Department of State
Division of Publications
312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower
Nashville, TN 37243
Phone: 615-741-2650
Email: publications.information@tn.gov

For Department of State Use Only

Sequence Number: 03-20-23
Rule ID(s): 9862
File Date: 3/29/2023
Effective Date: 6/27/2023

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission:	Department of Commerce and Insurance
Division:	Division of Insurance
Contact Person:	Will Kerby
Address:	500 James Robertson Parkway, Nashville, TN
Zip:	37243
Phone:	(615) 360-4358
Email:	william.kerby@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

X Content based on previous emergency rule filed on December 29, 2022
___ Content is identical to the emergency rule

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
0780-01-95	Pharmacy Benefits Managers
Rule Number	**Rule Title**
0780-01-95-.01	Scope
0780-01-95-.02	Definitions
0780-01-95-.03	Approval of Initial Application
0780-01-95-.04	Actions During and After an Initial Appeal
0780-01-95-.05	Timing and Notice Requirements for Initial Appeal Processes
0780-01-95-.06	External Appeal Process
0780-01-95-.07	Fees
0780-01-95-.08	Plans Utilizing a Reimbursement Methodology Identical to the Methodology Used by the State Plan for Medical Assistance Approved by the Federal Centers for Medicare and Medicaid Services
0780-01-95-.09	Audits by Pharmacy Benefits Managers
0780-01-95-.10	Determination of Pharmacy's Professional Dispensing Fee
0780-01-95-.11	Violations

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to https://sos.tn.gov/products/division-publications/rulemaking-guidelines.

Chapter 0780-01-95
Pharmacy Benefits Managers
New

Rule 0780-01-95-.01 Scope is a new rule.

This chapter applies to all pharmacies and pharmacy benefits managers, including agents designated to handle matters on behalf of pharmacies or pharmacy benefits managers, conducting business in the State of Tennessee.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.02 Definitions is a new rule.

(1) All words and phrases used but not defined in this chapter that are defined in T.C.A. title 56, chapter 7, part 31 or part 32 shall have the meaning set forth therein.

(2) For the purposes of this chapter:

(a) "Cash discount" means a deduction from the invoice paid by a pharmacy for a prescription drug or device if the invoice is paid on or before a specified date or in cash.

(b) "Commissioner" means the commissioner of the department of commerce and insurance or the commissioner's designee.

(c) "Department" means the department of commerce and insurance.

(d) "Initial appeal" means the process required under T.C.A. § 56-7-3206(c)(2) and administered by a pharmacy benefits manager by which a pharmacy, or a pharmacy services administrative organization acting on behalf of a pharmacy, may appeal a reimbursement received from a pharmacy benefits manager that is not at least the actual cost to the pharmacy for a prescription drug or device.

(e) "Majority wholesaler" means the wholesaler from whom a pharmacy purchased the majority of its prescription pharmaceutical products for resale in the calendar year preceding the calendar year during which the claim that is the subject of an initial appeal is processed.

(f) "PBM" means a pharmacy benefits manager as defined in T.C.A. § 56-7-3102.

(g) "Pharmacy" means a pharmacy as defined in T.C.A. § 56-7-3102 and includes an agent acting on behalf of a pharmacy, including but not limited to a pharmacy services administrative organization.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.03 Approval of Initial Appeal Process is a new rule.

(1) No PBM may utilize an initial appeal process until it has received approval from the Commissioner stating the PBM's initial appeal process meets the requirements of T.C.A. § 56-7-3206(c)(2) and this chapter. A PBM shall utilize only one appeal process for all initial appeals filed with the PBM.

(2) PBMs must submit the following to the Commissioner as part of an application for approval of an initial appeal process, along with the application fee required under Rule 0780-01-95-.07(1):

(a) The name of the PBM;

(b) The contact information, including phone number and email address, for the primary individual responsible for managing the application for the PBM;

(c) The contact information, including phone number and email address, for the primary individual who will manage the PBM's appeal process. This may be the same individual designated in subparagraph (b);

(d) Certification the PBM will accept from a pharmacy the standard appeal form created by the Department to file an initial appeal;

(e) The appeal form the PBM will accept from a pharmacy to file an initial appeal, if the PBM intends to offer its own appeal form in addition to the standard appeal form created by the Department;

(f) A comprehensive list of all information and documents requested from a pharmacy at the initiation of an initial appeal in addition to the standard appeal form provided by the Department or the PBM's appeal form submitted to the Department pursuant to subparagraph (e) of this paragraph, including any forms used to request such information;

(g) A list of the position(s) responsible for reviewing initial appeals received from a pharmacy, along with the training, experience, and education required of the position(s);

(h) A summary, sufficient to the Commissioner, of how the PBM will comply with the timing and notice requirements under T.C.A. § 56-7-3206(c)(2)(B)(ii) and Rule 0780-01-95-.05;

(i) Certification the PBM will not assess any costs to the pharmacy for any services provided in connection with the initial appeal;

(j) The email address to which the Commissioner shall send notice to the PBM of an external appeal to the Commissioner pursuant to T.C.A. § 56-7-3206(g)(2);

(k) Certification the PBM will require the name of a pharmacy's wholesaler or manufacturer, as applicable, from which the pharmacy purchased the drug or medical product or device at issue as part of its processing of claims for reimbursement from pharmacies. A PBM shall request this information as part of its processing of claims for reimbursement;

(l) A description, sufficient to the Commissioner, of how the PBM will track initial appeals such that it can reasonably determine, upon being provided the wholesaler or manufacturer in a claim, if an adjusted rate of reimbursement applies; and

(m) Any other documentation or information requested by the Commissioner regarding an initial appeal process.

(3)

(a) Within 60 days of receipt of a complete application for approval of an initial appeal process containing all information required and requested under paragraph (2) of this rule and the required application fee, the Commissioner may:

1. Approve the initial appeal process upon determining that, in the Commissioner's discretion, the initial appeal process:

   (i) Meets the requirements of paragraph (2) of this rule; and

   (ii) Is reasonable and efficient;

2. Deny an initial appeal process for failure to meet, in the Commissioner's discretion, the requirements of subparts (3)(a)1.(i) or (ii) of this rule. The Commissioner shall provide the reason for denial in writing to the applicant; or

3. Extend the timeline for rendering a decision by providing the parties with written notice that includes a good-faith estimate of the additional time needed to make a decision. The Commissioner may subsequently further extend any such extended timeline by providing additional written notice to the parties of an updated good-faith estimate of the additional time needed to make a decision prior to the expiration of the previous extension.

(b) If the Commissioner does not take one of the actions listed in subparagraph (3)(a) of this rule within 60 days of receipt of a complete application, or within the extended timeline if extended pursuant to part (3)(a)3. of this rule, the application shall be deemed approved.

(4) Denial under part (3)(a)2. of this rule shall not preclude a PBM from submitting a new application for approval of an initial appeal process, accompanied by a new application fee, upon correcting any defects that caused the previous denial.

(5) A PBM may utilize an approved initial appeal process without the need for additional review by the Commissioner unless:

(a) The PBM materially changes the structure of, or the steps contained in, its initial appeal process. Material changes include but are not limited to:

1. Changing deadlines that are not otherwise set out in law or rule;

2. Any change to the information required from pharmacies to participate in any part of an initial appeal process. Changing or editing the forms on which pharmacies submit information to a PBM, without changing the type or scope of information required on a form, is not a material change; or

3. Assessing any cost to a pharmacy for any services provided in connection with an initial appeal; or

(b) There is a change in the position(s) assigned to review an initial appeal. Staffing turnover for the position(s) that review initial appeals does not constitute a change under this subparagraph.

(6) No less than 60 days prior to the date on which a PBM plans to implement a change to its initial appeal process as described in paragraph (5) of this rule, a PBM shall notify the Commissioner and pay the fee required under Rule 0780-01-95-.07(2). The notice shall contain a detailed explanation of the change and include any supporting documentation necessary to fully explain the change. The Commissioner shall review the notice and any supporting documentation and may:

(a) Request additional information;

(b) Require the PBM submit an application under paragraph (2) of this rule, including the required application fee, that reflects the changed initial appeal process;

(c) Approve the changed initial appeal process contingent on the PBM meeting certain conditions outlined in writing and sent to the PBM;

(d) Approve the changed initial appeal process; or

(e) Deny the changed initial appeal process.

(7) Notwithstanding paragraph (5) of this rule, the Commissioner may, after notice and hearing, revoke approval of an initial appeal process that has been previously approved or deemed approved for any violation of this chapter.

(8) This rule shall not apply to a PBM that meets the requirements of T.C.A. § 56-7-3206(d) by utilizing a reimbursement methodology that is identical to the methodology provided for in the state plan for medical assistance approved by the federal Centers for Medicare and Medicaid Services.

(9) Beginning January 1, 2023, a PBM may utilize a temporary appeal process that is deemed temporarily approved as set out in this paragraph until the PBM's initial appeal process is approved by the Commissioner pursuant to paragraph (3) of this rule.

(a) In order to utilize a temporary appeal process to review initial appeals, a PBM must:

1. Prior to January 31, 2023, submit a certification, on a form provided by the Commissioner, that the PBM's temporary appeal process complies:

   (i) With T.C.A. § 56-7-3206(c)(2)(B)(ii) and (iii); and

   (ii) To the greatest extent possible, this chapter;

2. Submit a description of the steps involved in its temporary appeal process, and how that process differs, if at all, from the requirements of this chapter;

3. Pay the fee required under rule 0780-01-95-.07(3); and

4. Certify that all information submitted pursuant to this subparagraph is true and accurate to the best of the PBM's knowledge.

(b) A PBM's submission of all information required under subparagraph (a) of this paragraph shall constitute the Commissioner's approval for purposes of T.C.A. § 56-7-3206(c)(2)(B)(i) and paragraph (1) of this rule. The Commissioner's approval under this paragraph constitutes only temporary, terminable permission to utilize a temporary appeal process. The Commissioner's temporary approval of a PBM's initial temporary appeal process shall expire 60 days after the PBM's first submission of all information required under subparagraph (a) of this paragraph, except as provided in subparagraph (c) of this paragraph.

1. Notwithstanding a temporary appeal process being deemed temporarily approved pursuant to subparagraph (b) of this paragraph, the Commissioner may withdraw approval of a PBM's temporary appeal process for any reason in the sole discretion of the Commissioner by providing the PBM with written notice stating the temporary approval of the PBM's temporary appeal process is withdrawn and a statement of deficiencies in the temporary appeal process that must be addressed. Upon receiving this deficiency notice from the Commissioner, the PBM shall cease utilizing the temporary appeal process for which temporary approval was withdrawn within five business days after receipt of the deficiency notice. If the PBM does not submit a corrected approval process as set out in part 2. of this subparagraph within five business days of receipt of the Commissioner's notice, the PBM shall not process initial appeals until a corrected temporary appeal process is submitted pursuant to part 2. of this subparagraph or an approved appeal process is otherwise in place.

2. The PBM may resume using a temporary appeal process after receiving a deficiency notice pursuant to part 1. of this subparagraph, if the PBM's temporary approval process is not expired pursuant to subparagraph (c) of this paragraph, by submitting a corrected temporary appeal process to the Commissioner accompanied by a signed, written statement by the PBM certifying it has addressed all deficiencies identified by the Commissioner in the deficiency notice. Upon submission of the corrected temporary appeal process and signed statement, the corrected temporary appeals process shall be deemed temporarily approved and subject to part 1. of this subparagraph. The PBM may use its corrected temporary appeal process to review any initial appeals received between the time it received a denial notice from the Commissioner pursuant to part 1. of this subparagraph and its corrected temporary appeal process was deemed temporarily approved. The Commissioner's approval of a PBM's corrected temporary appeal process shall expire 60 days after the PBM's submission of the corrected information pursuant to this part, except as provided in subparagraph (c) of this paragraph.

