stroke. Carefully selected by their physicians, these patients will have a specialized pump implanted in the intrathecal space surrounding the spinal cord during a surgical procedure in an inpatient or outpatient setting and their medication regimen started. Implanted pump infusion therapy may be appropriate for patients who have the care and resources available to manage potential risks such as infection, narcotic withdrawal, drug compounding errors and pump programming errors. Typical patient diagnoses include Chronic Pain Syndrome, Complex Regional Pain Syndrome, Multiple Sclerosis, Cerebral Palsy, Abnormal Involuntary Movement (Spasticity) and Traumatic Brain Injury. (*For further detail regarding the ICD-9 codes that apply to these patients please see page 9, Supplemental 2).*

- **Specialty Patients Requiring Ig-G Replacement Therapy** - Intravenous immunoglobulin, a fraction of blood containing antibodies, is given intravenously or by subcutaneous infusion as a plasma protein replacement therapy to immune and/or auto-immune deficient patients who cannot replace antibodies naturally. The frequency of Ig-G Replacement Therapy is different for 2 types of patients – (1) those with primary immune deficiency, a genetic disorder that typically requires lifetime treatment on a monthly basis; or (2) patients with auto immune deficiency that may require lifetime treatment but more typically have a treatment regimen consisting of three, six or twelve month segments in consecutive daily sessions of several hours per session. Typical patient diagnose include Primary Immune Deficiency and Auto Immune Disorder.

Ownership

The applicant is a Pennsylvania Corporation first formed in 1983 under the name Delaware Valley Home Care Corporation and was later changed to Pentec Health Inc. in September 2006. It is a wholly owned subsidiary of Pentec Holdings, Inc. a Delaware Corporation, which has as its ultimate parent, Pentec Healthcare Infusions, Inc., also a Delaware Corporation. Related information about the applicant is provided below.

- The parent has 4 members with 5% ownership interest or greater, including Norwest Equity Partners IX, LP (69.06%), Norwest Mezzanine partners III, LP (5.06%), DW Healthcare Partners, LP (10.12%) and Frazier Healthcare V, LP (10.12%). Please see the table and chart on pages 101 and 102 of the application.
- The applicant has 2 major operating divisions - Specialty Infusion (includes home health care), and Renal Nutrition.
- The 2 operating divisions are supported by other operating units such as pharmacy, nursing, information services, quality assurance.
- An executive level organizational chart is provided on page 7 of Supplemental 2.
- As noted, Pentec operates a closed door specialty pharmacy with locations in Boothwyn, Pennsylvania and Mansfield, Massachusetts. The pharmacy is licensed in 50 states and supports the prescriptive needs of its intrathecal pump, infusion therapy and renal nutrition patients.
- The Tennessee pharmacy currently only focuses on the supply of renal nutrition products for use by Tennessee residents. It was first licensed in December 2004 (recently renewed through 3/31/2016). The applicant clarified that its pharmacy has the ability, capacity and trained staff to also prepare and supply intrathecal and intravenous compounded products (*please see page 4, Supplemental 2*).

- A table on pages 16 and 17 of Supplemental 1 provides a list of Pentec Health, Inc.'s active pharmacy and home health services for each of the 50 states and District of Columbia.
- Pentec has an active home health agency license in 34 states. It is also pending licensure approval in New Mexico, New York and the District of Columbia.
- The fiscal year end intrathecal pump patient census of Pentec's Infusion Division grew by approximately 67% from 1,303 patients ending December 31, 2011 to 2,177 patients ending December 31, 2013.
- As addressed in the TDH summary, the applicant provided a copy of a $10,000 civil penalty notice and order dated 08/22/2011 from the Indiana State Department of Health for violation of a licensure requirement during the applicant's initial state licensure survey.
- Also provided was copy of a 10/17/2011 letter from the program manager of the Acute Care Division, Indiana State Department of Health indicating that the plan of correction was found to be acceptable.

Facility Information

- The parent office of the proposed project will be in approximately 87 square feet of leased space in an existing office building in downtown Nashville at 424 Church Street.
- The office will be used solely for administrative support purposes as a repository for home health service policies and procedures, personnel records and other required documentation.
- There is no construction, renovation or modification required to implement the proposed project.
- Per Item 6, page 20 of Supplemental 1, branch offices would not be considered unless required with regional licensure requirements. The applicant attributes the nature of its specialized but limited service, its patient scheduling (7 to 10 day in advance of targeted pump refill or "alarm" date) and its nursing staffing plan as key factors in this regard.

Project Need

- The applicant indicates that traditional home health agencies do not typically provide in-home skilled nursing care for patients with surgically implanted intrathecal infusion pumps and patients receiving Ig-G replacement therapy.
- The nature of the proposed service differs from traditional home health agencies. The applicant provided a comparison in the table below.

Comparison of Applicant to Other Types of Home Health Agencies

Variable	Medicare Home Health Agency	Infusion Nursing Agency	Pentec Intrathecal Pump Service
Average Visit Duration	One to Two Hours	Up to six hours	One to Two Hours*
Equipment	Generally not involved	Typically includes infusion equipment	Administration kit (syringes & other disposable items) Pump programmer
Payor	80% Medicare and TennCare Patients	Private Insurance mainly	Mostly private insurance
Age	Approximately 68% Over Age 65+	Majority under Age 65	Approximately 71% under age 65
Service Provided	44% is skilled nursing. Additional services may include therapy, home health aide, and medical social services.	100% specialized skilled nursing	100% specialized skilled nursing
Patient Status	Homebound	Patient may or may not be homebound	May or may not be homebound

**Note: while duration of the visit is comparable, the applicant states that skilled nursing visits occur less frequently – approximately every 30- 60 days.*

- Patients may qualify for intrathecal pump therapy only when all other attempts for relief by the patient's physician have failed.
- Limited supply of physicians with practice specialties in pain management.
- Difficulty by patients to travel to physician for pump refills and office visits, especially patients with limited mobility or who are homebound.
- Discharged hospital patients requiring infusion nursing services either have to travel to the hospital or other outpatient facilities such as physician offices or infusion therapy centers to continue receiving this service.
- Need for accurate, reliable and timely information systems support to maintain patient medical record and facilitate communication with physicians through secure means. Pentec's electronic medical record system and secure web portal for attending physicians appears to be innovative initiatives in addressing this need.

