RULES
OF
THE DEPARTMENT OF COMMERCE AND INSURANCE
DIVISION OF INSURANCE

CHAPTER 0780-01-95
PHARMACY BENEFITS MANAGERS

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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:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023.*

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) "Audit" means an examination by the Commissioner to determine the financial condition of, or legality of conduct by, a PBM pursuant to T.C.A. § 56-7-3101(b)(1)(A). This definition shall not apply to a PBM's audit of a pharmacy referenced in Rule 0780-01-95-.09 and Rule 0780-01-95-.15(1)(g).

(b) "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.

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

(d) "Control" has the same meaning as that term is defined in T.C.A. § 56-11-101(3).

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

(f) "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

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reimbursement received from a pharmacy benefits manager that is not at least the actual cost to the pharmacy for a prescription drug or device.

(g) "MAC list" means a maximum allowable cost list as defined in T.C.A. § 56-7-3102.

(h) "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.

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

(j) "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:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023. Amendments filed March 28, 2024; effective June 26, 2024.*

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);

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(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;

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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

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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:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023.*

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;

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

(d) Written notification the PBM has issued payment to the pharmacy showing the exact amount of the payment.

(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

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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. §

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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;

(d) If applicable, written notification the PBM has issued payment to the pharmacy showing the exact amount of the payment; and

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(e) 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) (a) 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 adjust the rate of reimbursement and make such payment within seven business days after notice of the initial appeal is received by the PBM. However, subject to subparagraph (b), the timeline for making the payment(s) shall not begin until the appealing pharmacy has reversed and rebilled its claim showing the adjusted rate of reimbursement.

(b) If the appealing pharmacy fails to reverse and rebill its claim pursuant to subparagraph (a), the PBM shall adjust the rate of reimbursement and make the payment(s) no later than fifteen business days after the PBM receives notice of the initial appeal.

(8) A PBM shall retain all records related to an initial appeal pursuant to Rule 0780-01-95-.14. 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 an audit by the Department.

(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) 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:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023. Amendments filed March 28, 2024; effective June 26, 2024.*

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

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(c) Each PBM shall 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 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 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.

(Rule 0780-01-95-.05, continued)

Authority: *T.C.A. §§ 56-7-3101 and 56-7-3206.* ***Administrative History:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023. Amendments filed March 28, 2024; effective June 26, 2024.*

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

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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.

(Rule 0780-01-95-.06, continued)

(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.* ***Administrative History:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023.*

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

(4) Review of a delinquent license renewal application under Rule 0780-01-95-.13(5): $250.00

(5) Review of an annual report under Rule 0780-01-95-.15: $2,000.00

(Rule 0780-01-95-.07, continued)

Authority: *T.C.A. §§ 56-7-3101 and 56-7-3206.* ***Administrative History:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023. Amendments filed March 28, 2024; effective June 26, 2024.*

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:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023.*

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:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023.*

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 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

(Rule 0780-01-95-.10, continued)

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.* ***Administrative History:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023.*

0780-01-95-.11 AUDITS AND AUDIT REPORTS.

(1) Pursuant to T.C.A. § 56-7-3101(b)(1)(A), the Commissioner may, at any time the Commissioner believes it is reasonably necessary, audit any PBM licensed by the Department to determine whether the PBM is compliant with Tennessee laws pertaining to PBMs, including but not limited to T.C.A. Title 56, Chapter 7, Parts 31 and 32 and T.C.A. Title 56, Chapter 8, Part 1.

(2) The Commissioner shall have, and a PBM shall provide the Commissioner, convenient and free access to all books, records, securities, documents, and any and all files relating to the PBM's property, assets, business, and affairs any time the Commissioner determines it is necessary. The officers, directors, employees, and agents of the PBM shall facilitate and aid in the audit so far as it is in their power to do so.

(3) Pursuant to T.C.A. § 56-1-204, the Commissioner may administer oaths and examine under oath any person relative to the business of the PBM being audited.

(4) When conducting an audit of a PBM pursuant to paragraph (1) of this rule, the Commissioner may retain subject matter experts, attorneys, appraisers, independent actuaries, independent certified public accountants, certified financial examiners, or other professionals and specialists to assist in the audit.

(5) The Commissioner shall make a full and true report of the audit, which shall comprise only facts ascertained from the books, papers, records, securities, or documents of the PBM, or other evidence obtained by investigation of the Commissioner, or ascertained from the testimony of officers or agents or other persons examined under oath concerning the business, affairs, assets, and obligations of the PBM. The report of the audit shall be verified by the oath of the

(Rule 0780-01-95-.11, continued)

auditor in charge of the audit and shall be prima facie evidence in any action or proceeding in the name of the state against the PBM, its officers or agents upon the facts stated in the report.