(c) A PBM that utilizes a temporary appeal process must submit a complete application pursuant to paragraph (2) of this rule prior to the expiration of the Commissioner's approval of its temporary appeal process. Notwithstanding subparagraph (b) of this paragraph, if a PBM submits a complete application pursuant to paragraph (2) of this rule, the PBM may, upon notice from the Commissioner that a complete application has been received, continue to utilize a temporary appeal process that has been deemed temporarily approved until the Commissioner approves its application pursuant to paragraph (3) of this rule unless the Commissioner withdraws approval of the temporary appeal process pursuant to part (b)1. of this paragraph.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.04 Actions during and after an Initial Appeal is a new rule.

(1) Upon filing an initial appeal with a PBM, the pharmacy shall provide the PBM with a copy of the invoice(s) demonstrating the pharmacy's actual cost as of the date of the filing of the initial appeal by the pharmacy. If the pharmacy receives any additional discounts, price concessions, rebates, or other reductions, excluding cash discounts, during the pendency of an initial appeal, the pharmacy shall inform the PBM of the additional discount, price concession, rebate, or other reduction, excluding a cash discount. The PBM may consider the additional discount, price concession, rebate, or other reduction, excluding a cash discount, when calculating the pharmacy's actual cost. Additional discounts, price concessions, rebates, or other reductions received after the resolution of an initial appeal shall not be grounds for reconsideration of any initial appeal previously considered and resolved.

(2) A PBM shall request from each pharmacy filing an initial appeal the name and contact information of the wholesaler or manufacturer from which it purchased the prescription drug or device at issue. Failure of a pharmacy to provide this information shall not constitute grounds to deny an initial appeal; provided, however, if a PBM denies an initial appeal as otherwise allowed by law or this chapter and the pharmacy fails to provide this information or the PBM does not already have this information on file pursuant to Rule 0780-01-95-.03(2)(k), a PBM may presume the prescription drug or device at issue is available at a lower cost from the wholesaler or manufacturer from which the pharmacy purchased the prescription drug or device at issue.

(3) If a pharmacy's initial appeal is resolved in favor of the appealing pharmacy, the PBM shall comply with the provisions of T.C.A. § 56-7-3206(c)(3) and, further, provide the pharmacy the following in writing:

(a) A statement the initial appeal is granted, along with a summary outlining the basis for its decision;

(b) Notification the PBM has adjusted the challenged rate of reimbursement; and

(c) Detailed instructions for how to reverse and rebill the claim upon which the initial appeal is based.

(4)

(a) When applying the findings from an initial appeal that was resolved in favor of a pharmacy to other similarly situated pharmacies as to the rate of reimbursement and actual cost for the particular drug or medical product or device that was at issue in the initial appeal, a PBM shall, within seven business days of resolution of an initial appeal, apply the findings retroactively as set out in subparagraph (b) of this paragraph to all similarly situated pharmacies that received the challenged rate of reimbursement for the particular drug or medical product or device that was at issue in the initial appeal, including any appeals pending with a PBM where the challenged rate of reimbursement is the subject of the pending appeal, by:

1. Notifying all similarly situated pharmacies of the adjusted rate of reimbursement in writing. The notice shall contain the applicable national drug code number or the unique device identifier at issue, as appropriate, and the rate of reimbursement to which the similarly situated pharmacy is now entitled for the drug or medical product or device; and

2. Paying all similarly situated pharmacies the difference in the original rate of reimbursement the similarly situated pharmacy received and the adjusted rate of reimbursement that resulted from the initial appeal resolved in favor of a pharmacy. The PBM shall not charge any fees or require any additional documentation from similarly situated pharmacies to pay the difference required under this part.

(b) The findings from an initial appeal resolved in favor of a pharmacy shall be applied retroactively under subparagraph (a) of this paragraph by applying the adjusted rate to all similarly situated pharmacies beginning on the date of service of the claim that was the subject of the initial appeal and continuing to apply that rate going forward until the appealing pharmacy and the similarly situated pharmacy or pharmacies were no longer entitled to the same rate of reimbursement for the drug or medical product or device at issue.

(c) A PBM shall track initial appeals such that it can reasonably determine if an adjusted rate of reimbursement applies.

(5) If a pharmacy's initial appeal is resolved against the appealing pharmacy, the PBM shall comply with the provisions of T.C.A. § 56-7-3206(c)(4).

(a)

1. The PBM shall determine whether the product associated with the national drug code number or unique device identifier is available at a cost that is less than the challenged rate of reimbursement from a pharmaceutical wholesaler in this state as of the date the initial appeal was received from the appealing pharmacy. The PBM shall make a reasonable effort to identify such information and must provide to the pharmacy any information complying with, and as set out in, T.C.A. § 56-7-3206(c)(4)(A).

2. For purposes of this subparagraph (a), the product associated with the national drug code number or unique device identifier at issue shall be deemed available if, at the time the initial appeal was received by the PBM, the product was in stock with a wholesaler operating in this state.

3. If, after a reasonable effort to identify the information needed to make the determination required under part 1. of this subparagraph, the PBM is unable to make the determination solely because the wholesalers contacted by the PBM failed to provide the information needed by the PBM within the timeframe within which the PBM must resolve initial appeals, the PBM shall presume that the product associated with the national drug code number or unique device identifier at issue was not available at a cost that is less than the challenged rate of reimbursement from a pharmaceutical wholesaler in this state as of the date the initial appeal was received from the appealing pharmacy.

4. If a PBM fails to provide the information required under T.C.A. § 56-7-3206(c)(4)(A) within the required timeframe, it shall be deemed to have determined there is no pharmaceutical wholesaler operating in this state that offered the product associated with the national drug code number or unique device identifier at issue at a cost that is less than the challenged rate of reimbursement as of the date the initial appeal was received from the appealing pharmacy.

(b)

1. The pharmacy shall provide the PBM with the name of its majority wholesaler for the purpose of allowing the PBM to accurately fulfill its obligations under T.C.A. § 56-7-3206(c)(4)(B). The PBM shall then determine whether the prescription drug or device at issue is available from the pharmaceutical wholesaler at a cost that is less than the challenged rate of reimbursement as of the date the initial appeal was received from the appealing pharmacy. If the pharmacy fails to provide the name of its majority wholesaler within two business days of a request by the PBM to provide that name, the PBM may presume the prescription drug or device at issue is available at a cost that is less than the challenged rate of reimbursement from the pharmacy's majority wholesaler and take no further action pursuant to T.C.A. § 56-7-3206(c)(4) or this subparagraph (b).

2. For purposes of this subparagraph (b), the product associated with the national drug code number or unique device identifier at issue shall be deemed available if, at the time the initial appeal was received by the PBM, the product was in stock from the pharmacy's majority wholesaler.

3. If, after contacting the pharmacy's majority wholesaler to identify the information needed to make the determination required under part 1. of this subparagraph, the PBM is unable to make the determination solely because the wholesaler failed to provide the information needed by the PBM within the timeframe within which the PBM must resolve initial appeals, the PBM shall presume that the product associated with the national drug code number or unique device identifier at issue was not available at a cost that is less than the challenged rate of reimbursement from the wholesaler as of the date the initial appeal was received from the appealing pharmacy.

(c) The pharmacy shall cooperate with the PBM to assist in its search under subparagraphs (a) and (b) of this paragraph; provided, however, that, except as provided in part (b)1. of this paragraph, neither the pharmacy's nor a wholesaler's failure to cooperate or provide the PBM information shall be grounds for the PBM to fail to meet its obligations under T.C.A. § 56-7-3206(c)(4) or this paragraph.

(d) Even if the PBM determines it has a basis to deny an initial appeal for a reason other than that the pharmacy was reimbursed actual cost, the PBM shall follow the requirements set out in T.C.A. § 56-7-3206(c)(4).

(e) If a pharmacy's initial appeal is resolved against the appealing pharmacy and the PBM is required to adjust the challenged rate of reimbursement pursuant to T.C.A. § 56-7-3206(c)(4)(B), the PBM shall, to effectuate adjustment of the challenged rate, apply the findings from the appeal as to the rate of reimbursement for the drug or medical product or device at issue to other similarly situated pharmacies in the same manner as set forth in paragraph (4) of this rule.

(6) If a pharmacy's initial appeal is resolved against the appealing pharmacy, the PBM shall provide the pharmacy the following in writing:

(a) A statement the initial appeal is denied, along with a summary outlining the basis for its decision;

(b) If applicable, evidence the PBM has adjusted the challenged rate of reimbursement;

(c) If applicable, detailed instructions for how to reverse and rebill the claim upon which the initial appeal is based; and

(d) Instructions on how to make an external appeal of the PBM's decision to the Commissioner by:

1. Explaining how to submit an appeal, including the appropriate phone number or website address for the Department where appeals are accepted. Each PBM shall be responsible for ensuring the information provided to pharmacies pursuant to this part 1. is accurate; and

2. Including the following statement:

Pursuant to T.C.A. § 56-7-3206(g)(2), you have the right to appeal this decision to the Commissioner of the Tennessee Department of Commerce and Insurance.

(7) If a PBM is required to pay a pharmacy any additional money upon resolution of an initial appeal, including a payment to a similarly situated pharmacy under part (4)(a)2. of this rule, the PBM shall make such payment within seven business days after notice of the initial appeal is received by the PBM.

(8) A PBM shall retain all records related to an initial appeal for the greater of five years or until the PBM is audited by the Department. A PBM shall provide the Department access to all records upon request and comply with requests for information regardless of whether the request is part of a departmental audit.

(9) A PBM shall not assess any costs to a pharmacy for any services provided by the PBM in connection with an initial appeal.

(10) An initial appeal shall not result in a pharmacy, whether the appealing pharmacy or a similarly situated pharmacy, being required to reimburse or refund a PBM any portion of a payment previously received by the pharmacy.

(11) On or before July 1 of each year, each PBM shall provide the Commissioner with a written report that contains the following aggregated information for the preceding calendar year:

(a) The number of initial appeals filed with the PBM;

(b) The number of initial appeals resolved in favor of pharmacies;

(c) The number of initial appeals resolved against pharmacies;

(d) The total amount of money paid to appealing pharmacies as a result of initial appeals resolved in favor of pharmacies;

(e) The total amount of money paid to similarly situated pharmacies as a result of initial appeals resolved in favor of pharmacies;

(f) The number of initial appeals that were appealed to the Commissioner of which the PBM received notice; and

(g) Any other information requested by the Commissioner.

(12) This rule applies only to initial appeals submitted to a PBM under the PBM's initial appeal process established in accordance with T.C.A. § 56-7-3206(c)(2)(A) and approved pursuant to Rule 0780-01-95-.03.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.05 Timing and Notice Requirements for Initial Appeal Process is a new rule.

(1) A PBM's initial appeal process, or a pharmacy's participation in an initial appeal, must meet the following requirements:

(a) The pharmacy must file its initial appeal within seven business days of its submission of the initial claim for reimbursement for the drug or medical product or device;

(b) The PBM or covered entity must make a final determination resolving the pharmacy's initial appeal within seven business days of the PBM's or covered entity's receipt of an initial appeal that includes all information required by paragraph (2) of this rule; and

(c) A PBM or covered entity shall make available on its secure website information about the initial appeal process, including, but not limited to, a telephone number, email address, web portal, or any other process that a pharmacy may use to submit initial appeals. The website shall clearly state that the PBM's initial appeal process is available for all prescription drugs or devices in Tennessee for which a pharmacy alleges it did not receive its actual cost.

(2) The timeline for making a final determination resolving an initial appeal under T.C.A. § 56-7-3206(c)(2)(B)(ii) shall not begin until the PBM has received all required information sufficient to allow the PBM to conduct a complete analysis of the initial appeal. A PBM shall be deemed to have received all required information sufficient to allow the PBM to conduct a complete analysis of the initial appeal upon receipt of:

(a) A complete version of either an initial appeal form provided by the Commissioner to be used by a pharmacy to file an initial appeal or the PBM's appeal form submitted and approved pursuant to Rule 0780-01-95-.03(2)(e); and

(b) Certification from the pharmacy it has provided the PBM with all invoices or other records demonstrating the pharmacy's actual cost for the drug or medical product or device at issue, which shall take into account all discounts, price concessions, rebates, or other reductions received as of the date the pharmacy filed its initial appeal.