- ***Note to Agency members: The attachment to the Department of Health Report indicated that based on 2013 data, 102,200 service area residents will need home health care in 2018; however 182,973 patients are projected to be served in 2018 resulting in a net excess of (80,773). Please note that this need is calculated for all home health patients, not just those needing home infusion services.***

Service Area Demographics

- The proposed service area was revised from 95 to 92 counties during initial review based on publication in newspapers that did not meet the requirements for "newspapers of general circulation" in accordance with HSDA Rules. Per the TDH project summary, the total population of the 92 county statewide service area is estimated at 6,629,335 residents in calendar year (CY) 2015 increasing by approximately 3.7% to 6,874,743 residents in CY 2019.
- The population of the 3 counties not included in the service area (Hancock, Perry and Van Buren Counties) is estimated at approximately 20,103 residents in 2015 increasing by 0.08% to 20,254 residents in 2019.
- The overall statewide population is projected to grow by 3.7% from 2015 to 2019.
- The 65 and under population will increase by approximately 12% from 1,008,671 in 2015 to 1,129,890 in 2018. The statewide 65 and under population will increase by approximately 12% between 2015 and 2019.
- The latest 2014 percentage of the statewide population enrolled in the TennCare program is approximately 18.1%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

Service Area Historical Utilization

Using licensure and provider utilization records maintained by the Tennessee Department of Health, the applicant identified approximately 157 existing licensed home health agencies in Tennessee. The name of the agency, location of parent office, licensed counties and utilization for 2011 - 2013 is provided in the table on pages 22-26 of Supplemental 1. As a whole, the agencies served approximately 176,910 patients in 2011 decreasing by 0.5% to 175,924 patients in 2013. Utilization for the 3 counties that were excluded from the applicant's proposed service area (Hancock, Perry and Van Buren Counties) increased slightly from 1,168 patients to 1,180 patients during the period.

Note to Agency members: The Joint Annual Report does not capture utilization data specific to implanted intrathecal pump or Ig-G replacement therapy

patients. There is not a known public database available that reports this type of data.

During review in 2012 of a previous Certificate of Need application for home infusion nursing (Coram Alternative Site Services), HSDA staff contacted the Tennessee Association of Home Care (TAHC) regarding home health providers and the Tennessee Hospital Association (THA) regarding hospital-based home care providers.

TAHC indicated the following:

- *TAHC membership applications on file indicate that 224 home health offices (parents and branches) offer infusion therapy services.*
- *Standard home health policy is that first dose should be completed in the hospital setting.*
- *The majority of home health agencies partner with an infusion company for administration of the second dose in the home.*
- *The home health nurse continues to support the patient's needs with observations and reports to the physician. It is unrealistic to think that a home health provider could limit their care to only infusion therapy. Infusion may be the primary need but these are typically patients with multiple chronic illnesses and co-morbidities who need a holistic, multi-disciplinary approach to their health care*
- *The barriers to home infusion therapy are generally noted as staffing and adequate payment. This is a growing issue for all homecare providers as both governmental and commercial payors continue to look to provider payments to cut costs.*
- *Homebound status is only a Medicare issue. An infusion company would be held to the same standard if it were a Medicare-certified home health agency.*

THA's response included that a "typical" home care provider does not provide infusion administration for:

- *Patients requiring 6 hour therapies.*
- *Medicare patients who are not homebound which is a requirement that applies only to Medicare.*
- *Many non-Medicare patients who are not homebound are served*
- *Patients requiring first dose administration*
- *Patients requiring three doses daily*

THA also advised that member home health agencies see patients in every county in the state and that there are pediatric programs often affiliated with

pediatric hospitals such as Vanderbilt, Methodist LeBonheur, and East Tennessee Children's Hospital.

During review of this application and 2 Coram/CVS Certificate of Need projects for specialty infusion services (please see descriptions for CN1406-017A and CN1406-018A at the end of this summary), HSDA staff received confirmation by phone and by an email from a representative of TAHC that the TAHC information provided in 2012 was still accurate at the time the applicant's proposal was under review in 2014.

Applicant's Projected Utilization

- In Year 1 the applicant projects an average daily census (ADC) of 20 patients per day increasing to 52 patients per day in Year 2 (*note: the applicant states that projected utilization focuses solely on intrathecal pump patients*).
- The applicant is projecting 121 total visits in Year 1 increasing to approximately 314 visits in Year 2. The applicant bases the projected intrathecal pump patient visit schedule on approximately 6 skilled nursing visits per patient per year.
- Year 1 projected utilization amounts to approximately 6.0% of the estimated 1,976 intrathecal pump patients in Tennessee in CY2014.
- Utilization for Year 1 is based on ramp-up of Pentec operations in Tennessee - beginning with 5 patients in the first month of operations going forward to 39 patients at year end.
- Of the 39 patients at year end, 20 are commercially insured and 19 are partial-reimbursement patients where Pentec receives compensation for some services rendered (usually medications) but assumes the patient's nursing care as a financial loss in accordance with its Compassionate Care policy. (*Sources: Application, page 36 and Supplemental 1, page 39*).
- Per the table on page 32 of Supplemental 1, the distribution of patients by **Grand Division of Tennessee** at the end of Year 1 is as follows: East (17), Middle (14) and West (8).

Project Cost

Major costs of the $142,028 total estimated project cost are:

- Architectural and Engineering Fee- $28,500 or 20% of total cost
- Office Lease- $8,028 or 5.7% of total cost
- Reserve/Contingency Fund-$100,000 or 70.4% of total cost

For other details on Project Cost, see the Project Cost Chart on page 40 of the application.

Historical Data Chart

- The applicant provided a historical data chart on page 44 of the application for their existing renal and specialty infusion division operations that are active in 30 states of the country. Pentec realized favorable net operating income of $8,458,000 in 2011 decreasing to ($41,262,000) in 2012 and (2,857,000) in 2013.
- As clarified by the applicant on page 39 of Supplemental 1, the negative amounts on line D.4 in the Historical Data Chart are based on tax benefits related to Pentec's net losses in 2012 and 2013.
- Review of the Consolidated Statements of Operations and the notes by the auditor on pages 9, 14 and 15 of audited financial statements confirmed the 2012 and 2013 net losses resulting from what appears to be a $46,482,000 accounting assessment in fiscal year 2012 for "Impairment of Goodwill and Trade names". As noted, the assessment appears to be based on an estimated reduction in Medicare Part D reimbursement rates for renal nutrition services provided by Pentec during the period.
- The applicant states that it expects a favorable net income of $4.2 million for the fiscal period ending December 31, 2014 (*please see page 51 of the revised application for more details*).

Projected Data Chart

The financial performance of the project appears to be favorable as proceeds from operating revenues cover operational costs. Highlights from the Projected Data Chart on page 46 of the revised application and the proformas on pages 123-125 in the attachments are as follows:

- Projected gross operating revenue increases from $304,573 on approximately 121 patient visits (approximately $2,517 per visit) to $853,923 on 314 visits in Year 2 (approximately $2,737 per visit).
- Net operating income is estimated at a loss of -$1,251 in Year One improving to a favorable margin of $117,812 in Year 2.
- Projected NOI calculates to approximately 13.8% of gross operating revenue in Year 2.
- Deductions from operating revenue consist entirely of bad debt estimated at $19,797 increasing to $55,505 in Year 2.
- As noted on page 39 of Supplemental 1 and pages 22 and 24 of Supplemental 2, Pentec's financial statements treat gross revenue as "net patient services operating revenue" and do not record charity care or contractual adjustments, although these amounts are taken into consideration.
- The applicant expects to provide charity care to one patient in Year 1.

