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# 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).*

<b>Agency/Board/Commission:</b>	Department of Commerce and Insurance
<b>Division:</b>	Division of Insurance
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**Revision Type (check all that apply):**

- Amendment  Content based on previous emergency rule filed on \_\_\_\_\_  
 New  Content is identical to the emergency rule  
 Repeal

**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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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-.02	Definitions
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-.07	Fees
0780-01-95-.11	Violations [renamed Audits and Audit Reports]
0780-01-95-.12	Exclusions [renamed Audit Costs]

0780-01-95-.13	Licensing
0780-01-95-.14	Record Keeping
0780-01-95-.15	Annual Reports
0780-01-95-.16	Violations; Control of PBM
0780-01-95-.17	Exclusions

Chapter 0780-01-95  
Pharmacy Benefits Managers

Amendments

Rule 0780-01-95-.02 Definitions is amended by deleting paragraph (2) and substituting:

- (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 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.

Rule 0780-01-95-.04 Actions During and After an Initial Appeal is amended by deleting paragraph (3) and substituting:

- (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.

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

Rule 0780-01-95-.04 Actions During and After an Initial Appeal is amended by deleting paragraph (6) and substituting:

- (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
  - (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.

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

Rule 0780-01-95-.04 Actions During and After an Initial Appeal is amended by deleting paragraph (7) and substituting:

- (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.

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

Rule 0780-01-95-.04 Actions During and After an Initial Appeal is amended by deleting paragraph (8) and substituting:

- (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.

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

Rule 0780-01-95-.04 Actions During and After an Initial Appeal is amended by deleting paragraphs (11) and (12) and substituting:

- (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.

Rule 0780-01-95-.05 Timing and Notice Requirements for Initial Appeal Processes is amended by deleting subparagraph (1)(c) and substituting:

- (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.

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

Rule 0780-01-95-.05 Timing and Notice Requirements for Initial Appeal Processes is amended by deleting paragraphs (6) and (7) and substituting:

- (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.

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

Rule 0780-01-95-.05 Timing and Notice Requirements for Initial Appeal Processes is amended by deleting paragraph (8).

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

Rule 0780-01-95-.07 Fees is amended by adding the following as new paragraphs:

- (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

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

Rule 0780-01-95-.11 Violations is amended by deleting the rule in its entirety and substituting:

Rule 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 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.

Rule 0780-01-95-.12 Exclusions is amended by deleting the rule in its entirety and substituting:

Rule 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.

New

Rule 0780-01-95-.13 Licensing is a new rule.

- (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.

- (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.

Rule 0780-01-95-.14 Record Keeping is a new rule.

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.

Rule 0780-01-95-.15 Annual Reports is a new rule.

- (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;
  - (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;
  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).
- (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.

Rule 0780-01-95-.16 Violations; Control of PBM is a new rule.

- (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.

Rule 0780-01-95-.17 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 (board/commission/ other authority) on March 27, 2024 (mm/dd/yyyy), 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 20, 2023

Rulemaking Hearing(s) Conducted on: (add more dates). February 9, 2024

Date: Mar 27, 2024

Signature:   
Carter Lawrence (Mar 27, 2024 10:53 CDT)

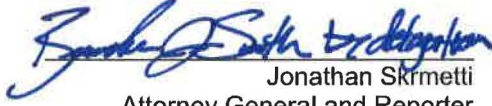
Name of Officer: Carter Lawrence

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.

  
Jonathan Skirmetti  
Attorney General and Reporter  
3-28-2024  
Date

**Department of State Use Only**

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**RECEIVED**

Mar 28 2024, 3:45 pm

Secretary of State  
Division of Publications

  
Tre Hargett  
Secretary of State

## Public Hearing Comments

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

1. The Department received a comment regarding the requirement to notify pharmacies when a PBM issues payment after adjusting the reimbursement rate retroactively, stating the PBMs' process requires the pharmacy to reverse and resubmit the claim before the PBM can calculate the reimbursement. The commenter stated PBMs cannot timely provide reimbursement information since it relies on factors individual to each claim.