(3) If a PBM receives an initial appeal from a pharmacy that does not contain all information required under paragraph (2) of this rule, the PBM shall accept the incomplete initial appeal and hold it open pending receipt of additional information from the pharmacy. Within five business days of receipt of an incomplete initial appeal, the PBM shall notify the pharmacy of the information needed to complete the initial appeal and initiate the PBM's review. The pharmacy may respond within five business days of receipt of the PBM's notice outlining the requested information. If the pharmacy provides the requested information, the timeline for making a final determination outlined in subparagraph (1)(b) of this rule shall start. If the pharmacy fails to provide the requested information within five business days of receipt of the PBM's notice, the PBM may deny the initial appeal pursuant to T.C.A. § 56-7-3206(c)(4).

(4) A PBM may not delay the start of its review of an initial appeal by:

(a) Requiring additional or different information from a pharmacy beyond what is required to be submitted to the PBM under its initial appeal process approved by the Commissioner pursuant to Rule 0780-01-95-.03(3)(a)1.; or

(b) Basing the delay on administrative or non-substantive errors or omissions in any of the filings that do not affect the overall validity of the initial appeal.

(5) If a PBM fails to comply with the timing and notice requirements under T.C.A. § 56-7-3206(c)(2)(B)(ii) and this rule, the pharmacy's initial appeal shall be resolved by the PBM in favor of the pharmacy. If a pharmacy fails to comply with the timing requirements under T.C.A. § 56-7-3206(c)(2)(B)(ii) and this rule, the PBM may deny the initial appeal pursuant to T.C.A. § 56-7-3206(c)(4).

(6) Each PBM must make its initial appeal process available on its secure website. The PBM's secure website must include all deadlines applicable to its initial appeal process, a description of the steps contained within its initial appeal process, and clearly state that its initial appeal process is available for all prescription drugs or devices in Tennessee for which a pharmacy alleges it did not receive its actual cost.

(7) Each PBM must submit the initial appeal process it will use for approval by the Commissioner regardless of whether it outsources the administration of its initial appeal process to a third-party administrator or a different PBM. Each PBM will retain ultimate responsibility for ensuring it complies with this paragraph regardless of whether the PBM conducts its own initial appeal process or utilizes another PBM or a third-party administrator.

(8) On or before July 1 of each calendar year, each PBM shall provide the Commissioner with a written statement certifying it meets the requirements of paragraph (6) of this rule along with timestamped screenshots of the PBM's website showing the required information is on the PBM's website and is readily accessible by pharmacies.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.06 External Appeal Process is a new rule.

(1) A pharmacy that alleges it did not receive at least its actual cost for a prescription drug or device after resolution of an initial appeal filed with a PBM shall have the right to appeal the decision of the PBM to the Commissioner. The Commissioner may delegate the review and resolution of a pharmacy's appeal under this paragraph, and any decision by the third-party reviewer shall have the same force and effect as a decision by the Commissioner. Any reference to the Commissioner in this rule shall also include a third-party reviewer properly designated by the Commissioner to review and resolve appeals.

(2) An appeal filed pursuant to paragraph (1) of this rule must:

(a) Be filed with the Commissioner, in such manner as the Commissioner may require, within 30 days of the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal, unless a different timeframe is approved in writing pursuant to paragraph (3) of this rule;

(b) Contain a summary of:

1. The grounds of the appeal to the Commissioner;

2. The relief requested by the pharmacy; and

3. The basis on which the pharmacy believes it is due the relief;

(c) Include a copy of the written decision rendered by the PBM;

(d) Contain a copy of the invoice(s) showing the pharmacy's purchase price for the drug or medical product or device at issue;

(e) Contain a list of all discounts, price concessions, rebates, or other reductions, excluding cash discounts, that were, or should have been, reported to the PBM pursuant to Rule 0780-01-95-.04(1), including supporting documentation for each discount, price concession, rebate, or other reduction;

(f) Be submitted on a form or through an electronic process made available by the Department;

(g) Contain a certification that all information submitted pursuant to paragraph (1) of this rule is true and accurate to the best of the pharmacy's knowledge; and

(h) Provide any other documentation or information requested by the Commissioner regarding the pharmacy's appeal.

(3) The Commissioner will not consider any information or documentation received from the pharmacy more than 30 days after the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal filed with the PBM unless the information reasonably should have been submitted and the withholding of information prevented the Commissioner from reviewing relevant or necessary information as part of the appeal. Prior to the expiration of the 30-day timeframe, the pharmacy may request in writing additional time to investigate and compile the information needed to submit an appeal pursuant to paragraph (1) of this rule. Upon receipt of the pharmacy's written request, or upon the Commissioner's own determination, the Commissioner may, in the Commissioner's discretion, grant the pharmacy an additional period of time determined to be necessary by the Commissioner for good cause shown.

(4) Appeals that do not contain all information required under paragraph (2) of this rule shall be considered incomplete and will not qualify for review by the Commissioner under paragraph (7) of this rule until all information has been received. If an appeal is still incomplete more than 30 days after the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal, or such other timeframe approved in writing pursuant to paragraph (3) of this rule, the pharmacy's appeal shall be automatically denied.

(5) The pharmacy whose appeal was denied pursuant to paragraph (4) of this rule may petition the Commissioner in writing for reconsideration and the Commissioner may, in the Commissioner's discretion, grant the petition for reconsideration upon showing good cause for failing to meet the required deadline.

(a) When granting a petition for reconsideration, the Commissioner shall establish a new deadline by which all information must be received, and the pharmacy's failure to meet that deadline for any reason will result in an automatic denial of the appeal, which shall be final.

(b) For purposes of this paragraph (5), good cause shall not include reasons or processes that were totally or mostly within the control of the appealing pharmacy, including but not limited to administrative oversight, clerical errors, or lack of sufficient personnel.

(6) Within ten business days of receipt of notice from the Commissioner the PBM's decision has been appealed, the PBM may file a response to the pharmacy's appeal by providing information supporting its decision made during its internal appeal process.

(7) No more than 90 days after the later of the receipt of a complete appeal containing all information required and requested under paragraph (2) of this rule or the receipt of the PBM's response allowed under paragraph (6) of this rule, the Commissioner may:

(a) Grant the appeal, in whole or in part, and order the PBM to make such portion of the requested payment to the pharmacy as the Commissioner determines is appropriate to result in the pharmacy receiving at least its actual cost for the prescription drug or medical product or device at issue;

(b) Deny the appeal, in whole or in part; or

(c) Extend the timeline for rendering a decision by providing the parties with written notice that includes a good-faith estimate of the additional time needed to make a decision.

(8) Upon granting or denying an appeal pursuant to paragraph (7) of this rule, the Commissioner shall send the parties a copy of the decision that contains a written justification. The decision of the Commissioner rendered pursuant to paragraph (7) of this rule is final and is not eligible for additional administrative review.

(9) If a PBM is required to pay a pharmacy any additional money upon resolution of an appeal pursuant to this rule, the PBM shall make such payment within seven business days of receipt of the Commissioner's written notice issued pursuant to paragraph (8) of this rule. The PBM shall also provide the Department with proof the PBM has reimbursed the pharmacy at least its actual cost for the prescription drug or medical product or device at issue,

including a statement of the additional amount paid to the pharmacy, within seven business days of issuing the payment to the pharmacy.

(10) If a PBM is required to adjust a challenged rate of reimbursement after an appeal pursuant to this rule is resolved against the PBM, the PBM shall apply the findings from the appeal as to the rate of reimbursement for the drug or medical product or device at issue to other similarly situated pharmacies in the same manner as set forth in Rule 0780-01-95-.04(4).

(11) All costs associated with conducting an appeal under this rule, including the expenses of the Department, shall be paid by the applicable PBM. The Commissioner shall bill the PBM upon the conclusion of the appeal. The PBM shall pay the bill in full within 30 days of receipt. Failure to pay a bill in full within 30 days of receipt shall, pursuant to T.C.A. § 56-7-3110, be grounds for the Commissioner to:

(a) Suspend, revoke, or refuse to renew a PBM's license issued by the Department; and

(b) Order the PBM to pay additional monetary penalties.

(12) If a PBM fails to timely pay a bill due pursuant to paragraph (11) of this rule and the Department incurs any costs associated with conducting an appeal under this rule, including but not limited to reimbursement to a third-party contractor, the PBM shall reimburse the Department for those costs, which shall include any fees or interest paid by the Department due to the PBM's failure to pay. The Commissioner shall bill the PBM upon incurring those costs and the PBM shall pay the bill in full within 30 days of receipt. Failure to pay a bill in full within 30 days of receipt shall be grounds for the Commissioner to take any action outlined in paragraph (11) of this rule.

(13) When possible, a pharmacy may aggregate and submit appeals for simultaneous review by the Commissioner, or the Commissioner may, in the Commissioner's discretion, aggregate appeals, when the specific reason for denial of the appeals aggregated involves a dispute regarding a common substantive question of fact or law. The mere fact that a claim is not paid, or that appeals relate to the same PBM, does not create a common substantive question of fact or law.

(14) This rule applies only to appeals of a PBM's decision rendered pursuant to its initial appeal process established in accordance with T.C.A. § 56-7-3206(c)(2)(A) and approved pursuant to Rule 0780-01-95-.03.

Authority: T.C.A. §§ 56-2-305, 56-7-3101, 56-7-3110, and 56-7-3206.

Rule 0780-01-95-.07 Fees is a new rule.

Fees for services provided by the Department pursuant to this chapter shall be as follows:

(1) Review of an application for approval of an initial appeal process under Rule 0780-01-95-.03(2), including but not limited to a request for review and approval of an initial appeal process outsourced pursuant to Rule 0780-01-95-.05(7): $1,000.00

(2) Review of a request to change an initial appeal process under Rule 0780-01-95-.03(6): $1,000.00

(3) Review of an application for a temporary appeal process under Rule 0780-01-95-.03(9): $1,000.00

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.08 Plans Utilizing a Reimbursement Methodology Identical to the Methodology Used by the State Plan for Medical Assistance Approved by the Federal Centers for Medicare and Medicaid Services is a new rule.

(1) As used in T.C.A. § 56-7-3206(d)(2), a reimbursement methodology is identical to the methodology provided for in the state plan for medical assistance approved by the federal Centers for Medicare and Medicaid Services if the reimbursement methodology is identical in all respects, including, but not limited to, that requests for reimbursement are submitted to the Division of TennCare as set out in that methodology and the methodology complies with the

Division of TennCare Pharmacy Provider Manual, or a successor manual, as amended or updated, and all laws and rules of the Division of TennCare related to reimbursement.

(2) A pharmacy that alleges it did not receive at least its actual cost for a prescription drug or device after resolution of an appeal filed with a PBM pursuant to T.C.A. § 56-7-3206(d)(2) shall appeal the decision to the Division of TennCare as set out in the applicable laws and rules. Such appeals are not subject to review or appeal under this chapter.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.09 Audits by Pharmacy Benefits Managers is a new rule.

(1) A PBM's recoupment of funds from a pharmacy after an audit pursuant to T.C.A. § 56-7-3103 may not reduce the pharmacy's compensation for the prescription drug or device at issue to an amount that is less than the pharmacy's actual cost for the prescription drug or device as of the date the audit is commenced unless specifically allowed in law.

(2) When a PBM's audit of a pharmacy pursuant to T.C.A. § 56-7-3103 results in a recoupment, in addition to any other requirement imposed in law or rule, a PBM shall include in the documentation of the audit information that demonstrates how the recoupment did not result in the pharmacy receiving less than its actual cost for each affected prescription drug or device at issue, including but not limited to:

(a) The rationale that led the PBM to decide the pharmacy was overpaid for each claim that is subject to recoupment, along with supporting documentation; and

(b) An itemized breakdown for each claim that is subject to recoupment showing, at least, a comparison of what the pharmacy actually received and what the pharmacy should have received.

(3) A PBM shall retain all records related to an audit of a pharmacy pursuant to T.C.A. § 56-7-3103 for the greater of five years or until the PBM is audited by the Department. A PBM shall provide the Department access to all records upon request and comply with requests for information regardless of whether the request is part of a departmental audit.