Charges

In Year One of the proposed project, the average charge per visit is as follows:

- The proposed average gross charge is $2,517.00 per intrathecal pump patient visit.
- The average deduction for bad debt is $164.00 per patient visit, producing an average net charge of $2,353.00 per patient visit.
- The applicant's expected gross charge per visit in Year 2 is expected to be $2,720 per visit.
- The applicant provided an infusion therapy services fee schedule on page 157 of the revised application.
- The schedule includes charges that consist of the following general categories – per diem, drugs, nursing, supplies and other. As a cross reference, these categories are also reflected in the proforma on page 123 of the application and in the tables on page 21 of Supplemental 2.
- The applicant bases its projected charges on Pentec's infusion therapy operations experience in other states. Per clarification provided on page 41 of Supplemental 1, Pentec's typical reimbursement by commercial plans such as those shown on page 57 of the application averages approximately $92 per visit for visits up to 2 hours and $50-$70 per day for per diem charges.

Medicare/TennCare Payor Mix

The applicant is only certified by Medicare and Medicaid as a pharmacy and durable medical equipment (DME) provider and will not seek Medicare and TennCare certification for the proposed specialty infusion home health agency.

- Even if the applicant wanted to apply for Medicare/TennCare, it may not be eligible since its services are limited to the provision of skilled nursing specialty infusion therapy services. The proposed limited scope of service would not be providing the full range of home health services prescribed by the Medicare Conditions of Participation.
- The applicant states that fee for service Medicare/TennCare would only cover drugs dispensed by its existing licensed Tennessee pharmacy for patients of the proposed agency. They would not cover skilled nursing services to administer them or mange patient conditions (*please see page 52 of the application*).
- While it will not seek Medicare/TennCare certification, Pentec maintains that it will accept traditional fee for service patients of these programs on a limited, compassionate care basis in accordance with existing corporate policies (*source: page 4, Supplemental 1*).
- The applicant's projected payor mix is 86% commercial insurance, 7% Medicare and 7% TennCare in Year 1.

Financing

The project will be funded from cash reserves. Per Mr. Art Rea, Chief Financial Officer of Pentec Health, Inc., Pentec had cash on hand of approximately $7.5 million as of October 31, 2014.

Review of Pentec's audited financial statements submitted with the revised application confirmed the availability of cash reserves to fund the $142,028 proposed project. Per the Consolidated Balance Sheet, there was $3,867,673 in cash for the 12-month period ending December 31, 2013. In addition, Pentec reported total current assets of $20,785,836, total current liabilities of $15,562,693 resulting in a current ratio of 1.34 to 1.0.

Note to Agency Members: Current Ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant plans to use a 40 to 1 patient to nurse staffing ratio for the proposed agency. However, the applicant expects to staff one full time equivalent (FTE) licensed nurse in Year 1 despite the lower projected patient census that is expected for the first full year of the project. In addition, the applicant has allocated a 0.2 FTE Pentec Regional Nurse Manager to the project consistent with its practice in other states.

Licensure/Accreditation

If approved, the proposed Pentec Health, Inc. home health agency will be licensed by the Tennessee Department of Health.

- The applicant provided information regarding the licensing and accreditation of all of its existing home health and pharmacy sites, including its licensed Tennessee pharmacy, on pages 16 and 17 of Supplemental 1. A copy of the Tennessee pharmacy license is found on page 159 of the application.
- As noted, a letter dated October 17, 2011 from the Indiana State Department of Health states that the plan of correction in response to its 8/10/2011 initial state licensure survey was acceptable.
- A copy of Pentec Health Inc.'s 3-year Joint Commission accreditation award effective June 7, 2014 for the Home Health Accreditation Program with copy of applicable sites is shown on pages 162-165 of the application.

Corporate documentation, copies of the office lease and copies of corporate policies and procedures, including Infection Control, Pharmacy Quality Assurance and Pentec's

Performance Improvement Plan are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in **two** years.

Note to Agency members: Should the Agency choose to approve this application, Staff recommends the Agency limit any future expansion of services by requiring a new application to expand services beyond implanted intrathecal pump infusion services and Ig-G replacement therapy services rather than a modification request through the General Counsel's Report. This could be accomplished with the following condition:

Home Health Agency services are limited to specialized skilled nursing services under physician ordered plans of care for (1) patients with surgically implanted intrathecal pumps and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion. The expansion of services beyond the home infusion services described in the application will require the filing of a new certificate of need application.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent for other health care organizations in the service area proposing this type of service.

Pending Applications

Implanted Pump Management, CN1407-027, has a pending application that will be heard under simultaneous review with CN1411-046 at the HSDA meeting on March 25, 2015 for the establishment of a home health agency to service intrathecal pump services to patients across all 95 counties in the State of Tennessee. The estimated project cost is **$275,000**.

The Home Option by Harden Healthcare, CN1501-001, has a pending application that will be heard under CONSENT CALENDAR REVIEW at the March 25, 2015 Agency meeting for the initiation of home health services in

Blount, Campbell, Claiborne, Grainger, Monroe, Morgan, Roane and Scott Counties focusing on home health services to eligible individuals covered under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), United States Department of Labor. If approved, the applicant's sister agency, Gentiva Certified Healthcare Corporation, will de-license the same 8 counties. The Home Health Option by Harden is located at 800 Oak Ridge Turnpike, Suite A208, Oak Ridge (Anderson County), TN 37830 and is currently licensed in Anderson, Jefferson, Knox, Loudon, Sevier and Union Counties. The estimated project cost is **$38,000.00.**

Denied Applications:

Home Care Agency of Middle Tennessee, CN1001-001D, was denied at the June 23, 2010 Agency meeting for the establishment of a home care organization focusing on a full range of home health services and skilled nursing psychiatric services for the elderly population in a four (4) county service area including Davidson, Rutherford, Sumner, and Williamson Counties from a parent office located at 5115 Maryland Way, Brentwood, (Williamson County), Tennessee. The estimated project cost was **$69,000.00.** *Reasons for Denial: There is not a need as there are other agencies in the proposed service area that are providing home health services, including services to the mentally ill, and it is not economically feasible to have another agency. The project will not contribute to the orderly development of adequate and effective health care.*

Rainbow Home Health, CN1111-045D, was denied at the February 22, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services, including skilled nursing, physical/occupational/speech therapies, and medical social services for individuals residing in Cheatham County from a home office located at 112 Frey Street in Ashland City (Cheatham County), Tennessee 37015. The estimated cost was **$262,600.00.** *Reasons for Denial: the prevailing reason for the vote leading to the denial of the project (4 ayes, 6 nays, 0 ties) was based on concerns with nature and scope of information provided by the applicant that did not support the need for the project, the economic feasibility or the orderly development of the project.*

Rainbow Home Health, CN1203-013D, was denied at the June 27, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services from a home office located at 112 Frey Street, Ashland City (Cheatham County), Tennessee. The estimated project cost was **$27,950.00.** *Reasons for Denial: the application was denied by unanimous vote based on the following: there was no need due to services being adequately provided by existing licensed agencies in the service area; the project was not economically feasible due to the*

numbers not being justified or showing how the applicant could feasibly provide the service; and the project did not contribute to orderly development as it will impact the utilization and staffing of existing agencies in the service area.