Department response: Currently, Tenn. Comp. R. & Regs. 0780-01-95-.04(3) requires PBMs to follow the process outlined in Tenn. Code Ann. § 56-7-3206(c)(3)(A) upon resolution of an initial appeal (not a MAC appeal as incorrectly stated in the comment) in favor of a pharmacy, thus giving the pharmacy the opportunity to reverse and rebill a claim and provide the PBM with the needed information to adequately populate the claims history. In addition, this rulemaking also proposes to allow the timeline a PBM must follow when reimbursing a pharmacy pursuant to Tenn. Code Ann. § 56-7-3206(c)(3)(A) to begin only after a pharmacy has reversed and rebilled the claim at issue, subject to a final deadline meant to ensure the PBM cannot permanently withhold the pharmacy's reimbursement. However, the Department cannot force pharmacies to reverse and resubmit claims since the Department does not have jurisdiction over pharmacies generally and Tenn. Code Ann. § 56-7-3206 does not grant the Department that authority specifically. Similarly, PBMs cannot condition or withhold a pharmacy's reimbursement to which it is entitled after resolution of an initial appeal in the pharmacy's favor except as allowed in law or rule. While the Department understands the PBM must have sufficient information in order to properly effectuate the processes outlined in Tenn. Code Ann. § 56-7-3206(c)(3)(A) and Tenn. Comp. R. & Regs. 0780-01-95-.04, the Department cannot alter the statutory requirements regarding reimbursement of pharmacies, as the statute contains no exception for a pharmacy's failure to reverse and rebill.

2. The Department received multiple comments raising concerns on PBMs being required to provide a Tennessee-specific secure website for the submission of initial appeals, noting PBMs have not historically had to provide this and that it would be duplicative and hard to navigate for pharmacies.

Department response: This requirement was instituted as part of the first rulemaking for PBMs and initial appeals effective June 27, 2023. The Department did not receive any comments during that rulemaking indicating PBMs would not be able to meet the requirements of the rule and Tenn. Code Ann. § 56-7-3108 on which the requirement is based. As the comment does not provide specific examples of how this requirement has burdened PBMs or confused pharmacies such that pharmacies are not properly or timely filing initial appeals, the Department respectfully disagrees with the comment.

3. The Department received a comment stating the \$2,000 fee for the review of a PBM's annual report is excessive.

Department response: The Department disagrees that the fee for reviewing an annual report is excessive. It will take Department staff a considerable amount of time to thoroughly review all information contained in the annual reports. This fee amount was based on a reasonable estimate of the time it will take for Department staff to review and analyze each annual report.

4. The Department received a comment stating that access to PBM records should be limited to only books, records, and other files necessary to determine compliance with state laws applicable to PBMs, with a reasonable limitation to access instead of any time.

Department response: The proposed language mirrors the Department's examination authority for insurance companies granted in Tenn. Code Ann. § 56-1-411. Further, this language is implementing the statutory rulemaking authority and audit and investigation mandate enacted in Tenn. Code Ann. § 56-7-3101(b)(1)(A). That section establishes the expectation that the Department's audits and investigations ensure PBMs' compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32. Recognizing that the scope of compliance audits and investigations will necessarily vary at times, the rules are drafted within the statutory grant of authority.

5. The Department received a comment stating that there should be confidentiality protections for information received during an audit, as well as the ability for PBMs to object to the examiner due to possible conflicts of interest.

Department response: Tenn. Code Ann. § 56-7-3123 makes any information obtained or produced by the Department during an audit of a PBM confidential. However, audit findings are considered public records. These confidentiality provisions extend to any vendor retained by the Department to conduct audit services on behalf of the Department. Further, the Department disagrees that the rules should provide PBMs the ability to object to an examiner based on possible conflicts of interest. The Department encourages PBMs to notify the Department if a PBM believes a vendor conducting an audit has a potential conflict of interest. Additionally, all Department employees participating in an audit, and vendors conducting audits on behalf of the Department, must identify potential conflicts of interest so that these may be appropriately addressed by the Department.