(6) In the conduct of an audit, the Commissioner shall, to the extent deemed prudent by the Commissioner, adhere to the criteria set forth in the National Association of Insurance Commissioners Market Regulation Handbook and Financial Condition Examiners Handbook, as applicable, that were in effect when the audit commenced. The Commissioner may also employ other guidelines or procedures the Commissioner deems appropriate. The Commissioner shall disclose in writing to the PBM any other guidelines or procedures to be used prior to commencing an audit.

(7) Upon receipt of the verified report from the auditor in charge, the Commissioner shall transmit the report to the PBM examined, together with a notice that affords the PBM no less than thirty calendar days, or such shorter time period as determined by the Commissioner based on the circumstances of the audit, to make a written submission or rebuttal with respect to any matters contained in the audit report.

(8) Upon expiration of the end of the PBM's rebuttal period, the Commissioner shall fully consider and review the report, together with any submissions or rebuttals from the PBM and any relevant portions of the auditor's work papers, and enter an order:

(a) Adopting the report as filed or with modifications or corrections; or

(b) Rejecting the report with directions to the auditors to reopen the audit for purposes of obtaining additional data, documentation, or information, and refiling pursuant to paragraph (7).

(9) If the audit reveals that the PBM is operating in violation of any law, rule, or prior order of the Commissioner, the Commissioner may, by order issued pursuant to the Uniform Administrative Procedures Act compiled in T.C.A. Title 4, Chapter 5, require the PBM to take any action the Commissioner considers necessary or appropriate to cure the violation, including but not limited to the payment of civil penalties. No PBM shall violate any order issued under this paragraph.

Authority: *T.C.A. §§ 56-7-3101, 56-7-3206, and 56-7-3210.* ***Administrative History:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023. Amendments filed March 28, 2024; effective June 26, 2024.*

0780-01-95-.12 AUDIT COSTS.

(1) A PBM audited under Rule 0780-01-95-.11 shall pay all proper charges incurred in the audit, including the expenses of the Commissioner.

(2) The compensation of third parties retained by the Commissioner to assist with an audit pursuant to Rule 0780-01-95-.11(4) shall be fixed by the Commissioner at a reasonable amount commensurate with usual compensation for like services, which may include an overhead expense factor to cover the cost of employee benefits as well as the per diem expense allowance and transportation costs paid to the third parties.

Authority: *T.C.A. §§ 56-7-3101 and 56-7-3206.* ***Administrative History:*** *Emergency rules filed December 29, 2022; effective through June 27, 2023. New rules filed March 29, 2023; effective June 27, 2023. Amendments filed March 28, 2024; effective June 26, 2024.*

0780-01-95-.13 LICENSING.

(1) No person or entity may act as a PBM in this state without first receiving a PBM license from the Department in accordance with T.C.A. § 56-7-3113 and this rule.

(2) In addition to the requirements of T.C.A. § 56-7-3113, an applicant must also submit the following as directed by the Department as part of an application for a PBM license, which must be current as of the date of submission:

(a) Any trade names or d/b/a names used by the applicant;

(b) The name and address of the applicant's agent for service of process in this state;

(c) The applicant's federal employer identification number;

(d) Copies of the original, certified organizational documents of the applicant, including but not limited to the following, as applicable:

1. Articles of incorporation or association, as applicable, and all amendments;

2. Partnership agreements and all amendments;

3. Trade name certificates and all amendments;

4. Trust agreements and all amendments;

5. Shareholder agreements and all amendments;

6. Bylaws and all amendments; and

7. For PBMs not domiciled in Tennessee, proof of registration with the Tennessee Secretary of State;

(e) Certification that all information submitted pursuant to this paragraph is true and accurate to the best of the applicant's knowledge;

(f) An audited financial statement accompanied by an audit report prepared by a certified public accountant for the applicant's most recently ended fiscal year for which an audited financial statement is available; and

(g) Any other documentation or information requested by the Department.

(3) An applicant—or upon approval of an application and issuance of a license, a PBM—shall report any material changes in the information provided pursuant to paragraph (2) to the Department within sixty days of the change.

(4) When submitting a renewal application, a PBM must only submit information required under paragraph (2) that was either not previously submitted in a prior application, or that has changed since it was last submitted. For information required under paragraph (2) that was previously submitted and has not since changed, a PBM may submit a certification stating this, along with references to the particular paragraphs or subparagraphs of this rule to which the certification applies.