Critical Nurse Staffing, CN1210-049D, was denied at the January 23, 2013 Agency meeting for the establishment of a home care organization located at 575 Oak Ridge Turnpike, Oak Ridge (Anderson County), Tennessee focusing on individuals eligible for benefits under either the Energy Employees Occupational Illness Compensation Program Act or the Federal Black Lung program that reside in Anderson, Campbell, Knox, Loudon, Monroe, Morgan, Roane, and Union Counties. The estimated project cost was **$155,937.00**. *Reasons for Denial: There was no real need - care was being adequately provided by other agencies in the proposed service area and adequate evidence did not support or prove that there was a need for the proposed agency.*

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby, Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was **$177,800.00**. *Reasons for Denial: The need for the proposed agency was not supported in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility - the project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.*

Outstanding Certificates of Need:

Coram Alternate Site Services, Inc. d/b/a Coram Specialty Infusion Services CN1406-018A has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to the provision and administration of home infusion products and related services ancillary to its pharmacy services in a 25 county service area of West Tennessee, including the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, McNairy, Madison, Obion, Perry, Shelby, Stewart, Tipton, Wayne and Weakley Counties. The parent office will be located in its licensed home infusion pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee, 38134. The estimated project cost is **$98,000.00.** *Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram,*

the licensure application has been submitted to the Tennessee Department of Health. The initial licensing inspection for the parent office in Memphis, TN has been scheduled for March 13, 2015. An Annual Project Report is due on or before July 1, 2015.

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, CN1406-017A, has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, and Washington Counties, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is **$95,200.00**. *Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the Tennessee Department of Health. Notice of the inspection date is pending. An Annual Project Report is due on or before July 1, 2015.*

Maxim Healthcare Services, CN1406-015A, has an outstanding Certificate of Need that will expire on October 1, 2016. The project was approved at the August 27, 2014 Agency meeting for the initiation of home health care services in a 5 county service area including Carter, Johnson, Sullivan, Unicoi, and Washington Counties focusing primarily on private duty hourly care to TennCare medically complex pediatric patients. Maxim Healthcare Services seeks an unrestricted home health agency license and will obtain Medicare certification to meet TennCare provider enrollment requirements. The estimated project cost is **$463,825.00.** *Project Status Update: per 2/27/15 e-mail from legal consel for Maxim Health Care Services, the project was appealed but it appears that the parties have reached a settlement and the appeal may be dismissed in the near future. Confirmation of same will follow as soon as possible.*

Hemophilia Preferred Care of Memphis, CN1202-002, has an outstanding certificate of need that will expire on August 1, 2015. The CON was approved at the June 27, 2012 agency meeting for the establishment of a home health agency and the initiation of home health services limited to patients suffering from hemophilia or similar blood disorders who are patients of the pharmacy operated by Hemophilia Preferred Care of Memphis. The estimated project cost

is **$43,000.** *Project Status: The applicant requested and received approval at the June 25, 2014 Agency meeting for a one year extension from August 1, 2014 to August 1, 2015.*

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG
03/04/2015

Saul Ewing LLP

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November 7, 2014

VIA FEDERAL EXPRESS (Tel. 615-741-2364)

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

Re: Pentec Health, Inc. / Letter of Intent

Dear Sir or Madam:

This firm represents Pentec Health, Inc. ("Pentec") in connection with its application for a Certificate of Need for establishment of a home care organization to provide specialty infusion services in Tennessee.

We have enclosed Pentec's Letter of Intent, including the form of Publication of Intent and an attachment listing the newspapers of general circulation in which the Publication of Intent will be published and the counties in which Pentec proposes to operate.

If you have any questions, please feel free to contact me (contact information provided above), or contact Doug Wynd at 636-751-6481 or dwynd@pentechealth.com. We look forward to working with the Agency in connection with Pentec's Certificate of Need application.

Sincerely,

Richard D. Leigh

Enclosure

cc: Robert Provonche – Pentec Health, Inc.
Doug Wynd – Pentec Health, Inc.
Karen McHenry, RN – Pentec Health, Inc.
George W. Bodenger, Esq. – Saul Ewing LLP

LETTER OF INTENT

Pentec Health, Inc.

Attachment 1

The Publication of Intent is to be published in the following newspapers of general circulation, whose combined circulation area covers all 95 counties in Tennessee:

	City	Newspaper		City	Newspaper
1.	Bristol	Bristol Herald Courier	9.	Kingsport	The Kingsport Times-News
2.	Chattanooga	Chattanooga Times Free	10.	Knoxville	Knoxville News Sentinel
3.	Clarksville	The Leaf-Chronicle	11.	Memphis	The Commercial Appeal
4.	Cookeville	Herald-Citizen	12.	Murfreesboro	The Daily News Journal
5.	Dyersburg	State Gazette	13.	Nashville	The Tennessean
6.	Greeneville	Greeneville Sun	14.	Paris	The Paris Post-Intelligencer
7.	Jackson	The Jackson Sun	15.	Union City	Union City Daily Messenger
8.	Johnson City	Johnson City Press			

Pentec Health, Inc. proposes to serve patients in all 95 counties in Tennessee, listed in alphabetical order:

1.	Anderson	33.	Hamilton	65.	Morgan
2.	Bedford	34.	Hancock	66.	Obion
3.	Benton	35.	Hardeman	67.	Overton
4.	Bledsoe	36.	Hardin	68.	Perry
5.	Blount	37.	Hawkins	69.	Pickett
6.	Bradley	38.	Haywood	70.	Polk
7.	Campbell	39.	Henderson	71.	Putnam
8.	Cannon	40.	Henry	72.	Rhea
9.	Carroll	41.	Hickman	73.	Roane
10.	Carter	42.	Houston	74.	Robertson
11.	Cheatham	43.	Humphreys	75.	Rutherford
12.	Chester	44.	Jackson	76.	Scott
13.	Claiborne	45.	Jefferson	77.	Sequatchie
14.	Clay	46.	Johnson	78.	Sevier
15.	Cocke	47.	Knox	79.	Shelby
16.	Coffee	48.	Lake	80.	Smith
17.	Crockett	49.	Lauderdale	81.	Stewart
18.	Cumberland	50.	Lawrence	82.	Sullivan
19.	Davidson	51.	Lewis	83.	Sumner
20.	Decatur	52.	Lincoln	84.	Tipton
21.	DeKalb	53.	Loudon	85.	Trousdale
22.	Dickson	54.	McMinn	86.	Unicoi
23.	Dyer	55.	McNairy	87.	Union
24.	Fayette	56.	Macon	88.	Van Buren
25.	Fentress	57.	Madison	89.	Warren
26.	Franklin	58.	Marion	90.	Washington
27.	Gibson	59.	Marshall	91.	Wayne
28.	Giles	60.	Maury	92.	Weakley
29.	Grainger	61.	Meigs	93.	White
30.	Greene	62.	Monroe	94.	Williamson
31.	Grundy	63.	Montgomery	95.	Wilson
32.	Hamblen	64.	Moore		

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in the The Tennessean (and others - see Attachment 1) (Name of Newspaper) which is a newspaper of general circulation in Davidson County (and others - see Attachment 1) (County), Tennessee, on or before November 10 (Month / day), 20 14 (Year), for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Pentec Health, Inc. (Name of Applicant) N/A (Facility Type-Existing)

owned by: Pentech Holdings, Inc. with an ownership type of Corporation

and to be managed by: Jamie Schultz, R.N. intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: Establishment of a home care organization and initiation of home health services consisting of specialized skilled nursing services provided under physician-ordered plans of care to (1) patients with implanted intrathecal pumps, and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion, in the patients' places of residence, in all 95 counties in the State of Tennessee. The organization will serve the entire state from its office at 424 Church Street, Suite 2000, Nashville, TN 37219. The estimated project cost is $142,000, including a $100,000 reserve fund.