6. The Department received a comment asserting that standalone audited financial statements would be onerous and burdensome for PBMs to produce, and that consolidated financial statements are adequate.

Department response: The Department disagrees with this comment. Having detailed, audited financial statements is a critical insight into PBMs' financial situation meant to ensure the Department can adequately monitor PBMs' compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32.

7. The Department received a comment requesting that all application requirements be listed in the proposed rules.

Department response: The application requirements listed in proposed rule 0780-01-95-.13(2) are specific. There are occasions in which additional information may be needed regarding a specific PBM applicant, and proposed rule 0780-01-95-.13(2)(g) gives the Department the ability to request additional information to consider in its review of an application to ensure the PBM applicant is authorized to transact business in this state and financially responsible as required by Tenn. Code Ann. § 56-7-3113.

8. The Department received a comment requesting the reporting of material changes be included within the annual renewal process under proposed rule 0780-01-95-.13(4).

Department response: Providing the Department notice of material changes within sixty days ensures the Department has the most up-to-date information on each PBM.

9. The Department received a comment requesting the reporting of administrative, judicial, or disciplinary actions against PBMs be limited to violations of insurance laws.

Department response: The Department disagrees with this comment because other actions taken against PBMs, though not directly related to an insurance law or rule, may have an important bearing on a PBM's compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32 (e.g., whether a PBM is financially responsible as required by Tenn. Code Ann. § 56-7-3113(b)(2)).

10. The Department received multiple comments expressing the belief that the Department does not have the authority to request the data that is contained in 0780-01-95-.15.

Department response: The Department disagrees with this comment. This report is meant to ensure the Department can properly and timely determine whether PBMs are complying with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, and to properly and timely determine whether there is a need to investigate the financial condition of or legality of conduct by a PBM, all of which is expected by Tenn. Code Ann. § 56-7-3101.

11. The Department received a comment stating the compiling of information for the annual report imposes a burden on companies, and questioning whether the Department is equipped to handle the massive amount of data that will be received by the Department in annual reports.

Department response: Annual reports are a crucial part of the Department's regulatory responsibility to regulate PBMs and ensure PBMs' compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32. While the Department recognizes that additional work will be necessary to comply with the reporting requirements, these reports are critical to ensure both PBMs and the Department are complying with Tennessee law. And though the information will be more than what has previously been required to be reported, the Department is aware and is taking steps to ensure it can receive, store, manage, and analyze the relevant data.

12. The Department received a comment suggesting information be provided to the Department in response to complaints, presumably, since it is not explicitly stated, replacing the annual reports as the primary means of information gathering by the Department.

Department response: The Department disagrees with the premise of this comment and believes the commenter is focusing on one aspect of the Department's regulatory oversight at the expense of another. First, as outlined in the response to comment # 11, the information received via annual reports is to monitor for compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, as part of the auditing program. This monitoring is not intended to be in response to specific violations, but to determine, among other things, if there are unreported violations that warrant further review. The second process, highlighted in the comment, is the Department's response to specific complaints. This triggers an investigatory process that includes the gathering of information as it relates to the complaint allegations. The Department appreciates the spirit of cooperation embodied in the comment and welcomes the sharing of information as part of the investigation of complaints, while acknowledging it cannot be the only means by which the Department receives information.

13. The Department received a comment asserting the Department does not have authority to request data from health plans, pharmacies, and enrollees outside of Tennessee.

Department response: This high level, aggregated information is not confidential and should be easily generated by PBMs. Knowing this number, in conjunction with other information submitted in annual reports, will allow the Department to determine, among other things, a PBM's overall market share of Tennessee business and the proportion of a PBM's business that comes from Tennessee. This information is intended to allow the Department to understand critical data points such as whether a PBM is generating a disproportionate number of complaints.

14. The Department received a comment questioning the value in the Department having the total number of claims paid by a PBM to pharmacies physically located in Tennessee, as well as to mail order pharmacies or specialty pharmacies on behalf of Tennessee residents, noting that claims are not paid based on members' state of residence, but rather where the pharmacy is located.