(4) This rule does not limit or prohibit a PBM's ability to audit a pharmacy or recoup funds as allowed by T.C.A. § 56-7-3103.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.10 Determination of Pharmacy's Professional Dispensing Fee is a new rule.

(1)

(a) To determine whether a pharmacy's annual prescription volume for calendar year 2023 is at a level that, if the pharmacy were a TennCare-participating ambulatory pharmacy, would qualify the pharmacy for the enhanced professional dispensing fee for a low-volume pharmacy, each pharmacy that expects to qualify as a low-volume pharmacy for calendar year 2023 shall file with a PBM from whom the pharmacy expects to receive a dispensing fee during 2023 a certification stating the pharmacy expects to qualify as a low-volume pharmacy for calendar year 2023. Each certification shall contain a statement that the certification is true and accurate to the best of the knowledge of the individual filing the certification on behalf of the pharmacy.

(b) Beginning with certifications made for dispensing fees to be paid during calendar year 2024, to determine whether a pharmacy's annual prescription volume is at a level that, if the pharmacy were a TennCare-participating ambulatory pharmacy, would qualify the pharmacy for the enhanced professional dispensing fee for a low-volume pharmacy, each pharmacy that will qualify as a low-volume pharmacy, as determined pursuant to subparagraph (2)(b) of this rule, shall, on or before December 1 of each year, file with a PBM from whom the pharmacy expects to receive a dispensing fee a certification stating the pharmacy will qualify

as a low-volume pharmacy for the coming calendar year. Each certification shall contain a statement that the certification is true and accurate to the best of the knowledge of the individual filing the certification on behalf of the pharmacy. The pharmacy's certification submitted, or failure to submit a certification, pursuant to this paragraph shall determine the pharmacy's dispensing fee for the respective calendar year, unless a pharmacy submits a certification pursuant to paragraphs (3) or (4) of this rule.

(c) Upon receipt of a pharmacy's certification pursuant to subparagraph (1)(b) of this rule, the PBM shall pay the pharmacy the appropriate dispensing fee for prescriptions filled on or after January 1 of the calendar year for which the certification was submitted. Except as provided in Tenn. Code Ann. § 56-7-3103, a PBM may not recoup any portion of a dispensing fee from a pharmacy that accurately certifies its annual prescription volume.

(2)

(a) When submitting a certification pursuant to subparagraph (1)(a) of this rule, a pharmacy shall base the determination of whether its prescription volume for the coming calendar year will qualify the pharmacy for the enhanced professional dispensing fee on the pharmacy's actual prescription volume from July 1, 2021, to June 30, 2022.

(b) When submitting a certification pursuant to subparagraph (1)(b) of this rule, a pharmacy shall:

1. Base the determination of whether it will qualify for the enhanced professional dispensing fee on the pharmacy's actual prescription volume from July 1 of the year prior to the year during which the certification is due to June 30 of the year during which the certification is due. For example, certifications submitted on or before December 1, 2024, for calendar year 2025 shall be based on a pharmacy's actual prescription volume from July 1, 2023, to June 30, 2024; and

2. Along with the certification, submit proof of the pharmacy's actual prescription volume, which may be in the form of aggregate claims data or similar information. A pharmacy's certification shall not be considered complete until the pharmacy has also submitted proof pursuant to this part.

(3) If a pharmacy fails to timely submit a certification pursuant to paragraph (1) of this rule with a PBM with whom the pharmacy has an ongoing business relationship, the pharmacy shall be presumed to be a high-volume pharmacy. However, if a pharmacy later certifies it qualifies for the enhanced professional dispensing fee for a low-volume pharmacy by meeting the requirements of parts 1. and 2. of subparagraph (2)(b) of this rule, the PBM shall pay the certifying pharmacy the enhanced professional dispensing fee for prescriptions dispensed beginning on the seventh business day after the PBM receives the complete certification.

(4) If a pharmacy receives, or expects to receive, a dispensing fee from a PBM with whom the pharmacy did not anticipate doing business at the time the pharmacy was required to file the certification under paragraph (1) of this rule, the pharmacy shall file the certification with the PBM simultaneously with the claim for reimbursement or within one business day of discovering the need to file the certification, whichever is later. The certification submitted pursuant to this paragraph must meet the requirements of parts 1. and 2. of subparagraph (2)(b) of this rule. The PBM shall pay the certifying pharmacy the enhanced professional dispensing fee for prescriptions dispensed on or after the day the PBM receives the complete certification.

(5) For calendar year 2023, a pharmacy shall file the certification required under paragraph (1)(a) of this rule on or before January 31, 2023. Until a pharmacy files the certification required under paragraph (1)(a) of this rule, the pharmacy shall be presumed to be a high-volume pharmacy and shall not qualify for the enhanced professional dispensing fee for a low-volume pharmacy. If a pharmacy certifies it qualifies for the enhanced professional dispensing fee for a low-volume pharmacy, the PBM shall pay the certifying pharmacy the enhanced professional dispensing fee for prescriptions dispensed on or after the seventh business day after the PBM receives the certification.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Rule 0780-01-95-.11 Violations is a new rule.

A violation of this chapter may subject a PBM to the sanctions described in T.C.A. § 56-2-305.

Authority: T.C.A. §§ 56-7-3101, 56-7-3206, and 56-7-3210.

Rule 0780-01-95-.12 Exclusions is a new rule.

This chapter shall not apply to a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, other long-term care, or plans subject to regulation under Medicare Part D.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Commissioner of Commerce and Insurance on February 3, 2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: December 13, 2022

Rulemaking Hearing(s) Conducted on: (add more dates). February 3, 2023

Date: March 28, 2023

Signature: Carter Lawrence (Mar 28, 2023 14:48 CDT)

Name of Officer: Carter Lawrence

Title of Officer: Commissioner

Agency/Board/Commission: Department of Commerce and Insurance

Rule Chapter Number(s): 0780-01-95

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

by delegation
Jonathan Skrmetti
Attorney General and Reporter

3-29-23
Date

Department of State Use Only

Filed with the Department of State on: 3/29/2023

Effective on: 6/27/2023

Tre Hargett
Secretary of State

RECEIVED
Mar 29 2023, 3:25 pm
Secretary of State
Division of Publications

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

1. The Department received multiple comments encouraging the Department to promulgate rules on sections 5 and 6 of Public Chapter 1070.

Department Response: The Department is currently receiving and processing complaints for potential violations of sections 5 and 6 of Public Chapter 1070. If the Department determines it is necessary to further clarify these statutes, the Department may do so in a future rulemaking under the authority granted in T.C.A. § 56-7-3101.

2. The Department received multiple comments suggesting further definition of the term steerage.

Department Response: The definition of steerage is not within the scope of these rules. If the Department determines it is necessary, the Department may do so in a future rulemaking under the authority granted in T.C.A. § 56-7-3101.

3. The Department received a comment encouraging the Department to focus on the PBM examination process in order to properly access information from the PBM.

Department Response: The Department is required to promulgate rules regarding audits of PBMs in T.C.A. § 56-7-3101 and plans do so in the near future.

4. The Department received a comment suggesting the Department thoroughly define its process for a complaint against Sections 5 and 6 of Public Chapter 1070.

Department Response: The Department disagrees the complaint process needs further clarification via rule.

5. The Department received a comment suggesting the Department create an internal process for pharmacies to submit an attestation directly to the Department.

Department Response: The Department does not plan to perform this function at this time.

6. The Department received a comment suggesting that the Department remove paragraph (5) from Rule 0780-01-95-.10.

Department Response: The Department disagrees since pharmacies may continue to submit certifications for the remainder of 2023.

7. The Department received a comment informing the Department of a PBM increasing patient co-payments to reflect enhanced dispensing fees and suggested this would lead to steering of patients.

Department Response: Complaints regarding potential violations of law should be submitted to the Department at pbm.compliance@tn.gov.

8. The Department received a comment suggesting the Department issue a bulletin to further detail the processes that PBMs need to follow in order to comply with the rules of the Department.

Department Response: The Department issues bulletins as it determines bulletins are needed and will continue to do so in the future. However, the issuance of a bulletin is outside the scope of this rulemaking.

9. The Department received a comment suggesting the Department strike the language in Rule 0780-01-95-.04(2) that a pharmacy's failure to provide its wholesaler information is not grounds to deny an initial appeal and, further, require pharmacies to provide wholesaler information in order for an appeal to be considered complete and proceed to review under Rule 0780-01-95-.05(2).

Department response: The Department does not agree Rule 0780-01-95-.04(2) should be amended to remove the prohibition on PBMs denying an appeal if a pharmacy fails to provide its wholesaler information. Denying an appeal solely for this reason would, in the Department's opinion, be a violation of Tennessee law. However, the Department recognizes that PBMs need this piece of information in order to meet their statutory obligation to apply the findings of an appeal to other similarly situated pharmacies. Therefore, PBMs who wish to ensure they have a pharmacy's wholesaler information on file may include that as a field on its appeal form submitted and approved pursuant to Rule 0780-01-95-.03(2)(e). By

including this as a field on its form, the timeline within which a PBM must make a final determination resolving an initial appeal would not begin until the pharmacy provides the information since the timeline does not begin until the PBM receives a "complete version of either an initial appeal form provided by the Commissioner to be used by a pharmacy to file an initial appeal or the PBM's appeal form submitted and approved pursuant to Rule 0780-01-95-.03(2)(e)." *See* Rule 0780-01-95-.05(2)(a). The Department intends to include wholesaler information as a line item on its standard appeal form as well.

10. The Department received a comment stating that PBMs do not have visibility to a pharmacy's wholesaler unless and until the pharmacy has provided a PBM with that information. The commenter further observed that two pharmacies that have the same wholesaler may not have the same pricing from that wholesaler, relating to factors of their business such as size and buying power. Thus, the commenter asserted PBMs are not able to accurately assess pharmacies that are similarly situated for purposes of proactive notification. Additionally, the commenter noted that while the statute requires notification of similarly situated pharmacies by PBMs when an appeal is approved, it does not require identification of those pharmacies to be performed by PBMs.

Department Response: PBMs should have a pharmacy's wholesaler information pursuant to Rule 0780-01-95-.04(2) and 0780-01-95-.03(2)(k), and as further outlined in the answer to comment #9 above. And since price is not a factor in the determination of whether a pharmacy is similarly situated pursuant to T.C.A. § 56-7-3206(c)(3)(C), PBMs should have all three pieces of information needed to make that determination and then identify and notify the affected pharmacies.

11. The Department received a comment suggesting that, if an appeal is filed by a PSAO, notification of the outcome of that appeal to the PSAO should satisfy the requirement to notify similarly situated pharmacies. Further, the commenter stated that PSAOs should provide information to PBMs on which pharmacies are similarly situated so that the adjusted rate of reimbursement related to the appeal can be accurately implemented.

Department Response: The Department disagrees with this comment since a notification to a PSAO would not satisfy the statutory requirement to notify all similarly situated pharmacies in light of the fact that a pharmacy that meets the statutory definition of similarly situated may not be contracted with the PSAO that filed the appeal.

12. The Department received a comment suggesting that pharmacies or PSAOs pay for external appeals that are not found in favor of the appealing pharmacy.

Department Response: The Department disagrees with this comment.

13. The Department received a comment suggesting that, for PBMs that intend to utilize a reimbursement methodology that is identical to the methodology utilized by the TennCare program pursuant to T.C.A. § 56-7-3206(d), the Department should strike the language requiring claims for reimbursement to be submitted to the Division of TennCare and for those transactions to be subject to TennCare's provider manual.

Department Response: The Department disagrees with this comment.

14. The Department received multiple comments suggesting pharmacies must provide information regarding discounts from wholesalers with whom they have direct contracts.

Department Response: Rule 0780-01-95-.04(1) specifically requires pharmacies provide invoices demonstrating the pharmacy's actual cost as of the date of the filing of the initial appeal. Actual cost is defined in T.C.A. § 56-7-3206(h)(1) and includes any "discounts, price concessions, rebates, or other reductions" received by the pharmacy, which includes discounts received wholesalers.