The anticipated date of filing the application is: November 14, 20 14

The contact person for this project is Doug Wynd (Contact Name) National Sales Director, Specialty Infusion (Title)

who may be reached at: Pentec Health, Inc. (Company Name) 4 Creek Parkway (Address)

Boothwyn (City) Pennsylvania (State) 19061 (Zip Code) 636 / 751-6481 (Area Code / Phone Number)

(Signature) Nov. 03, 2014 (Date) dwynd@pentechealth.com (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

State of Tennessee
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243
www.tn.gov/hsda Phone: 615-741-2364 Fax: 615-741-9884

PUBLICATION OF INTENT

The following shall be published in the "Legal Notices" section of the newspaper in a space no smaller than two (2) columns by two (2) inches.

NOTIFICATION OF INTENT TO APPLY FOR A CERTIFICATE OF NEED

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Pentec Health, Inc., N/A
(Name of Applicant) (Facility Type-Existing)

owned by: Pentech Holdings, Inc. with an ownership type of Corporation

and to be managed by: Jamie Schultz, R.N. intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]: Establishment of a home care organization and initiation of home health services consisting of specialized skilled nursing services provided under physician-ordered plans of care to (1) patients with implanted intrathecal pumps, and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion, in the patients' places of residence, in all 95 counties in the State of Tennessee, listed alphabetically as follows (see Attachment 1). The organization will serve the entire state from its office at 424 Church Street, Suite 2000, Nashville, Tennessee, 37219. The estimated project cost is $142,000, including a $100,000 reserve fund.

The anticipated date of filing the application is: November 14, 20 14

The contact person for this project is Doug Wynd (Contact Name), National Sales Director, Specialty Infusion (Title)

who may be reached at: Pentec Health, Inc. (Company Name), 4 Creek Parkway (Address)

Boothwyn (City), Pennsylvania (State), 19061 (Zip Code), 636 / 751-6481 (Area Code / Phone Number)

Upon written request by interested parties, a local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

NHC

NATIONAL HEALTHCARE CORPORATION

MAR 9 '15 AM 9:

March 5, 2015

Ms. Melanie Hill, Executive Director
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Pentec Health, Inc., CN1411-046 **OPPOSITION LETTER**

Dear Ms. Hill:

We are aware of the intent of Pentec Health, Inc. to establish a new Home Health Care service organization to provide specialty infusion services (patients with intrathecal pumps and patients receiving immunoglobulin-G replacement therapy) to all 95 counties in the State of Tennessee from one office in Nashville. **NHC has serious concerns regarding numerous aspects of the referenced CON application including but not limited to whether there is a demonstrated need in the State of Tennessee for such services, whether or not the proposed service delivery model is even legal in the State, that approval of said application would duplicate existing similar services already approved by HSDA, and that the project would adversely impact the existing home health care delivery system. Therefore, I am writing this letter in opposition to the referenced project pursuant to T.C.A., Section 68-11-1609(g) (1).**

In recent months, there has been an alarming trend of applicants requesting Home Care CON's to service all 95 counties in Tennessee with limited staff, single office locations and with a single specialty focus that will do nothing more than further fragment the health care delivery system in our State. In addition, these recent CON's appear to fall outside the established criteria for the home care service. Consequently, it would seem appropriate that until further study is conducted on what criteria should actually be used to evaluate said CON's, a moratorium should be imposed on CON's of this type prohibiting their acceptance and review before the agency

In summary, I am opposed to this CON and ask that it not be approved. There are many unanswered questions regarding this application and more than adequate existing providers delivering high quality home health services to populations of all race and payment source. If you need any additional information please do not hesitate to call me.

Sincerely,

NHC/OP, L.P. d/b/a NHC HomeCare

Lisa Reed, RN
Vice President/HomeCare

Cc: Mr. Doug Wynd
Pentec Health, Inc.
4 Creek Parkway
Boothwyn, PA 19061

CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954

DATE: February 27, 2015

APPLICANT: Pentech Health, Inc.
424 Church Street, Suite 2000
Nashville, Tennessee 37219

CN1411-046

CONTACT PERSON: Doug Wynd, National Sales Director
Specialty Infusion
4 Creek Parkway
Boothwyn, Pennsylvania 19061

COST: $142,028

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:
The applicant, Pentech Health, Inc., located at 424 Church Street, Suite 2000, Nashville, Tennessee, 37219 seeks Certificate of Need (CON) approval for the establishment of a Home Health Organization and the initiation home health services consisting of specialized skilled nursing services under physician-ordered plans of care to (1) patients with implanted intrathecal pumps and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion, in the patients' places of residence. The organization will serve the entire state with the exception of Hancock, Perry, and Van Buren counties, from its office in Nashville.

The applicant will lease an 87 square foot office at a cost of $8,028 annually. The cost per square foot is $92.28.

The total estimated project cost is $142,028 and will be funded through cash reserves as documented by the Chief Financial Officer in Attachment C, Economic Feasibility.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

NEED:
The applicant's designated service area includes the entire State of Tennessee with the exception of Hancock, Perry, and Van Buren counties.

The population and Need for these counties are located in Attachment 1 following the Specific Criteria.

Pentech Health, Inc. proposal involves the establishment the establishment of an HHA that will provide very specialized services to a complex and underserved category of patients in Tennessee, specifically those individuals with implanted intrathecal pumps, and those in need of immunoglobulin-G replacement therapy through IV or subcutaneous infusion. Both categories may be considered chronically ill. The applicant asserts this proposal will improve the health of these

patients.

The patients the applicant intends to provide services to suffer from conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke, and severe acute pain secondary to cancer. Many of these patients have failed to find relief from more traditional treatments and could find relief from intrathecal pump therapy. Some of these patients are able to resume many normal activities as a result of intrathecal treatments.

Pentech estimates about 1,976 people are presently using intrathecal pumps in Tennessee. The applicant states relatively few physicians practice in this specialty and home health services are very limited. Most patients currently receive visits only every 30 days. For patient s who are home-bound or who have limited mobility, physician office visits are burdensome. Missed appointments may cause a potentially life threatening situation. Because Pentech provides services to its patients in their home, and because its specially-trained nurses are available on a 24/7 basis, Pentech believes that can eliminate both travel burdens and the serious risks to patients from failure to have their pumps filled in a timely manner.

Additionally, Pentech estimates that approximately 1,020 Tennessean are present in need of Ig-G replacement therapy. These patients have compromised immune deficiencies that require lifetime treatment on a monthly basis, or auto-immune deficiency which may require lifetime treatment on a 3 – 6 -12 month therapy segment.