Department response: Tenn. Code Ann. § 56-7-3102(1) defines covered entity as "an individual or entity that provides health coverage to covered individuals who are employed or reside in this state." In addition to pharmacies physically located in Tennessee, pharmacies located outside of Tennessee can and do provide prescription drugs or devices to individuals who are employed in or reside in this state. Knowing the total number of claims administered by a PBM to covered individuals who are employed or reside in this state, regardless of how the prescription was filled, is another crucial piece of information that allows the Department to understand the market and each PBM's share of the overall market.

15. The Department received multiple comments urging the Department to promulgate rules to protect the confidentiality of information submitted in an annual report.

Department response: It is the Department's position that it does not have the rulemaking authority to promulgate rules making records confidential when the statutory grant of rulemaking authority does not specifically include that authority. This position has been verified with the Office of the Attorney General.

16. The Department received a comment observing the reporting requirement in proposed rule 0780-01-95-.15(1)(g)1. conflates credible investigations of fraud, waste, and abuse with routine contractual audits, and that such review should be limited to health plans located in Tennessee.

Department response: The Department disagrees with both aspects of this comment. First, the broad scope of audits covered by this rule is intended to ensure all instances where a PBM investigates or monitors a pharmacy's activities are

reported to the Department to check for compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32. Second, Tenn. Code Ann. § 56-7-3102(1) defines covered entity as “an individual or entity that provides health coverage to covered individuals who are employed or reside in this state.” In addition to pharmacies physically located in Tennessee, pharmacies located outside of Tennessee can and do provide prescription drugs or devices to individuals who are employed in or reside in this state. Since the definition of covered entity does not limit its application to entities or health plans located in Tennessee, but rather hinges on whether the covered individual is employed in or resides in this state, by necessity the requirements of Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32 will apply to entities or health plans located outside of Tennessee.

17. The Department received a comment noting a possible error with the language in proposed rule 0780-01-95-.15(1)(g)(2).

Department response: The Department agrees with this comment and has updated the reference in proposed rule 0780-01-95-.15(1)(g)(2) to say “this subparagraph (g)”.

18. The Department received a comment stating that moving the due date of the 2024 annual report from October 1, 2024, to August 1, 2024, creates a burden upon payors and the Tennessee business community, and does not allow companies enough lead time to gather the relevant materials, which discourages compliance.

Department response: The report due on August 1, 2024, under proposed rule 0780-01-95-.15(3) is the same scope as the report that is currently required under existing Tenn. Comp. R. & Regs. 0780-01-95-.04(11) regarding initial appeals, except that the report is currently due July 1, 2024. The proposed rules would effectively grant PBMs an additional month to submit the report that is currently due on July 1, 2024. PBMs would not have to begin submitting full annual reports (i.e., all information listed under proposed rule 0780-01-95-.15(1)) until April 1, 2025.

19. The Department received a comment asking that the phrase “while in the Department's possession” be stricken from proposed rule 0780-01-95-.15(5)(b) due to the uncertainty of when information would be disseminated by the Department and how the Department determines what information is available for public inspection.

Department response: This subparagraph is intended to make it clear that when the Department receives information from PBMs that is deemed confidential under Tennessee or federal law, the Department will be mindful of the applicable confidentiality laws and will adhere to them should public inspection requests be made to the Department for PBM records. Additionally, subparagraph (b) exists because PBMs should not improperly redact information from annual reports on the premise of confidentiality, proprietary information, or trade secret protections when the information should be appropriately provided to the Department for regulatory purposes. As a further clarification, the Department agrees with the statement in the comment “Even if archived material, this would still be confidential or proprietary or trade secret. And the restriction on public inspection should still apply” to the extent such material is confidential under applicable state or federal law. The fact that the restriction on public inspection would still apply supports the reasoning that potentially confidential or proprietary information or trade secrets can be provided to the Department in full confidence it will be and remain protected.