15. The Department received a comment suggesting wholesaler distributers should be responsible for providing the information necessary to determine a pharmacy's actual cost.

Department Response: The Department believes requiring a pharmacy to provide the required information is sufficient.

16. The Department received a comment indicating the commenter believes a retroactive reimbursement to similarly situated pharmacies is outside the statutory authority granted in Public Chapter 1070.

Department Response: The statutory definition of similarly situated does not contain a temporal criterion and therefore is not limited to a given time period (i.e., after a pharmacy submits an initial appeal). Therefore, any pharmacy that meets the definition of similarly situated, regardless of whether the similarly situated pharmacy's initial claim was filed before or after the appealing pharmacy's, must be reimbursed as required in T.C.A. § 56-7-3206(c).

17. The Department received a comment suggesting the language of Rule 0780-01-95-.09(2) should be amended to reference existing law to clarify the rule does not apply to recoupments made pursuant to T.C.A. § 56-7-3103.

Department Response: The Department agrees with this comment and will add language clarifying that the rule does not limit or prohibit a PBM's ability to audit a pharmacy or recoup funds as allowed by T.C.A. § 56-7-3103.

18. The Department received a comment that included several questions asking what would happen in various scenarios the commenter believes are unanswered in the current rules regarding dispensing fees.

Department Response: The Department has clarified Rule 0780-01-95-.10 so that, beginning with calendar year 2024, a pharmacy's certification must be based on its actual prescription volume for the period from July 1 to June 30 immediately preceding the calendar year for which the certification is submitted. This certification will determine whether a pharmacy is entitled to the enhanced dispensing fee for that calendar year, which means the commenter's questions are no longer applicable in the new process.

19. The Department received multiple comments indicating the commenters believe laws directed at PBMs are preempted by ERISA.

Department Response: Pursuant to T.C.A. § 56-7-3102(1), the definition of "covered entity" includes plans governed by the Employee Retirement Income Security Act of 1974.

20. The Department received a comment requesting clarification that, when PBMs certify they will require pharmacies provide the name of wholesalers or manufactures from which they purchase drugs or medical products under Rule 0780-01-95-.03(2)(k), the requirement refers to the initiation of an appeal, rather than when claims are submitted for processing.

Department Response: This is incorrect. Rule 0780-01-95-.03(2)(k) requires PBMs to request the name of a pharmacy's wholesaler or manufacturer, as applicable, as part of the PBM's processing of claims.

21. The Department received a comment suggesting TennCare's published report on drug cost based on information obtained from manufacturers and wholesalers be the appeal determinant rather than a specific response to a PBM.

Department Response: The Department disagrees with this comment. The Department believes TennCare's report on drug cost is an improper basis for determining whether a pharmacy was properly reimbursed under T.C.A. §§ 56-7-3206.

22. The Department received a comment suggesting the lack of oversight of pharmacies by the Department on unsupported appeals by pharmacies will result in increased workloads and costs to PBMs and the Department.

Department Response: The Department cannot state with certainty whether these rules will result in increased workloads and costs to PBMs and the Department.

23. The Department received a comment observing that there is no standard attestation form for pharmacies to submit a certification/attestation to PBMs. The comment asks whether the Department envisions using the standard complaint form for this purpose. The commenter also asks whether PBMs or the Department wants to use a complaint process rather than the informative attestation.

Department Response: Assuming the commenter is referring to the certification pharmacies must submit under Rule 0780-01-95-.10 regarding dispensing fees, the rules do not require pharmacies to use a specific form when making this certification. This is the process intended by the Department.

24. The Department received a comment suggesting the Department hold pharmacies to the same standard and timeframes as attestations received from low-volume pharmacies.

Department Response: The Department is unsure of the specific question or request this comment is intending to communicate. However, the Department intends to hold all pharmacies to the standards and timeframes outlined in the rules.

25. The Department received a comment seeking clarification on whether the intent of Rule 0780-01-95-.10 is to expand to the types of pharmacies that qualify for the enhanced dispensing fee to include the types of pharmacies listed in the TennCare provider manual, and if so, who defines these pharmacies and drugs?

Department Response: All pharmacies doing business in the state of Tennessee are eligible to receive the enhanced dispensing fee if they qualify as outlined in Rule 0780-01-95-.10 regardless of whether the pharmacy is a specialty pharmacy or not.

26. The Department received a comment requesting clarification on whether the regulation applies to non-ERISA state public employee self-funded plans, fully insured policies, and Tennessee self-funded employers (ERISA plans).

Department Response: The rules apply to all PBMs as defined in T.C.A. §§ 56-7-3102(5).

27. The Department received a comment suggesting pharmacies should be required to provide proof of their low-volume status with their certification.

Department Response: The Department agrees with this comment and has edited Rule 0780-01-95-.10 to require proof of the pharmacy's actual prescription volume to be submitted along with the certification.

28. The Department received a comment suggesting a volume threshold for each pharmacy since PBMs processing low volumes of claims will have little incentive to continue working with low volume pharmacies.

Department Response: The Department does not believe a volume threshold is appropriate.

29. The Department received a comment suggesting an exemption should be available to PBMs that have fewer than 100 claims with a pharmacy.

Department Response: The Department disagrees with this comment since this exemption is not allowed in statute.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

The Department has determined that the rules will have the least impact on small businesses possible while still effectuating the intent of the authorizing statutes.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

These rules are not expected to have any financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

These rules implement 2022 Pub. Ch. 1070 and set out various processes and requirements intended to ensure pharmacies are reimbursed at least their actual cost for all prescription drugs or devices dispensed. They also create a procedure for approval by the Department of initial appeals processes used by pharmacy benefits managers (PBMs) to review pharmacy claims and create an external appeal process to review those PBM decisions to ensure pharmacies are reimbursed at least their actual cost for all prescription drugs or devices dispensed.

A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

2022 Pub. Ch. 1070 requires the Department promulgate rules to effectuate the requirements in the public chapter. Further, Tenn. Code Ann.§§ 56-7-3101 and 56-7-3206 give the Department rulemaking authority to further implement the general requirements contained in Tenn. Code Ann. title 56, chapter 7, parts 31 and 32.

Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Pharmacies and pharmacy benefit managers (PBMs) doing business in Tennessee will be most directly affected by these rules. In general, pharmacies urge adoption, while, in general, PBMs do not support the rules.

Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

No attorney general opinions or judicial rulings directly relate to the rules.

An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars ($500,000), whichever is less;

While there will be increases in both departmental revenues and expenditures because of these rules, the net result is expected to be near zero since the rules assess fees intended to offset the Department's costs stemming from administration.

Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Scott McAnally, Director of Insurance, Jud Jones, Director of PBM Compliance, and Will Kerby, Chief Counsel for Insurance and TennCare Oversight

Identification of the appropriate agency representative or representatives who will explain the rule at scheduled meeting of the committees;

Scott McAnally, Director of Insurance, Jud Jones, Director of PBM Compliance, and Will Kerby, Chief Counsel for Insurance and TennCare Oversight

Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Scott McAnally
500 James Robertson Pkwy, 10th Floor
Nashville, TN 37243
615-741-9739
Scott.mcanally@tn.gov

Jud Jones
500 James Robertson Pkwy, 10th Floor
Nashville, TN 37243
615-532-0413
Jud.jones@tn.gov

Will Kerby
500 James Robertson Pkwy, 12th Floor
Nashville, TN 37243
615-360-4358
William.kerby@tn.gov

Any additional information relevant to the rule proposed for continuation that the committee requests;

None

0780-01-95-.01. SCOPE

This chapter applies to all pharmacies and pharmacy benefits managers, including agents designated to handle matters on behalf of pharmacies or pharmacy benefits managers, conducting business in the State of Tennessee.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.02. DEFINITIONS

(1) All words and phrases used but not defined in this chapter that are defined in T.C.A. title 56, chapter 7, part 31 or part 32 shall have the meaning set forth therein.

(2) For the purposes of this chapter:

(a) "Cash discount" means a deduction from the invoice paid by a pharmacy for a prescription drug or device if the invoice is paid on or before a specified date or in cash.

(b) "Commissioner" means the commissioner of the department of commerce and insurance or the commissioner's designee.

(c) "Department" means the department of commerce and insurance.

(d) "Initial appeal" means the process required under T.C.A. § 56-7-3206(c)(2) and administered by a pharmacy benefits manager by which a pharmacy, or a pharmacy services administrative organization acting on behalf of a pharmacy, may appeal a reimbursement received from a pharmacy benefits manager that is not at least the actual cost to the pharmacy for a prescription drug or device.

(e) "Majority wholesaler" means the wholesaler from whom a pharmacy purchased the majority of its prescription pharmaceutical products for resale in the calendar year preceding the calendar year during which the claim that is the subject of an initial appeal is processed.

(f) "PBM" means a pharmacy benefits manager as defined in T.C.A. § 56-7-3102.

(g) "Pharmacy" means a pharmacy as defined in T.C.A. § 56-7-3102 and includes an agent acting on behalf of a pharmacy, including but not limited to a pharmacy services administrative organization.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.03. APPROVAL OF INITIAL APPEAL PROCESS

(1) No PBM may utilize an initial appeal process until it has received approval from the Commissioner stating the PBM's initial appeal process meets the requirements of T.C.A. § 56-7-3206(c)(2) and this chapter. A PBM shall utilize only one appeal process for all initial appeals filed with the PBM.

(2) PBMs must submit the following to the Commissioner as part of an application for approval of an initial appeal process, along with the application fee required under Rule 0780-01-95-.07(1):

(a) The name of the PBM;

(b) The contact information, including phone number and email address, for the primary individual

responsible for managing the application for the PBM;

(c) The contact information, including phone number and email address, for the primary individual who will manage the PBM's appeal process. This may be the same individual designated in subparagraph (b);

(d) Certification the PBM will accept from a pharmacy the standard appeal form created by the Department to file an initial appeal;

(e) The appeal form the PBM will accept from a pharmacy to file an initial appeal, if the PBM intends to offer its own appeal form in addition to the standard appeal form created by the Department;

(f) A comprehensive list of all information and documents requested from a pharmacy at the initiation of an initial appeal in addition to the standard appeal form provided by the Department or the PBM's appeal form submitted to the Department pursuant to subparagraph (e) of this paragraph, including any forms used to request such information;

(g) A list of the position(s) responsible for reviewing initial appeals received from a pharmacy, along with the training, experience, and education required of the position(s);

(h) A summary, sufficient to the Commissioner, of how the PBM will comply with the timing and notice requirements under T.C.A. § 56-7-3206(c)(2)(B)(ii) and Rule 0780-01-95-.05;

(i) Certification the PBM will not assess any costs to the pharmacy for any services provided in connection with the initial appeal;

(j) The email address to which the Commissioner shall send notice to the PBM of an external appeal to the Commissioner pursuant to T.C.A. § 56-7-3206(g)(2);

(k) Certification the PBM will require the name of a pharmacy's wholesaler or manufacturer, as applicable, from which the pharmacy purchased the drug or medical product or device at issue as part of its processing of claims for reimbursement from pharmacies. A PBM shall request this information as part of its processing of claims for reimbursement;

(l) A description, sufficient to the Commissioner, of how the PBM will track initial appeals such that it can reasonably determine, upon being provided the wholesaler or manufacturer in a claim, if an adjusted rate of reimbursement applies; and

(m) Any other documentation or information requested by the Commissioner regarding an initial appeal process.

(3) (a) Within 60 days of receipt of a complete application for approval of an initial appeal process containing all information required and requested under paragraph (2) of this rule and the required application fee, the Commissioner may:

1. Approve the initial appeal process upon determining that, in the Commissioner's discretion, the initial appeal process:

(i) Meets the requirements of paragraph (2) of this rule; and

(ii) Is reasonable and efficient;

2. Deny an initial appeal process for failure to meet, in the Commissioner's discretion, the requirements of subparts (3)(a)1.(i) or (ii) of this rule. The Commissioner shall provide the reason for denial in writing to the applicant; or

3. Extend the timeline for rendering a decision by providing the parties with written notice that includes a good-faith estimate of the additional time needed to make a decision. The Commissioner may subsequently further extend any such extended timeline by providing additional written notice to the parties of an updated good-faith estimate of the additional time needed to make a decision prior to the expiration of the previous extension.