Pentech reports their proprietary technology will further enhance access to care by patients. This technology includes a centralized communication system that allows patients to reach their primary care nurse 24/7 on a patient portal on Pentech's web site that enables the patient to have access to their medical records and permits secure, HIPPA-compliant communication with Pentech: as well as a secure, two-way videoconferencing capability that allows physicians to observe treatment by Pentech's nurse and communicate with the nurse and patient during the in-home visit.

Pentech provides a listing of all States in which they are either licensed as a pharmacy and a home health agency (if required); Medicare or Medicaid certified, and accreditation in Supplement 1, page 17.

TENNCARE/MEDICARE ACCESS:
The applicant is only certified as a Pharmacy/DME by Medicaid and Medicare. They will not seek Medicaid and Medicare certification for this project.

The applicant estimates gross year one Medicare revenues are $21,545 or 7% of gross revenues. Medicaid revenues are estimated to be $21,545 or 7% of total revenues. First year commercial insurance is estimated to be $261,483 or 86% of total gross revenues.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY: FACTORS/FINANCIAL FEASIBILITY:
The Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and the projections are correct based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

> **Project Costs Chart:** The Project Cost Chart is located on page 40 of the application. The total estimated project cost is $142,028.
>
> **Historical Data Chart:** The Historical Data Chart is located on page 44 of the application. Pentech Health, Inc. revenues are derived from their Renal Nutrition and Specialty Infusion divisions and they are unable to specify a single unit of measurement for the purpose of completing the Historical Data Chart. The applicant's net operating

revenues for 2011, 2012, and 2013 were $8,458,000, ($41,262,000) and ($2,857,000) each year, respectively.

Projected Data Chart: The Projected Data Chart is located on page 46 of the application. The applicant projects 20.2 and 52.4 patients in years one and two, with net operating income of ($1,251) $ and $117,812 each year, respectively.

The applicant provided the average charges, deductions, net charge, and net operating income for Year 1 below.

	CY2015
Patients	20.2
Average Gross Charge Per visit	$2,517
Average adjustment per patient	$164
Average Net Charge (Net Operating Revenue) per patient	$2,354

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:
Pentech lists all healthcare providers, working relationships, contractual agreements, and transfer agreements on page 57 and 58 of the application.

Pentech is currently establishing relationships with physicians who practice in the field of intrathecal medicine in Tennessee. Pentech believes the patients treated in physician's offices may affect those practices' utilization to a limited extent. The applicant believes their services could offer a tangible benefit to the health care system by offsetting the effect on this utilization by providing services in the patient residence while improving access and quality. Reimbursable costs associated intrathecal refills are likely to be lower than the same services provided by a physician's office visit, resulting in a savings to the healthcare system. It is also likely there will be fewer incidences of intrathecal patients presenting to the hospital with related problems. Finally, the need for emergency transport would be reduced. If the proposed project was implemented, the applicant believes a further affect would be the reduction of the costs associated with services provided to intrathecal patients, thus resulting in financial competition among providers.

There are currently no Home Health Agencies providing intrathecal services in Tennessee. The applicant believes there should be no negative impact on current providers.

Pentech's proposed staffing will be 1.0 FTE registered nurse initially. Their average ratio is 40 patients to 1 nurse. As their census increases, additional full-time primary care nurses will be hired. Pentech reports they have a pool of registered nurses licensed to practice in Tennessee who are able to provide part-time or back-up staffing if needed.

Additionally, Pentech has allocated 1/5 for a Regional Nurse Manager (0.2 FTE).

Pentech does not offer training or access to health care professional schools.

The applicant will seek licensure from the Department of Health, Board for Licensing Health Care Facilities, and is accredited by The Joint Commission.

Not to Agency Members: Pentech received a notice from the Indiana State Department of Health dated August 22, 2011 alleging a breach of the licensure requirements of Ind. Code § 16-27-1-410 and Ind. Admin. Code § 17-10-1 (a) at docket number AC-227-11. This is attached in Attachment C, Contribution to the Orderly Development of Health Care, Item 8. A civil penalty of $10,000 was paid by Pentech.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan.*

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.

   Please see Attachment 1.

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

   The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

   There is no need for Home Health Services in Tennessee. The Department of Health, Division of Policy, Planning, and Assessment, calculated the need for Home Health Services to be a ***surplus of 80,773.***

3. Using recognized population sources, projections for four years into the future will be used.

   Please see Attachment 1.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

   Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

   There is no need for Home Health Services in Tennessee. The Department of Health, Division of Policy, Planning, and Assessment, calculated the need for Home Health Services to be a ***surplus of 80,733.***

5. Documentation from referral sources:

   a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

      The applicant supplies a letter from William Muench, MD of Hendersonville, Tennessee, a physician with Comprehensive Pain Specialists. It does not appear that the applicant adequately meets this criterion.

   b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

      The applicant states the referring physicians would be those who refer their patients to do all pump refills, titrations, and changes in status in the homecare setting.

   c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided no letters from potential patients or providers who have attempted to find such services but were unable find them.

d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

No other agency currently provides this service in Tennessee.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

a. The average cost per visit by service category shall be listed.

b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant provided the average charges, deductions, net charge, and net operating income for Year 1 below.

	CY2015
Patients	*20.2*
Average Gross Charge Per visit	*$2,517*
Average adjustment per patient	*$164*
Average Net Charge (Net Operating Revenue) per patient	*$2,354*