20. The Department received a comment stating that it is unclear what the parameters are for determining whether a PBM is financially responsible as required in proposed rule 0780-01-95-.16(1)(d). The comment also asks whether a PBM suffering a financial loss in the normal course of operating as a private business could be considered financially irresponsible.

Department response: The information received in annual reports and during audits will help the Department determine whether a PBM is financially responsible. There are multiple factors that go into making this determination and the determination is fact-dependent based upon all available information and, as such, the Department cannot speculate regarding such a determination without complete information. However, the Department agrees that additional parameters are needed to determine whether a PBM is financially responsible and the rule has been updated accordingly.

21. The Department received a comment requesting the Department issue a formal interpretive opinion. The exact topic of the requested interpretive opinion is not clear from the comment, though it appears to be to bring the Department's interpretation of the proposed rules' applicability to self-funded ERISA plans in line with the decisions reached in Tennessee Attorney General Opinions 14-71 and 16-42.



Department response: The Department disagrees an interpretive opinion is needed in this instance. The Department believes the proposed rules' applicability, which is derived from the plain language of Tenn. Code Ann. §§ 56-7-3101, -3102, -3122 and -3209, is sufficiently clear and that the proposed rules are distinguishable from the situations at issue in the two opinions identified.

22. The Department received a comment suggesting the Department clarify the proposed rules to state that self-insured ERISA plans are not PBMs and the rules applicable to PBMs do not apply to self-insured ERISA plans.

Department response: Both the definition of covered entity and of pharmacy benefits manager, found in Tenn. Code Ann. § 56-7-3102(1) and (5), respectively, clearly and unambiguously apply to self-insured entities and plans governed by ERISA. Further, Tenn. Code Ann. §§ 56-7-3122 and -3209 make self-insured ERISA plans subject to Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, respectively. For this reason, the Department disagrees with this comment and declines to attempt to alter the plain meaning of statute by rule.

23. The Department received multiple comments asserting the proposed rules, and specifically proposed rules 0780-01-95-.11, .14, and .15, are preempted and unenforceable under the United States Supreme Court's decision in Gobeille v. Liberty Mutual Insurance Company, 577 U.S. 312 (2016), and the subsequent Tennessee Attorney General Opinion 16-42.

Department response: The Department disagrees with this comment. Unlike the law at issue in Tenn. Op. Atty. Gen. 16-42, the proposed rules do not present the exact factual pattern at issue in Gobeille. The Department maintains that the reporting and record keeping requirements contained in the proposed rules are sufficiently distinguishable from the reporting requirements in the Tennessee all-payer-claims-database law such that the proposed rules are not unconstitutional, preempted, and unenforceable ab initio.

24. The Department received a comment asserting the proposed rules violate employer and employee rights of privacy and confidentiality.

Department response: The Department disagrees with this comment since proposed rule 0780-01-95-.15(5) provides meaningful and sufficient confidentiality protections within the reporting requirements. Under circumstances in which PBMs are required to submit information that is confidential or proprietary information or a trade secret under Tennessee or federal law, the Department adheres to the requirements under the applicable law to maintain the confidentiality of that information. Further, the Department believes that the information characterized as confidential in the comment, to which the commenter asserts the Department has no right to access, is also crucial to allowing the Department to carry out its regulatory duties to ensure compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, which the Department asserts is appropriate grounds to give the Department access to the information.

25. The Department received multiple comments suggesting the proposed rules, including but not limited to the rules relating to audits and annual reporting, impose unreasonable burdens on PBMs and will increase costs for Tennessee employers and employees.

Department response: The Department acknowledges the work that will be required for PBMs and covered entities to comply with the requirements of the proposed rules and Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32. However, the Department disagrees that the work is unreasonable and believes the work is a necessary consequence of the obligations placed on PBMs and covered entities by Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, and by extension Tenn. Comp. R. & Regs. 0780-01-95 (including the proposed rules).

26. The Department received a comment suggesting the proposed rules constitute an unreasonable restraint of trade under Tenn. Code Ann. § 4-5-212.