(b) If the Commissioner does not take one of the actions listed in subparagraph (3)(a) of this rule within 60 days of receipt of a complete application, or within the extended timeline if extended pursuant to part (3)(a)3. of this rule, the application shall be deemed approved.

(4) Denial under part (3)(a)2. of this rule shall not preclude a PBM from submitting a new application for approval of an initial appeal process, accompanied by a new application fee, upon correcting any defects that caused the previous denial.

(5) A PBM may utilize an approved initial appeal process without the need for additional review by the Commissioner unless:

(a) The PBM materially changes the structure of, or the steps contained in, its initial appeal process. Material changes include but are not limited to:

1. Changing deadlines that are not otherwise set out in law or rule;

2. Any change to the information required from pharmacies to participate in any part of an initial appeal process. Changing or editing the forms on which pharmacies submit information to a PBM, without changing the type or scope of information required on a form, is not a material change; or

3. Assessing any cost to a pharmacy for any services provided in connection with an initial appeal; or

(b) There is a change in the position(s) assigned to review an initial appeal. Staffing turnover for the position(s) that review initial appeals does not constitute a change under this subparagraph.

(6) No less than 60 days prior to the date on which a PBM plans to implement a change to its initial appeal process as described in paragraph (5) of this rule, a PBM shall notify the Commissioner and pay the fee required under Rule 0780-01-95-.07(2). The notice shall contain a detailed explanation of the change and include any supporting documentation necessary to fully explain the change. The Commissioner shall review the notice and any supporting documentation and may:

(a) Request additional information;

(b) Require the PBM submit an application under paragraph (2) of this rule, including the required application fee, that reflects the changed initial appeal process;

(c) Approve the changed initial appeal process contingent on the PBM meeting certain conditions outlined in writing and sent to the PBM;

(d) Approve the changed initial appeal process; or

(e) Deny the changed initial appeal process.

(7) Notwithstanding paragraph (5) of this rule, the Commissioner may, after notice and hearing, revoke approval of an initial appeal process that has been previously approved or deemed approved for any violation of this chapter.

(8) This rule shall not apply to a PBM that meets the requirements of T.C.A. § 56-7-3206(d) by utilizing a

reimbursement methodology that is identical to the methodology provided for in the state plan for medical assistance approved by the federal Centers for Medicare and Medicaid Services.

(9) Beginning January 1, 2023, a PBM may utilize a temporary appeal process that is deemed temporarily approved as set out in this paragraph until the PBM's initial appeal process is approved by the Commissioner pursuant to paragraph (3) of this rule.

(a) In order to utilize a temporary appeal process to review initial appeals, a PBM must:

1. Prior to January 31, 2023, submit a certification, on a form provided by the Commissioner, that the PBM's temporary appeal process complies:

(i) With T.C.A. § 56-7-3206(c)(2)(B)(ii) and (iii); and

(ii) To the greatest extent possible, this chapter;

2. Submit a description of the steps involved in its temporary appeal process, and how that process differs, if at all, from the requirements of this chapter;

3. Pay the fee required under rule 0780-01-95-.07(3); and

4. Certify that all information submitted pursuant to this subparagraph is true and accurate to the best of the PBM's knowledge.

(b) A PBM's submission of all information required under subparagraph (a) of this paragraph shall constitute the Commissioner's approval for purposes of T.C.A. § 56-7-3206(c)(2)(B)(i) and paragraph (1) of this rule. The Commissioner's approval under this paragraph constitutes only temporary, terminable permission to utilize a temporary appeal process. The Commissioner's temporary approval of a PBM's initial temporary appeal process shall expire 60 days after the PBM's first submission of all information required under subparagraph (a) of this paragraph, except as provided in subparagraph (c) of this paragraph.

1. Notwithstanding a temporary appeal process being deemed temporarily approved pursuant to subparagraph (b) of this paragraph, the Commissioner may withdraw approval of a PBM's temporary appeal process for any reason in the sole discretion of the Commissioner by providing the PBM with written notice stating the temporary approval of the PBM's temporary appeal process is withdrawn and a statement of deficiencies in the temporary appeal process that must be addressed. Upon receiving this deficiency notice from the Commissioner, the PBM shall cease utilizing the temporary appeal process for which temporary approval was withdrawn within five business days after receipt of the deficiency notice. If the PBM does not submit a corrected approval process as set out in part 2. of this subparagraph within five business days of receipt of the Commissioner's notice, the PBM shall not process initial appeals until a corrected temporary appeal process is submitted pursuant to part 2. of this subparagraph or an approved appeal process is otherwise in place.

2. The PBM may resume using a temporary appeal process after receiving a deficiency notice pursuant to part 1. of this subparagraph, if the PBM's temporary approval process is not expired pursuant to subparagraph (c) of this paragraph, by submitting a corrected temporary appeal process to the Commissioner accompanied by a signed, written statement by the PBM certifying it has addressed all deficiencies identified by the Commissioner in the deficiency notice. Upon submission of the corrected temporary appeal process and signed statement, the corrected temporary appeals process shall be deemed temporarily approved and subject to part 1. of this subparagraph. The PBM may use its corrected temporary appeal process to review any initial appeals received between the time it received a denial notice from the Commissioner pursuant to part 1. of this subparagraph and its corrected temporary appeal process was deemed temporarily approved. The

Commissioner's approval of a PBM's corrected temporary appeal process shall expire 60 days after the PBM's submission of the corrected information pursuant to this part, except as provided in subparagraph (c) of this paragraph.

(c) A PBM that utilizes a temporary appeal process must submit a complete application pursuant to paragraph (2) of this rule prior to the expiration of the Commissioner's approval of its temporary appeal process. Notwithstanding subparagraph (b) of this paragraph, if a PBM submits a complete application pursuant to paragraph (2) of this rule, the PBM may, upon notice from the Commissioner that a complete application has been received, continue to utilize a temporary appeal process that has been deemed temporarily approved until the Commissioner approves its application pursuant to paragraph (3) of this rule unless the Commissioner withdraws approval of the temporary appeal process pursuant to part (b)1. of this paragraph.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.04. ACTIONS DURING AND AFTER AN INITIAL APPEAL

(1) Upon filing an initial appeal with a PBM, the pharmacy shall provide the PBM with a copy of the invoice(s) demonstrating the pharmacy's actual cost as of the date of the filing of the initial appeal by the pharmacy. If the pharmacy receives any additional discounts, price concessions, rebates, or other reductions, excluding cash discounts, during the pendency of an initial appeal, the pharmacy shall inform the PBM of the additional discount, price concession, rebate, or other reduction, excluding a cash discount. The PBM may consider the additional discount, price concession, rebate, or other reduction, excluding a cash discount, when calculating the pharmacy's actual cost. Additional discounts, price concessions, rebates, or other reductions received after the resolution of an initial appeal shall not be grounds for reconsideration of any initial appeal previously considered and resolved.

(2) A PBM shall request from each pharmacy filing an initial appeal the name and contact information of the wholesaler or manufacturer from which it purchased the prescription drug or device at issue. Failure of a pharmacy to provide this information shall not constitute grounds to deny an initial appeal; provided, however, if a PBM denies an initial appeal as otherwise allowed by law or this chapter and the pharmacy fails to provide this information or the PBM does not already have this information on file pursuant to Rule 0780-01-95-.03(2)(k), a PBM may presume the prescription drug or device at issue is available at a lower cost from the wholesaler or manufacturer from which the pharmacy purchased the prescription drug or device at issue.

(3) If a pharmacy's initial appeal is resolved in favor of the appealing pharmacy, the PBM shall comply with the provisions of T.C.A. § 56-7-3206(c)(3) and, further, provide the pharmacy the following in writing:

(a) A statement the initial appeal is granted, along with a summary outlining the basis for its decision;

(b) Notification the PBM has adjusted the challenged rate of reimbursement; and

(c) Detailed instructions for how to reverse and rebill the claim upon which the initial appeal is based.

(4) (a) When applying the findings from an initial appeal that was resolved in favor of a pharmacy to other similarly situated pharmacies as to the rate of reimbursement and actual cost for the particular drug or medical product or device that was at issue in the initial appeal, a PBM shall, within seven business days of resolution of an initial appeal, apply the findings retroactively as set out in subparagraph (b) of this paragraph to all similarly situated pharmacies that received the challenged rate of reimbursement for the particular drug or medical product or device that was at issue in the initial appeal, including any appeals pending with a PBM where the challenged rate of reimbursement is the subject of the pending appeal, by:

1. Notifying all similarly situated pharmacies of the adjusted rate of reimbursement in writing. The notice shall contain the applicable national drug code number or the unique device identifier at issue, as appropriate, and the rate of reimbursement to which the similarly situated pharmacy is now entitled for the drug or medical product or device; and

2. Paying all similarly situated pharmacies the difference in the original rate of reimbursement the similarly situated pharmacy received and the adjusted rate of reimbursement that resulted from the initial appeal resolved in favor of a pharmacy. The PBM shall not charge any fees or require any additional documentation from similarly situated pharmacies to pay the difference required under this part.

(b) The findings from an initial appeal resolved in favor of a pharmacy shall be applied retroactively under subparagraph (a) of this paragraph by applying the adjusted rate to all similarly situated pharmacies beginning on the date of service of the claim that was the subject of the initial appeal and continuing to apply that rate going forward until the appealing pharmacy and the similarly situated pharmacy or pharmacies were no longer entitled to the same rate of reimbursement for the drug or medical product or device at issue.

(c) A PBM shall track initial appeals such that it can reasonably determine if an adjusted rate of reimbursement applies.

(5) If a pharmacy's initial appeal is resolved against the appealing pharmacy, the PBM shall comply with the provisions of T.C.A. § 56-7-3206(c)(4).

(a) 1. The PBM shall determine whether the product associated with the national drug code number or unique device identifier is available at a cost that is less than the challenged rate of reimbursement from a pharmaceutical wholesaler in this state as of the date the initial appeal was received from the appealing pharmacy. The PBM shall make a reasonable effort to identify such information and must provide to the pharmacy any information complying with, and as set out in, T.C.A. § 56-7-3206(c)(4)(A).

2. For purposes of this subparagraph (a), the product associated with the national drug code number or unique device identifier at issue shall be deemed available if, at the time the initial appeal was received by the PBM, the product was in stock with a wholesaler operating in this state.

3. If, after a reasonable effort to identify the information needed to make the determination required under part 1. of this subparagraph, the PBM is unable to make the determination solely because the wholesalers contacted by the PBM failed to provide the information needed by the PBM within the timeframe within which the PBM must resolve initial appeals, the PBM shall presume that the product associated with the national drug code number or unique device identifier at issue was not available at a cost that is less than the challenged rate of reimbursement from a pharmaceutical wholesaler in this state as of the date the initial appeal was received from the appealing pharmacy.

4. If a PBM fails to provide the information required under T.C.A. § 56-7-3206(c)(4)(A) within the required timeframe, it shall be deemed to have determined there is no pharmaceutical wholesaler operating in this state that offered the product associated with the national drug code number or unique device identifier at issue at a cost that is less than the challenged rate of reimbursement as of the date the initial appeal was received from the appealing pharmacy.

(b) 1. The pharmacy shall provide the PBM with the name of its majority wholesaler for the purpose of allowing the PBM to accurately fulfill its obligations under T.C.A. § 56-7-3206(c)(4)(B). The PBM shall then determine whether the prescription drug or device at

issue is available from the pharmaceutical wholesaler at a cost that is less than the challenged rate of reimbursement as of the date the initial appeal was received from the appealing pharmacy. If the pharmacy fails to provide the name of its majority wholesaler within two business days of a request by the PBM to provide that name, the PBM may presume the prescription drug or device at issue is available at a cost that is less than the challenged rate of reimbursement from the pharmacy's majority wholesaler and take no further action pursuant to T.C.A. § 56-7-3206(c)(4) or this subparagraph (b).