Attachment 1

Joint Annual Report of Home Health Agencies - 2013 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2018 vs. 2013)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Tennessee	1,619	1,457	175,924	6,528,014	0.0269	6,833,509	184,157	102,503	(81,654)
Anderson	22	19	2,893	76,182	0.0380	77,851	2,956	1,168	(1,789)
Bedford	20	19	1,120	46,700	0.0240	50,566	1,213	758	(454)
Benton	11	10	667	16,315	0.0409	16,104	658	242	(417)
Bledsoe	10	8	462	12,698	0.0364	12,599	458	189	(269)
Blount	18	18	2,507	126,809	0.0198	135,171	2,672	2,028	(645)
Bradley	16	14	2,021	102,235	0.0198	107,481	2,125	1,612	(512)
Campbell	21	18	1,715	41,163	0.0417	42,566	1,773	638	(1,135)
Cannon	19	16	423	14,013	0.0302	14,540	439	218	(221)
Carroll	13	13	1,246	28,213	0.0442	27,831	1,229	417	(812)
Carter	12	11	2,072	57,228	0.0362	57,680	2,088	865	(1,223)
Cheatham	24	25	772	39,603	0.0195	40,765	795	611	(183)
Chester	14	13	563	17,355	0.0324	17,999	584	270	(314)
Claiborne	19	15	2,002	32,457	0.0617	33,280	2,053	499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673	249	115	(133)
Cocke	16	14	1,467	36,330	0.0404	38,615	1,559	579	(980)
Coffee	20	16	1,874	53,784	0.0348	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0369	14,683	541	220	(321)
Cumberland	15	13	1,601	57,370	0.0279	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0230	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0542	12,080	655	181	(473)
DeKalb	21	16	469	18,918	0.0248	19,125	474	287	(187)
Dickson	25	24	1,617	50,596	0.0320	51,964	1,661	779	(881)
Dyer	11	10	1,671	38,205	0.0437	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0178	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0346	42,122	1,459	632	(828)
Gibson	15	14	1,924	50,748	0.0379	52,163	1,978	782	(1,195)
Giles	12	11	1,001	29,325	0.0341	29,285	1,000	439	(560)
Grainger	22	20	886	22,994	0.0385	23,675	912	355	(557)
Greene	20	17	2,454	69,888	0.0351	71,594	2,514	1,074	(1,440)
Grundy	18	16	529	13,396	0.0395	13,293	525	199	(326)
Hamblen	19	17	2,835	63,763	0.0445	65,570	2,915	984	(1,932)
Hamilton	16	16	8,038	345,447	0.0233	353,577	8,227	5,304	(2,924)
Hancock	14	11	682	6,652	0.1025	6,640	681	100	[redacted]
Hardeman	17	15	917	26,492	0.0346	26,067	902	391	(511)
Hardin	16	14	1,157	25,968	0.0446	26,244	1,169	394	(776)
Hawkins	21	18	2,148	57,273	0.0375	58,164	2,181	872	(1,309)
Haywood	15	13	612	18,199	0.0336	18,009	606	270	(335)
Henderson	14	13	1,015	28,080	0.0361	28,631	1,035	429	(605)
Henry	10	10	1,283	32,595	0.0394	32,956	1,297	494	(803)
Hickman	18	17	725	24,393	0.0297	24,698	734	370	(364)
Houston	12	11	281	8,358	0.0336	8,447	284	127	(157)
Humphreys	16	14	803	18,488	0.0434	18,561	806	278	(528)
Jackson	12	11	402	11,355	0.0354	11,495	407	172	(235)
Jefferson	20	19	1,749	53,006	0.0330	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
Lake	6	5	325	9,795	0.0332	9,468	314	142	(172)

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics

May 2014

Joint Annual Report of Home Health Agencies - 2013 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2018 vs. 2013)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Lauderdale	14	11	857	27,465	0.0312	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0394	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0332	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0313	35,697	1,116	535	(580)
Loudon	23	21	1,572	50,356	0.0312	53,192	1,661	798	(863)
McMinn	17	17	1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315	101,001	3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256	28,992	743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomery	19	20	2,903	184,087	0.0158	200,561	3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216	22,004	476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	[redacted]
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256	16,588	425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)
Stewart	10	10	339	13,436	0.0252	13,941	352	209	(143)
Sullivan	14	13	5,259	158,451	0.0332	161,136	5,348	2,417	(2,931)
Sumner	26	27	4,160	169,409	0.0246	183,406	4,504	2,751	(1,753)
Tipton	26	22	1,298	63,001	0.0206	67,545	1,392	1,013	(378)
Trousdale	16	14	431	8,046	0.0536	8,582	460	129	(331)
Unicoi	13	11	659	18,334	0.0359	18,511	665	278	(388)
Union	21	18	371	19,231	0.0193	19,605	378	294	(84)
Van Buren	12	11	240	5,456	0.0440	5,474	241	82	[redacted]
Warren	20	15	2,266	40,299	0.0562	41,155	2,314	617	(1,697)
Washington	16	14	4,181	128,537	0.0325	138,370	4,501	2,076	(2,425)
Wayne	11	9	640	16,887	0.0379	16,724	634	251	(383)
Weakley	13	11	1,180	38,255	0.0308	39,491	1,218	592	(626)
White	14	9	962	26,612	0.0361	27,974	1,011	420	(592)
Williamson	32	32	2,815	198,045	0.0142	223,333	3,174	3,350	176
Wilson	28	31	3,727	121,626	0.0306	133,357	4,086	2,000	(2,086)

*Most recent year of Joint Annual Report data for Home Health Agencies

Data is projected four years from the year the Home Health data was **finalized, not the actual year of Home Health data.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics

May 2014

Tennessee Population Estimates 2015 and 2019 *

	Population Estimate 2015			Population Estimate 2019			% Increase	
	Total	65+	%65+	Total	65+	%65+	65+	Total
Tennessee	6,649,438	1,012,937	15.2%	6,894,997	1,134,565	16.5%	12.0%	3.7%
Anderson	76,949	14,986	19.5%	78,123	16,737	21.4%	11.7%	1.5%
Bedford	48,099	7,002	14.6%	51,495	7,778	15.1%	11.1%	7.1%
Benton	16,208	3,763	23.2%	16,071	3,898	24.3%	3.6%	-0.8%
Bledsoe	12,610	2,360	18.7%	12,637	2,569	20.3%	8.9%	0.2%
Blount	129,973	23,812	18.3%	137,058	26,507	19.3%	11.3%	5.5%
Bradley	104,364	16,985	16.3%	108,511	19,036	17.5%	12.1%	4.0%
Campbell	41,783	7,793	18.7%	42,792	8,241	19.3%	5.7%	2.4%
Cannon	14,218	2,550	17.9%	14,631	2,742	18.7%	7.5%	2.9%
Carroll	28,012	5,628	20.1%	27,781	5,828	21.0%	3.6%	-0.8%
Carter	57,359	11,279	19.7%	57,828	12,208	21.1%	8.2%	0.8%
Cheatham	40,088	5,115	12.8%	40,965	6,076	14.8%	18.8%	2.2%
Chester	17,593	2,824	16.1%	18,151	2,951	16.3%	4.5%	3.2%
Claiborne	32,765	6,000	18.3%	33,449	6,471	19.3%	7.9%	2.1%
Clay	7,681	1,733	22.6%	7,684	1,792	23.3%	3.4%	0.0%
Cocke	37,207	6,762	18.2%	39,101	6,905	17.7%	2.1%	5.1%
Coffee	54,817	7,938	14.5%	57,619	7,261	12.6%	-8.5%	5.1%
Crockett	14,611	2,566	17.6%	14,715	2,673	18.2%	4.2%	0.7%
Cumberland	58,340	15,895	27.2%	61,077	15,456	25.3%	-2.8%	4.7%
Davidson	663,151	77,086	11.6%	688,318	88,812	12.9%	15.2%	3.8%
Decatur	11,883	2,583	21.7%	12,156	2,657	21.9%	2.9%	2.3%
DeKalb	18,996	3,448	18.2%	19,172	3,765	19.6%	9.2%	0.9%
Dickson	51,127	7,110	13.9%	52,248	7,795	14.9%	9.6%	2.2%
Dyer	38,246	6,424	16.8%	38,482	6,925	18.0%	7.8%	0.6%
Fayette	41,835	7,271	17.4%	45,963	8,408	18.3%	15.6%	9.9%
Fentress	18,553	3,625	19.5%	19,133	3,935	20.6%	8.6%	3.1%
Franklin	41,391	7,479	18.1%	42,408	7,402	17.5%	-1.0%	2.5%
Gibson	51,412	8,875	17.3%	52,350	9,353	17.9%	5.4%	1.8%
Giles	29,293	5,547	18.9%	29,282	6,036	20.6%	8.8%	0.0%
Grainger	23,236	4,329	18.6%	23,850	4,607	19.3%	6.4%	2.6%
Greene	70,520	14,144	20.1%	71,989	15,120	21.0%	6.9%	2.1%
Grundy	13,322	2,693	20.2%	13,303	2,837	21.3%	5.3%	-0.1%
Hamblen	64,438	11,522	17.9%	65,952	12,198	18.5%	5.9%	2.3%
Hamilton	349,273	57,974	16.6%	354,610	64,174	18.1%	10.7%	1.5%
[redacted]	6,645	1,349	20.3%	6,663	1,436	21.6%	6.4%	0.3%
Hardeman	26,231	4,308	16.4%	26,035	4,631	17.8%	7.5%	-0.7%
Hardin	26,075	5,508	21.1%	26,310	5,900	22.4%	7.1%	0.9%
Hawkins	57,741	11,739	20.3%	58,241	13,425	23.1%	14.4%	0.9%
Haywood	18,044	2,821	15.6%	18,032	3,136	17.4%	11.2%	-0.1%
Henderson	28,279	4,892	17.3%	28,743	5,371	18.7%	9.8%	1.6%
Henry	32,766	7,033	21.5%	33,015	7,351	22.3%	4.5%	0.8%
Hickman	24,465	4,076	16.7%	24,784	4,751	19.2%	16.6%	1.3%
Houston	8,413	1,671	19.9%	8,449	1,791	21.2%	7.2%	0.4%
Humphreys	18,519	3,656	19.7%	18,581	3,864	20.8%	5.7%	0.3%
Jackson	11,383	2,385	21.0%	11,520	2,593	22.5%	8.7%	1.2%
Jefferson	54,482	10,334	19.0%	57,707	11,606	20.1%	12.3%	5.9%
Johnson	18,090	3,822	21.1%	18,175	4,014	22.1%	5.0%	0.5%
Knox	459,124	69,186	15.1%	481,044	81,757	17.0%	18.2%	4.8%
Lake	9,676	1,162	12.0%	9,411	1,250	13.3%	7.6%	-2.7%
Lauderdale	27,264	3,922	14.4%	27,135	4,292	15.8%	9.4%	-0.5%
Lawrence	42,373	7,628	18.0%	42,373	8,140	19.2%	6.7%	0.0%