Department response: The Department disagrees with this comment on the grounds that this section of law does not apply to the proposed rules. Tenn. Code Ann. § 4-5-212 limits its application to only rules "filed by a regulatory board, as defined in [Tenn. Code Ann.] § 4-4-125(a)." Regulatory board is defined in Tenn. Code Ann. § 4-4-125(a)(1) as "any state board, commission, council, committee, or similar entity or body established by statute or rule that issues any license, certificate, registration, certification, permit, or other similar document for an occupation, profession, business, or trade in this state or otherwise regulates or controls any occupation, profession, business, or trade in this state." Considering the

plain and ordinary meaning of terms such as board, commission, and council, this definition makes clear that Tenn. Code Ann. § 4-5-212 only applies to rules issued by a multi-member deliberative body, not a lone official such as a commissioner. There is no plausible reading of Tenn. Code Ann. § 4-4-125(a)(1) where a single official could be considered similar to the list of multi-member bodies contained in the definition such that this section is deemed applicable to the proposed rules.

27. The Department received a comment suggesting the Department failed to provide a summary of the factual information on which the proposed rules are based as required by Tenn. Code Ann. § 4-5-204.

Department response: The Department disagrees with the assertion that the summary provided at the beginning of the public hearing held on February 9, 2024, and the additional explanation provided at the end of the hearing, fail to adequately summarize the factual information on which the proposed rules are based in violation of Tenn. Code Ann. § 4-5-204. The Department believes that comments made during the hearing adequately meet this undefined standard, including but not limited to statements that the rules were based on informal meetings and stakeholder input; that feedback from those conversations generally agreed with comments received during the February 9, 2024, hearing regarding federal preemption; and that feedback from those informal meetings led to various edits to the proposed rules in response to concerns raised by attendees. The Department also observed that changes made to draft versions of the proposed rules circulated prior to the informal meetings were the result of stakeholder input, evidencing specific facts that led to the proposed rules being worded as they are. In addition to the statements made during the hearing, the Department believes Tenn. Code Ann. § 56-7-3101 provides a sufficient basis for the rules, namely that the Department is required to promulgate the rules to effectuate the purposes of, and ensure PBMs' and covered entities' compliance with, Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32. The Department believes this, along with the experience gained by Department staff from the Department's implementation and enforcement of PBM-related rules for over a year, provides a sufficient basis of factual information to meet the intent of Tenn. Code Ann. § 4-5-204.

28. The Department received a comment requesting the Department issue a concise statement of the principal reasons for its actions in accordance with Tenn. Code Ann. § 4-5-205.

Department response: The Department acknowledges the commenter's request and will issue a concise statement of the principal reasons for adopting the proposed rules upon adoption as required in Tenn. Code Ann. § 4-5-205.

29. The Department received multiple comments asserting the Department has no authority to promulgate the proposed rules because the rules attempt to regulate areas governed by the Employee Retirement Income Security Act of 1974 ("ERISA") and are therefore preempted by ERISA and subsequent case law interpreting ERISA.

Department response: The Department disagrees with this comment. The definition of both covered entity and pharmacy benefits manager, found in Tenn. Code Ann. § 56-7-3102(1) and (5), respectively, clearly and unambiguously apply to self-insured entities and plans governed by ERISA. Further, Tenn. Code Ann. §§ 56-7-3122 and -3209 make self-insured ERISA plans subject to Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, respectively.

30. The Department received a comment approving of the requirement for PBMs to issue a written notification to a pharmacy once the PBM has issued payment to the pharmacy showing the exact amount of the payment. The comment observes that notification will assist pharmacies in knowing when an appeal has been resolved after it has been reversed and rebilled.

Department response: The Department appreciates this comment and hopes the notification has the intended effect of ensuring all parties are informed when payment is issued after an initial appeal is resolved.

31. The Department received a comment urging the Department to investigate the deadlines applicable to initial appeal processes posted on PBMs' websites to ensure uniformity among PBMs.