(5) Licenses no less than one calendar day and no more than thirty calendar days past their expiration date shall be considered delinquent but may still be renewed pursuant to paragraph (4) of this rule.

(Rule 0780-01-95-.13, continued)

(a) For licenses that have been expired no less than one day and no more than thirty calendar days, the PBM may submit a renewal application pursuant to paragraph (4) of this rule, along with the delinquent renewal fee required under Rule 0780-01-95-.07(4). This delinquent renewal fee shall be in addition to the renewal fee required under T.C.A. § 56-7-3113(e)(1).

(b) For licenses that have been expired more than thirty calendar days, the PBM must submit a new application pursuant to paragraph (2) of this rule.

(c) Approval of a delinquent renewal application shall be retroactive to the date the PBM submitted the application. However, approval of a delinquent renewal application shall not relieve the PBM of any penalties or other disciplinary action for unlicensed activity that occurred between the time the PBM's license expired and the PBM submitted a delinquent renewal application.

(6) A PBM shall report to the Commissioner any administrative, judicial, or disciplinary action taken against the PBM in another jurisdiction or by another governmental agency in this state within sixty days of the final disposition of the matter. The report must include a copy of any order entered or other relevant legal document that contains the terms of the resolution of the matter reported.

Authority: *T.C.A. § 56-7-3101.* ***Administrative History:*** *New rules filed March 28, 2024; effective June 26, 2024.*

0780-01-95-.14 RECORD KEEPING.

PBMs shall maintain all records and information necessary to appropriately demonstrate to the Commissioner compliance with all applicable laws and rules, including but not limited to T.C.A. Title 56, Chapter 7, Parts 31 and 32; T.C.A. Title 56, Chapter 8, Part 1; and this chapter. The records maintained pursuant to this rule include, but are not limited to, records regarding a PBM's activities pertaining to each covered entity to which the PBM provides services. PBMs shall maintain all records and information as required under this rule for a period of at least five years or as directed otherwise in writing by the Commissioner.

Authority: *T.C.A. § 56-7-3101.* ***Administrative History:*** *New rules filed March 28, 2024; effective June 26, 2024.*

0780-01-95-.15 ANNUAL REPORTS.

(1) Beginning April 1, 2025, and annually on or before April 1 of each year thereafter, each PBM shall file with the Commissioner a written report that contains the following information for the preceding calendar year on a form and in the manner provided by the Commissioner, along with the review fee required under Rule 0780-01-95-.07(5):

(a) The total number of claims paid by the PBM for prescription drugs or devices;

(b) The total number of claims paid by the PBM to pharmacies physically located in Tennessee, or to mail order pharmacies or specialty pharmacies on behalf of Tennessee residents, for prescription drugs or devices;

(c) Descriptions of all fees assessed by the PBM to pharmacies physically located in Tennessee, mail order pharmacies that serve Tennessee residents, or specialty pharmacies that serve Tennessee residents;

(Rule 0780-01-95-.15, continued)

(d) A schedule listing the unique identifier used by the PBM for internal distribution and identification of each MAC list used for pharmacy reimbursement at any point during the year for any pharmacy physically located in Tennessee, any mail order pharmacy that served Tennessee residents, or any specialty pharmacy that served Tennessee residents. For each MAC list, the PBM must specify:

1. Each pharmacy network that utilizes the MAC list as a basis for reimbursement, with each network identified by the unique identifier provided in part (e)1.;

2. The policies, procedures, or criteria used to determine which prescription drugs or devices are placed on the MAC list; and

3. The policies, procedures, or criteria used when updating the MAC list;

(e) A schedule of all the PBM's pharmacy networks that contain pharmacies physically located in Tennessee, mail order pharmacies that serve Tennessee residents, or specialty pharmacies that serve Tennessee residents. For each network, the schedule must include the following information:

1. The unique identifier of the network used by the PBM for internal distribution and identification;

2. A description of the network's purpose;

3. A schedule of all pharmacies physically located in Tennessee, mail order pharmacies that serve Tennessee residents, and specialty pharmacies that serve Tennessee residents that were removed from the network, along with the following information for each pharmacy removed;

(i) Pharmacy name and national provider identifier; and

(ii) The name of the network from which the applicant was removed; and

4. A schedule of denied network applications received from pharmacies physically located in Tennessee, mail order pharmacies that would have served Tennessee residents, or specialty pharmacies that would have served Tennessee residents, along with the following information for each application:

(i) Pharmacy name and national provider identifier; and

(ii) The name of the network into which the applicant was seeking entry;

(f) A schedule of all pharmacies contracted with the PBM that are physically located in Tennessee, mail order pharmacies that served Tennessee residents, or specialty pharmacies that served Tennessee residents. For each pharmacy listed, provide the following information:

1. Name and national provider identifier;

2. Total dollar amount of claims paid by the PBM to the pharmacy;

3. Total number of claims paid by the PBM to the pharmacy;

4. The unique identifier of the PBM's network(s) in which the pharmacy participates;

(Rule 0780-01-95-.15, continued)

5. The start and end date(s) of all contracts with the pharmacy, including all amendments, addendums, exhibits, provider manuals, and other documents that contain terms or conditions material to the contractual relationship between the PBM and the pharmacy;

6. Whether the pharmacy is an affiliate of or shares any common ownership through a parent entity with the PBM; and

7. Whether the pharmacy certified as a low-volume pharmacy with the PBM pursuant to Rule 0780-01-95-.10 for any portion of the calendar year;

(g) 1. A complete schedule of pharmacy audits completed during the previous calendar year for pharmacies physically located in Tennessee, mail order pharmacies that served Tennessee residents, or specialty pharmacies that served Tennessee residents, along with the following information on each completed audit:

(i) The name of the pharmacy audited and the pharmacy's national provider identifier;

(ii) The start and completion date of the audit;

(iii) Total number of claims audited;

(iv) Preliminary recoupment amount(s), if any; and

(v) Final recoupment amount(s), if any.

2. For purposes of this subparagraph (g), a PBM's audit of a pharmacy includes, but is not limited to, activities by a PBM that may be described as periodic audits; investigations; prescription validation requests; fraud, waste, and abuse reviews; desktop audits; or other similar processes or reviews intended to allow a PBM to inspect a pharmacy's internal records or processes;

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

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

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

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

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

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

(n) A written statement certifying the PBM meets the requirements of Rule 0780-01-95-.05(1)(c) 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; and

(o) Any other documentation or information requested by the Commissioner.

(2) PBMs may exclude information from the report required under paragraph (1) if the information pertains exclusively to plans in T.C.A. § 56-7-3102(1)(B).

(Rule 0780-01-95-.15, continued)

(3) On or before August 1, 2024, each PBM shall file with the Commissioner a written report that contains the information required under subparagraphs (h) through (o) of paragraph (1) for calendar year 2023 on a form and in the manner provided by the Commissioner, along with the review fee required under Rule 0780-01-95-.07(5).

(4) The Commissioner may extend a PBM's deadline for filing its annual report for good cause shown.

(5) (a) A PBM may redact information from its annual report that is confidential or proprietary information or a trade secret as those terms, or substantially similar terms as determined by the Department, are defined in Tennessee or federal law. Upon request from the Commissioner, a PBM shall provide the specific authority and rationale on which it based its determination that redacted information is confidential or proprietary or a trade secret.

(b) A PBM shall not redact information from annual reports pursuant to subparagraph (a) as confidential or proprietary information or trade secrets if such information is confidential under Tennessee or federal law such that the Department determines it is not available for public inspection while in the Department's possession.

Authority: *T.C.A. § 56-7-3101.* ***Administrative History:*** *New rules filed March 28, 2024; effective June 26, 2024.*

0780-01-95-.16 VIOLATIONS; CONTROL OF PBM.

(1) The following acts are violations of this chapter:

(a) A PBM fails to timely submit all information, including updates to information, required pursuant to this chapter;

(b) A PBM provides any false, misleading, or deceptive information to the Department;

(c) A PBM fails to comply with a requirement of, or engages in any action prohibited by, this chapter; or

(d) Information submitted to the Department indicates any of the following are not authorized to transact business in this state; are not financially responsible as indicated by evidence of financial negligence, financial fraud, or gross mismanagement; or have engaged in any false, fraudulent, or dishonest practices in the course of business:

1. The PBM;

2. Any of the PBM's officers, directors, partners, members, or managers; or

3. Any person or entity with control of a PBM.

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

(3) A person or entity that has, or that triggers a presumption of, control of a PBM may disclaim control in the same manner allowed under T.C.A. § 56-11-105(k).

Authority: *T.C.A. §§ 56-2-305 and 56-7-3101.* ***Administrative History:*** *New rules filed March 28, 2024; effective June 26, 2024.*

0780-01-95-.17 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:*** *New rules filed March 28, 2024; effective June 26, 2024.*