2. For purposes of this subparagraph (b), the product associated with the national drug code number or unique device identifier at issue shall be deemed available if, at the time the initial appeal was received by the PBM, the product was in stock from the pharmacy's majority wholesaler.

3. If, after contacting the pharmacy's majority wholesaler to identify the information needed to make the determination required under part 1. of this subparagraph, the PBM is unable to make the determination solely because the wholesaler failed to provide the information needed by the PBM within the timeframe within which the PBM must resolve initial appeals, the PBM shall presume that the product associated with the national drug code number or unique device identifier at issue was not available at a cost that is less than the challenged rate of reimbursement from the wholesaler as of the date the initial appeal was received from the appealing pharmacy.

(c) The pharmacy shall cooperate with the PBM to assist in its search under subparagraphs (a) and (b) of this paragraph; provided, however, that, except as provided in part (b)1. of this paragraph, neither the pharmacy's nor a wholesaler's failure to cooperate or provide the PBM information shall be grounds for the PBM to fail to meet its obligations under T.C.A. § 56-7-3206(c)(4) or this paragraph.

(d) Even if the PBM determines it has a basis to deny an initial appeal for a reason other than that the pharmacy was reimbursed actual cost, the PBM shall follow the requirements set out in T.C.A. § 56-7-3206(c)(4).

(e) If a pharmacy's initial appeal is resolved against the appealing pharmacy and the PBM is required to adjust the challenged rate of reimbursement pursuant to T.C.A. § 56-7-3206(c)(4)(B), the PBM shall, to effectuate adjustment of the challenged rate, apply the findings from the appeal as to the rate of reimbursement for the drug or medical product or device at issue to other similarly situated pharmacies in the same manner as set forth in paragraph (4) of this rule.

(6) If a pharmacy's initial appeal is resolved against the appealing pharmacy, the PBM shall provide the pharmacy the following in writing:

(a) A statement the initial appeal is denied, along with a summary outlining the basis for its decision;

(b) If applicable, evidence the PBM has adjusted the challenged rate of reimbursement;

(c) If applicable, detailed instructions for how to reverse and rebill the claim upon which the initial appeal is based; and

(d) Instructions on how to make an external appeal of the PBM's decision to the Commissioner by:

1. Explaining how to submit an appeal, including the appropriate phone number or website address for the Department where appeals are accepted. Each PBM shall be responsible for ensuring the information provided to pharmacies pursuant to this part 1. is accurate; and

2. Including the following statement:

Pursuant to T.C.A. § 56-7-3206(g)(2), you have the right to appeal this decision to the

Commissioner of the Tennessee Department of Commerce and Insurance.

(7) If a PBM is required to pay a pharmacy any additional money upon resolution of an initial appeal, including a payment to a similarly situated pharmacy under part (4)(a)2. of this rule, the PBM shall make such payment within seven business days after notice of the initial appeal is received by the PBM.

(8) A PBM shall retain all records related to an initial appeal for the greater of five years or until the PBM is audited by the Department. A PBM shall provide the Department access to all records upon request and comply with requests for information regardless of whether the request is part of a departmental audit.

(9) A PBM shall not assess any costs to a pharmacy for any services provided by the PBM in connection with an initial appeal.

(10) An initial appeal shall not result in a pharmacy, whether the appealing pharmacy or a similarly situated pharmacy, being required to reimburse or refund a PBM any portion of a payment previously received by the pharmacy.

(11) On or before July 1 of each year, each PBM shall provide the Commissioner with a written report that contains the following aggregated information for the preceding calendar year:

(a) The number of initial appeals filed with the PBM;

(b) The number of initial appeals resolved in favor of pharmacies;

(c) The number of initial appeals resolved against pharmacies;

(d) The total amount of money paid to appealing pharmacies as a result of initial appeals resolved in favor of pharmacies;

(e) The total amount of money paid to similarly situated pharmacies as a result of initial appeals resolved in favor of pharmacies;

(f) The number of initial appeals that were appealed to the Commissioner of which the PBM received notice; and

(g) Any other information requested by the Commissioner.

(12) This rule applies only to initial appeals submitted to a PBM under the PBM's initial appeal process established in accordance with T.C.A. § 56-7-3206(c)(2)(A) and approved pursuant to Rule 0780-01-95-.03.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.05. TIMING AND NOTICE REQUIREMENTS FOR INITIAL APPEAL PROCESSES

(1) A PBM's initial appeal process, or a pharmacy's participation in an initial appeal, must meet the following requirements:

(a) The pharmacy must file its initial appeal within seven business days of its submission of the initial claim for reimbursement for the drug or medical product or device;

(b) The PBM or covered entity must make a final determination resolving the pharmacy's initial appeal within seven business days of the PBM's or covered entity's receipt of an initial appeal that includes all information required by paragraph (2) of this rule; and

(c) A PBM or covered entity shall make available on its secure website information about the initial appeal process, including, but not limited to, a telephone number, email address, web portal, or any other process that a pharmacy may use to submit initial appeals. The website shall clearly state that the PBM's initial appeal process is available for all prescription drugs or devices in Tennessee for which a pharmacy alleges it did not receive its actual cost.

(2) The timeline for making a final determination resolving an initial appeal under T.C.A. § 56-7-3206(c)(2)(B)(ii) shall not begin until the PBM has received all required information sufficient to allow the PBM to conduct a complete analysis of the initial appeal. A PBM shall be deemed to have received all required information sufficient to allow the PBM to conduct a complete analysis of the initial appeal upon receipt of:

(a) A complete version of either an initial appeal form provided by the Commissioner to be used by a pharmacy to file an initial appeal or the PBM's appeal form submitted and approved pursuant to Rule 0780-01-95-.03(2)(de); and

(b) Certification from the pharmacy it has provided the PBM with all invoices or other records demonstrating the pharmacy's actual cost for the drug or medical product or device at issue, which shall take into account all discounts, price concessions, rebates, or other reductions received as of the date the pharmacy filed its initial appeal.

(3) If a PBM receives an initial appeal from a pharmacy that does not contain all information required under paragraph (2) of this rule, the PBM shall accept the incomplete initial appeal and hold it open pending receipt of additional information from the pharmacy. Within five business days of receipt of an incomplete initial appeal, the PBM shall notify the pharmacy of the information needed to complete the initial appeal and initiate the PBM's review. The pharmacy may respond within five business days of receipt of the PBM's notice outlining the requested information. If the pharmacy provides the requested information, the timeline for making a final determination outlined in subparagraph (1)(b) of this rule shall start. If the pharmacy fails to provide the requested information within five business days of receipt of the PBM's notice, the PBM may deny the initial appeal pursuant to T.C.A. § 56-7-3206(c)(4).

(4) A PBM may not delay the start of its review of an initial appeal by:

(a) Requiring additional or different information from a pharmacy beyond what is required to be submitted to the PBM under its initial appeal process approved by the Commissioner pursuant to Rule 0780-01-95-.03(3)(a)1.; or

(b) Basing the delay on administrative or non-substantive errors or omissions in any of the filings that do not affect the overall validity of the initial appeal.

(5) If a PBM fails to comply with the timing and notice requirements under T.C.A. § 56-7-3206(c)(2)(B)(ii) and this rule, the pharmacy's initial appeal shall be resolved by the PBM in favor of the pharmacy. If a pharmacy fails to comply with the timing requirements under T.C.A. § 56-7-3206(c)(2)(B)(ii) and this rule, the PBM may deny the initial appeal pursuant to T.C.A. § 56-7-3206(c)(4).

(6) Each PBM must make its initial appeal process available on its secure website. The PBM's secure website must include all deadlines applicable to its initial appeal process, a description of the steps contained within its initial appeal process, and clearly state that its initial appeal process is available for all prescription drugs or devices in Tennessee for which a pharmacy alleges it did not receive its actual cost.

(7) Each PBM must submit the initial appeal process it will use for approval by the Commissioner regardless of whether it outsources the administration of its initial appeal process to a third-party administrator or a different PBM. Each PBM will retain ultimate responsibility for ensuring it complies with this paragraph regardless of whether the PBM conducts its own initial appeal process or utilizes another PBM or a third-party administrator.

(8) On or before July 1 of each calendar year, each PBM shall provide the Commissioner with a written statement certifying it meets the requirements of paragraph (6) of this rule along with timestamped screenshots of the PBM's website showing the required information is on the PBM's website and is readily accessible by pharmacies.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.06. EXTERNAL APPEAL PROCESS

(1) A pharmacy that alleges it did not receive at least its actual cost for a prescription drug or device after resolution of an initial appeal filed with a PBM shall have the right to appeal the decision of the PBM to the Commissioner. The Commissioner may delegate the review and resolution of a pharmacy's appeal under this paragraph, and any decision by the third-party reviewer shall have the same force and effect as a decision by the Commissioner. Any reference to the Commissioner in this rule shall also include a third-party reviewer properly designated by the Commissioner to review and resolve appeals.

(2) An appeal filed pursuant to paragraph (1) of this rule must:

(a) Be filed with the Commissioner, in such manner as the Commissioner may require, within 30 days of the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal, unless a different timeframe is approved in writing pursuant to paragraph (3) of this rule;

(b) Contain a summary of:

1. The grounds of the appeal to the Commissioner;

2. The relief requested by the pharmacy; and

3. The basis on which the pharmacy believes it is due the relief;

(c) Include a copy of the written decision rendered by the PBM;

(d) Contain a copy of the invoice(s) showing the pharmacy's purchase price for the drug or medical product or device at issue;

(e) Contain a list of all discounts, price concessions, rebates, or other reductions, excluding cash discounts, that were, or should have been, reported to the PBM pursuant to Rule 0780-01-95-.04(1), including supporting documentation for each discount, price concession, rebate, or other reduction;

(f) Be submitted on a form or through an electronic process made available by the Department;

(g) Contain a certification that all information submitted pursuant to paragraph (1) of this rule is true and accurate to the best of the pharmacy's knowledge; and

(h) Provide any other documentation or information requested by the Commissioner regarding the pharmacy's appeal.

(3) The Commissioner will not consider any information or documentation received from the pharmacy more than 30 days after the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal filed with the PBM unless the information reasonably should have been submitted and the withholding of information prevented the Commissioner from reviewing relevant or necessary information as part of the appeal. Prior to the expiration of the 30-day timeframe, the pharmacy may request in writing additional time

to investigate and compile the information needed to submit an appeal pursuant to paragraph (1) of this rule. Upon receipt of the pharmacy's written request, or upon the Commissioner's own determination, the Commissioner may, in the Commissioner's discretion, grant the pharmacy an additional period of time determined to be necessary by the Commissioner for good cause shown.

(4) Appeals that do not contain all information required under paragraph (2) of this rule shall be considered incomplete and will not qualify for review by the Commissioner under paragraph (7) of this rule until all information has been received. If an appeal is still incomplete more than 30 days after the pharmacy's receipt of the PBM's final determination resolving the pharmacy's initial appeal, or such other timeframe approved in writing pursuant to paragraph (3) of this rule, the pharmacy's appeal shall be automatically denied.

(5) The pharmacy whose appeal was denied pursuant to paragraph (4) of this rule may petition the Commissioner in writing for reconsideration and the Commissioner may, in the Commissioner's discretion, grant the petition for reconsideration upon showing good cause for failing to meet the required deadline.

(a) When granting a petition for reconsideration, the Commissioner shall establish a new deadline by which all information must be received, and the pharmacy's failure to meet that deadline for any reason will result in an automatic denial of the appeal, which shall be final.

(b) For purposes of this paragraph (5), good cause shall not include reasons or processes that were totally or mostly within the control of the appealing pharmacy, including but not limited to administrative oversight, clerical errors, or lack of sufficient personnel.

(6) Within ten business days of receipt of notice from the Commissioner the PBM's decision has been appealed, the PBM may file a response to the pharmacy's appeal by providing information supporting its decision made during its internal appeal process.