Department response: The deadlines for initial appeal processes are clearly outlined in Tenn. Comp. R. & Regs. 0780-01-95, and PBMs are required to comply with these timelines. Any issue with a PBM's initial appeal process should be reported to the Department at [pbm.compliance@tn.gov](mailto:pbm.compliance@tn.gov). Further, the Department will review PBMs' compliance with relevant state law and rules, including the timelines regarding initial appeal processes, during audits.

32. The Department received a comment urging the Department to include the term "timely" when describing when and how the Department may access a PBM's records pursuant to proposed rule 0780-01-95-.11(2) to avoid PBMs withholding access to information and causing a delay in the audit process.

Department response: The Department believes the current language sufficiently allows the Department access to a PBM's records when needed, especially in light of the second sentence in paragraph (2) requiring the employees of a PBM to facilitate and aid in the audit.

33. The Department received multiple comments in support of the policy of assessing the costs of an audit of a PBM to the PBM being audited.

Department response: The Department appreciates these comments and notes that this is consistent with the practice for examinations of insurance companies under Tenn. Code Ann. § 56-1-413 and Tenn. Comp. R. & Regs. 0780-01-38.

34. The Department received a comment supporting the inclusion of additional details on licensing requirements.

Department response: The Department appreciates this comment and welcomes additional feedback from stakeholders as these requirements are put into practice.

35. The Department received a comment supporting proposed rule 0780-01-95-.15 generally, and specifically the language requiring disclosure of whether a pharmacy and a PBM are affiliated or share any common ownership through a parent entity in part (f)6.

Department response: The Department agrees this is an important piece of information.

36. The Department received a comment supporting having PBMs report denied network applications to the Department regarding pharmacies that attempted to gain entry into a PBM's network but were denied.

Department response: The Department agrees this is an important piece of information.

37. The Department received a comment suggesting paragraph (2) of proposed rule 0780-01-95-.15 is not needed since the exclusions referenced are mentioned in proposed rule 0780-01-95-.17.

Department response: The Department disagrees with this comment. The exclusions in proposed rule 0780-01-95-.15(2) are specific to the report required in proposed rule 0780-01-95-.15(1), while the general exclusions in proposed rule 0780-01-95-.17 apply to all of chapter 0780-01-95.

38. The Department received a comment supporting the exclusion in proposed rule 0780-01-95-.15(5)(b) regarding what information a PBM may redact from annual reports and urging the Department to strongly enforce this provision.

Department response: The Department appreciates this comment and intends to enforce the provision.

39. The Department received multiple comments suggesting the term "may" should be changed to "shall" in proposed rule 0780-01-95-.16.

Department response: This language is consistent with the current rule on violations of existing Tenn. Comp. R. & Regs. 0780-01-95. The Department does not intend to change this language so as to retain regulatory discretion on how to impose appropriate penalties for violations.

40. The Department received a comment encouraging the Department to track violations by PBMs to determine whether changes to Tenn. Code Ann. § 56-2-305 are necessary.

Department comment: The Department will monitor violations but cannot comment whether this information will lead to statutory changes.

41. The Department received a comment observing that the current proposed rules allow unlimited access by the Department to PBMs' records without at least a prima facie showing of wrongdoing, do not provide a means of appeal, and do not set limitations on penalty amounts or what a PBM could be ordered to do.

Department response: The proposed rules are tailored to allow the Department to ensure PBMs are complying with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32 as required, and to the extent authorized, by Tenn. Code Ann. § 56-7-3101. Further, the sanctions the Department may impose for violations of Tenn. Comp. R. & Regs. 0780-01-95 are limited by Tenn. Code Ann. § 56-2-305, which requires disciplinary actions follow the processes outlined in the Uniform Administrative Procedures Act compiled in Tenn. Code Ann. Title 4, Chapter 5.

42. The Department received a comment asserting that corporate greed was hurting pharmacists, not small PBMs who will bear the burden of compliance with the proposed rules. The comment pointed to growing corporate profits of large chain pharmacies such as CVS and Walgreens and compared those to the median rate of pay for Tennessee pharmacists.

Department response: The Department is not informed on the financial condition of pharmacies or pharmacists to adequately respond to this comment.