Tennessee Population Estimates 2015 and 2019 *

	Population Estimate 2015			Population Estimate 2019			% Increase	
	Total	65+	%65+	Total	65+	%65+	65+	Total
Lewis	12,112	2,269	18.7%	12,259	2,545	20.8%	12.2%	1.2%
Lincoln	34,624	5,104	14.7%	36,059	4,979	13.8%	-2.4%	4.1%
Loudon	51,495	13,107	25.5%	53,741	14,488	27.0%	10.5%	4.4%
McMinn	53,476	10,126	18.9%	54,457	10,845	19.9%	7.1%	1.8%
McNairy	26,755	5,194	19.4%	27,509	5,568	20.2%	7.2%	2.8%
Macon	23,419	3,775	16.1%	24,366	4,275	17.5%	13.2%	4.0%
Madison	99,971	14,747	14.8%	101,279	16,289	16.1%	10.5%	1.3%
Marion	28,652	5,502	19.2%	29,125	6,031	20.7%	9.6%	1.7%
Marshall	31,413	4,970	15.8%	32,322	5,668	17.5%	14.0%	2.9%
Maury	82,526	12,774	15.5%	83,485	14,550	17.4%	13.9%	1.2%
Meigs	12,331	2,560	20.8%	12,697	2,869	22.6%	12.1%	3.0%
Monroe	46,563	9,325	20.0%	48,648	10,680	22.0%	14.5%	4.5%
Montgomery	191,068	16,969	8.9%	203,460	19,759	9.7%	16.4%	6.5%
Moore	6,364	1,267	19.9%	6,415	1,257	19.6%	-0.8%	0.8%
Morgan	21,870	3,531	16.1%	22,076	3,897	17.7%	10.4%	0.9%
Obion	31,365	5,995	19.1%	31,218	6,347	20.3%	5.9%	-0.5%
Overton	22,593	4,364	19.3%	23,104	4,633	20.1%	6.2%	2.3%
[redacted]	8,025	1,768	22.0%	8,103	1,953	24.1%	10.5%	1.0%
Pickett	4,998	1,320	26.4%	4,930	1,350	27.4%	2.3%	-1.4%
Polk	16,570	3,341	20.2%	16,609	3,607	21.7%	8.0%	0.2%
Putnam	78,416	11,864	15.1%	83,992	12,498	14.9%	5.3%	7.1%
Rhea	33,767	6,217	18.4%	35,081	6,907	19.7%	11.1%	3.9%
Roane	54,079	11,701	21.6%	54,631	12,863	23.5%	9.9%	1.0%
Robertson	71,437	8,312	11.6%	75,312	9,689	12.9%	16.6%	5.4%
Rutherford	302,237	28,650	9.5%	338,904	34,874	10.3%	21.7%	12.1%
Scott	21,915	3,615	16.5%	22,021	3,927	17.8%	8.6%	0.5%
Sequatchie	15,246	2,916	19.1%	16,270	3,372	20.7%	15.6%	6.7%
Sevier	96,116	17,434	18.1%	101,929	19,842	19.5%	13.8%	6.0%
Shelby	946,559	112,753	11.9%	956,200	129,543	13.5%	14.9%	1.0%
Smith	19,771	3,134	15.9%	20,468	3,496	17.1%	11.6%	3.5%
Stewart	13,659	2,549	18.7%	14,027	2,785	19.9%	9.3%	2.7%
Sullivan	159,494	34,287	21.5%	161,707	38,477	23.8%	12.2%	1.4%
Sumner	175,054	26,272	15.0%	186,146	30,856	16.6%	17.4%	6.3%
Tipton	64,759	8,414	13.0%	68,477	9,778	14.3%	16.2%	5.7%
Trousdale	8,275	1,275	15.4%	8,667	1,431	16.5%	12.2%	4.7%
Unicoi	18,419	4,029	21.9%	18,558	4,318	23.3%	7.2%	0.8%
Union	19,347	3,287	17.0%	19,677	3,789	19.3%	15.3%	1.7%
[redacted]	5,433	1,149	21.1%	5,488	1,286	23.4%	11.9%	1.0%
Warren	40,662	6,823	16.8%	41,362	7,339	17.7%	7.6%	1.7%
Washington	132,599	22,369	16.9%	140,184	24,871	17.7%	11.2%	5.7%
Wayne	16,815	3,063	18.2%	16,691	3,286	19.7%	7.3%	-0.7%
Weakley	38,790	5,933	15.3%	39,709	6,292	15.8%	6.1%	2.4%
White	27,132	5,132	18.9%	28,275	5,423	19.2%	5.7%	4.2%
Williamson	207,872	24,219	11.7%	228,670	28,889	12.6%	19.3%	10.0%
Wilson	126,472	18,939	15.0%	135,567	22,683	16.7%	19.8%	7.2%

* 2013 Tennessee Population Projection Series.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.