(7) No more than 90 days after the later of the receipt of a complete appeal containing all information required and requested under paragraph (2) of this rule or the receipt of the PBM's response allowed under paragraph (6) of this rule, the Commissioner may:

(a) Grant the appeal, in whole or in part, and order the PBM to make such portion of the requested payment to the pharmacy as the Commissioner determines is appropriate to result in the pharmacy receiving at least its actual cost for the prescription drug or medical product or device at issue;

(b) Deny the appeal, in whole or in part; or

(c) Extend the timeline for rendering a decision by providing the parties with written notice that includes a good-faith estimate of the additional time needed to make a decision.

(8) Upon granting or denying an appeal pursuant to paragraph (7) of this rule, the Commissioner shall send the parties a copy of the decision that contains a written justification. The decision of the Commissioner rendered pursuant to paragraph (7) of this rule is final and is not eligible for additional administrative review.

(9) If a PBM is required to pay a pharmacy any additional money upon resolution of an appeal pursuant to this rule, the PBM shall make such payment within seven business days of receipt of the Commissioner's written notice issued pursuant to paragraph (8) of this rule. The PBM shall also provide the Department with proof the PBM has reimbursed the pharmacy at least its actual cost for the prescription drug or medical product or device at issue, including a statement of the additional amount paid to the pharmacy, within seven business days of issuing the payment to the pharmacy.

(10) If a PBM is required to adjust a challenged rate of reimbursement after an appeal pursuant to this rule is resolved against the PBM, the PBM shall apply the findings from the appeal as to the rate of reimbursement for the drug or medical product or device at issue to other similarly situated pharmacies in the same manner as set forth in Rule 0780-01-95-.04(4).

(11) All costs associated with conducting an appeal under this rule, including the expenses of the Department, shall be paid by the applicable PBM. The Commissioner shall bill the PBM upon the conclusion of the appeal. The PBM shall pay the bill in full within 30 days of receipt. Failure to pay a bill in full within 30 days of receipt shall, pursuant to T.C.A. § 56-7-3110, be grounds for the Commissioner to:

(a) Suspend, revoke, or refuse to renew a PBM's license issued by the Department; and

(b) Order the PBM to pay additional monetary penalties.

~~(12)~~ (12) If a PBM fails to timely pay a bill due pursuant to paragraph (11) of this rule and the Department incurs any costs associated with conducting an appeal under this rule, including but not limited to reimbursement to a third-party contractor, the PBM shall reimburse the Department for those costs, which shall include any fees or interest paid by the Department due to the PBM's failure to pay. The Commissioner shall bill the PBM upon incurring those costs and the PBM shall pay the bill in full within 30 days of receipt. Failure to pay a bill in full within 30 days of receipt shall be grounds for the Commissioner to take any action outlined in paragraph (11) of this rule.

(13) When possible, a pharmacy may aggregate and submit appeals for simultaneous review by the Commissioner, or the Commissioner may, in the Commissioner's discretion, aggregate appeals, when the specific reason for denial of the appeals aggregated involves a dispute regarding a common substantive question of fact or law. The mere fact that a claim is not paid, or that appeals relate to the same PBM, does not create a common substantive question of fact or law.

(~~13~~14) This rule applies only to appeals of a PBM's decision rendered pursuant to its initial appeal process established in accordance with T.C.A. § 56-7-3206(c)(2)(A) and approved pursuant to Rule 0780-01-95-.03.

Authority: T.C.A. §§ 56-2-305, 56-7-3101, 56-7-3110, and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.07. FEES

Fees for services provided by the Department pursuant to this chapter shall be as follows:

(1) Review of an application for approval of an initial appeal process under Rule 0780-01-95-.03(2), including but not limited to a request for review and approval of an initial appeal process outsourced pursuant to Rule 0780-01-95-.05(7): $1,000.00

(2) Review of a request to change an initial appeal process under Rule 0780-01-95-.03(6): $1,000.00

(3) Review of an application for a temporary appeal process under Rule 0780-01-95-.03(9): $1,000.00

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.08. PLANS UTILIZING A REIMBURSEMENT METHODOLOGY IDENTICAL TO THE METHODOLOGY USED BY THE STATE PLAN FOR MEDICAL ASSISTANCE APPROVED BY THE FEDERAL CENTERS FOR MEDICARE AND MEDICAID SERVICES

(1) As used in T.C.A. § 56-7-3206(d)(2), a reimbursement methodology is identical to the methodology provided for in the state plan for medical assistance approved by the federal Centers for Medicare and Medicaid Services if the reimbursement methodology is identical in all respects, including, but not limited to, that requests for reimbursement are submitted to the Division of TennCare as set out in that methodology and the

methodology complies with the Division of TennCare Pharmacy Provider Manual, or a successor manual, as amended or updated, and all laws and rules of the Division of TennCare related to reimbursement.

(2) A pharmacy that alleges it did not receive at least its actual cost for a prescription drug or device after resolution of an appeal filed with a PBM pursuant to T.C.A. § 56-7-3206(d)(2) shall appeal the decision to the Division of TennCare as set out in the applicable laws and rules. Such appeals are not subject to review or appeal under this chapter.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.09. AUDITS BY PHARMACY BENEFITS MANAGERS

(1) A PBM's recoupment of funds from a pharmacy after an audit pursuant to T.C.A. § 56-7-3103 may not reduce the pharmacy's compensation for the prescription drug or device at issue to an amount that is less than the pharmacy's actual cost for the prescription drug or device as of the date the audit is commenced unless specifically allowed in law.

(2) When a PBM's audit of a pharmacy pursuant to T.C.A. § 56-7-3103 results in a recoupment, in addition to any other requirement imposed in law or rule, a PBM shall include in the documentation of the audit information that demonstrates how the recoupment did not result in the pharmacy receiving less than its actual cost for each affected prescription drug or device at issue, including but not limited to:

(a) The rationale that led the PBM to decide the pharmacy was overpaid for each claim that is subject to recoupment, along with supporting documentation; and

(b) An itemized breakdown for each claim that is subject to recoupment showing, at least, a comparison of what the pharmacy actually received and what the pharmacy should have received.

(3) A PBM shall retain all records related to an audit of a pharmacy pursuant to T.C.A. § 56-7-3103 for the greater of five years or until the PBM is audited by the Department. A PBM shall provide the Department access to all records upon request and comply with requests for information regardless of whether the request is part of a departmental audit.

(4) This rule does not limit or prohibit a PBM's ability to audit a pharmacy or recoup funds as allowed by T.C.A. § 56-7-3103.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.10. DETERMINATION OF PHARMACY'S PROFESSIONAL DISPENSING FEE

(1) (a) To determine whether a pharmacy's annual prescription volume for calendar year 2023 is at a level that, if the pharmacy were a TennCare-participating ambulatory pharmacy, would qualify the pharmacy for the enhanced professional dispensing fee for a low-volume pharmacy, each pharmacy that expects to qualify as a low-volume pharmacy for ~~the coming~~ calendar year 2023 shall~~, on or before December 1 of each year,~~ file with a PBM from whom the pharmacy expects to receive a dispensing fee during 2023 a certification stating the pharmacy expects to qualify as a low-volume pharmacy for ~~the coming~~ calendar year 2023. Each certification shall contain a statement that the certification is true and accurate to the best of the knowledge of the individual filing the certification on behalf of the pharmacy.

~~(2) When submitting a certification pursuant to paragraph (1)~~(b) Beginning with certifications made for dispensing fees to be paid during calendar year 2024, to determine whether a pharmacy's annual prescription volume is at a level that, if the pharmacy were a TennCare-participating ambulatory pharmacy, would qualify the pharmacy for the enhanced professional dispensing fee for a low-volume pharmacy, each pharmacy that will qualify as a low-volume pharmacy, as determined pursuant to subparagraph (2)(b) of this rule, shall, on or before December 1 of each year, file with a PBM from whom the pharmacy expects to receive a dispensing fee a certification stating the pharmacy will qualify as a low-volume pharmacy for the coming calendar year. Each certification shall contain a statement that the certification is true and accurate to the best of the knowledge of the individual filing the certification on behalf of the pharmacy. The pharmacy's certification submitted, or failure to submit a certification, pursuant to this paragraph shall determine the pharmacy's dispensing fee for the respective calendar year, unless a pharmacy submits a certification pursuant to paragraphs (3) or (4) of this rule.

(c) Upon receipt of a pharmacy's certification pursuant to subparagraph (1)(b) of this rule, the PBM shall pay the pharmacy the appropriate dispensing fee for prescriptions filled on or after January 1 of the calendar year for which the certification was submitted. Except as provided in Tenn. Code Ann. § 56-7-3103, a PBM may not recoup any portion of a dispensing fee from a pharmacy that accurately certifies its annual prescription volume.

(2) (a) When submitting a certification pursuant to subparagraph (1)(a) of this rule, a pharmacy shall base the determination of whether its prescription volume for the coming calendar year will qualify the pharmacy for the enhanced professional dispensing fee on the pharmacy's actual prescription volume from July 1 ~~of the prior year~~, 2021, to June 30, 2022.

(b) When submitting a certification pursuant to subparagraph (1)(b) of this rule, a pharmacy shall:

1. Base the determination of whether it will qualify for the ~~current~~enhanced professional dispensing fee on the pharmacy's actual prescription volume from July 1 of the year prior to the year during which the certification is due to June 30 of the year during which the certification is due. For example, certifications submitted on or before December 1, 2024, for calendar year 2025 shall be based on a pharmacy's ~~annual~~actual prescription volume ~~for~~from July 1, 2023, to June 30, 2024~~.~~; and

2. Along with the certification, submit proof of the pharmacy's actual prescription volume, which may be in the form of aggregate claims data or similar information. A pharmacy's certification shall not be considered complete until the pharmacy has also submitted proof pursuant to this part.

(3) If a pharmacy fails to timely submit a certification pursuant to paragraph (1) of this rule with a PBM with whom the pharmacy has an ongoing business relationship, the pharmacy shall be presumed to be a high-volume pharmacy ~~until seven business days after it submits the certification. If~~. However, if a pharmacy later certifies it qualifies for the enhanced professional dispensing fee for a low-volume pharmacy by meeting the requirements of parts 1. and 2. of subparagraph (2)(b) of this rule, the PBM shall pay the certifying pharmacy the enhanced professional dispensing fee for prescriptions dispensed beginning on the seventh business day after the PBM receives the complete certification.

(4) If a pharmacy receives, or expects to receive, a dispensing fee from a PBM with whom the pharmacy did not anticipate doing business at the time the pharmacy was required to file the certification under paragraph (1) of this rule, the pharmacy shall file the certification with the PBM simultaneously with the claim for reimbursement or within one business day of discovering the need to file the certification, whichever is later. The certification submitted pursuant to this paragraph must meet the requirements of parts 1. and 2. of subparagraph (2)(b) of this rule. The PBM shall pay the certifying pharmacy the enhanced professional dispensing fee for prescriptions dispensed on or after the day the PBM receives the complete certification.

(5) For calendar year 2023, a pharmacy shall file the certification required under paragraph (1)(a) of this rule on

or before January 31, 2023. Until a pharmacy files the certification required under paragraph (1)(a) of this rule, the pharmacy shall be presumed to be a high-volume pharmacy and shall not qualify for the enhanced professional dispensing fee for a low-volume pharmacy. If a pharmacy certifies it qualifies for the enhanced professional dispensing fee for a low-volume pharmacy, the PBM shall pay the certifying pharmacy the enhanced professional dispensing fee for prescriptions dispensed on or after the seventh business day after the PBM receives the certification.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed

0780-01-95-.11. VIOLATIONS

A violation of this chapter may subject a PBM to the sanctions described in T.C.A. § 56-2-305.

Authority: T.C.A. §§ 56-7-3101, 56-7-3206, and 56-7-3210.

Administrative History: Original rule filed

0780-01-95-.12. EXCLUSIONS

This chapter shall not apply to a health plan that provides coverage only for accidental injury, specified disease, hospital indemnity, Medicare supplement, disability income, other long-term care, or plans subject to regulation under Medicare Part D.

Authority: T.C.A. §§ 56-7-3101 and 56-7-3206.

Administrative History: Original rule filed