43. The Department received a comment stating the proposed rules are incompatible with how prescription claims are processed and paid. The comment also encourages the Department to work with pharmacies and PBMs to tailor appeal processes in a way that does not disrupt the operations of both industries.

Department response: The rules regarding initial and external appeal processes were submitted for public review and comment in 2023. Any proposed edits or changes to the rules for either appeal process should be directed to [pbm.compliance@tn.gov](mailto:pbm.compliance@tn.gov).

44. The Department received a comment suggesting it is incumbent on the Department to give the model rules rather than making each PBM guess what the Department wants, submit a written plan, and pay \$2,000 "for the privilege."

Department response: Assuming the comment is referring to the submission of annual reports, the Department believes the criteria for the submission of annual reports is sufficiently clear based on proposed rule 0780-01-95-.15.

45. The Department received a comment recommending the Department abandon the proposed rules and instead focus on understanding the anti-competitive and self-dealing practices of PBMs.

Department response: The Department intends to carry out its mandate to implement and enforce the statutory requirements of Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32, which includes the requirement to promulgate rules pursuant to Tenn. Code Ann. § 56-7-3101(b)(1).

46. The Department received a comment asserting that, if the proposed rules are adopted, the commenter will exit Tennessee, and forecasts other, smaller PBMs will do the same.

Department comment: The Department does not intend for the proposed rules to reduce the number of PBMs operating in Tennessee.

47. The Department received a comment recommending the reporting of MAC lists in proposed rule 0780-01-95-.15 should be limited to the current MAC list in place during the reporting deadline.

Department comment: The Department does not intend for PBMs to submit detailed, drug-specific rate information for each drug contained in a MAC list utilized by a PBM in a calendar year. The intent of this reporting requirement is simply to allow the Department to gain a high-level understanding of how many MAC lists are utilized in the PBM's network(s) and the policies and procedures that govern how those lists are managed. The Department has updated the language of

proposed rule 0780-01-95-.15(1)(d) to clarify this. Questions regarding the exact scope of information that must be submitted pursuant to this requirement should be directed to [pbm.compliance@tn.gov](mailto:pbm.compliance@tn.gov).

48. The Department received a comment expressing support for the Department's authority to audit PBMs as found in proposed rule 0780-01-95-.11 and recommending adding the provision "not less than every three years" for appropriate oversight.

Department response: The Department believes the current audit authority is sufficient to allow the Department to audit PBMs as needed to determine compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32.

49. The Department received a comment expressing support for the Department having access to PBMs' records in proposed rule 0780-01-95-.11.

Department response: The Department appreciates this comment and welcomes additional feedback from stakeholders to better refine the processes for the benefit of all parties.

50. The Department received a comment expressing support for the detailed appeal processes in the proposed rules.

Department response: The Department appreciates this comment and welcomes additional feedback from stakeholders to better refine the processes for the benefit of all parties.

51. The Department received a comment stating that the broad enforcement policies in Tenn. Code Ann. § 56-2-305 are less helpful to community pharmacies and would be more helpful if they were included in Tenn. Comp. R. & Regs. 0780-01-95.

Department response: The Department disagrees with this comment. The Department believes the enforcement scheme in Tenn. Code Ann. § 56-2-305 is the appropriate means the Department should use when sanctioning PBMs for violations of Tenn. Comp. R. & Regs. 0780-01-95.

52. The Department received a comment recommending stronger language for civil penalties, with a minimum fine of \$10,000 per violation with no maximum. The comment then recommends penalties received be dedicated to funding PBM oversight. Finally, the comment recommends stricter penalties for repeat violations.

Department response: The Department disagrees with this comment. The Department believes the enforcement scheme in Tenn. Code Ann. § 56-2-305 is the appropriate means the Department should use when sanctioning PBMs for violations of Tenn. Comp. R. & Regs. 0780-01-95.

## 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.

- 1. The type or types of small business and an identification and estimate of the number of small businesses subject to the rule being proposed that would bear the cost of, or directly benefit from the rule being proposed;**

Small pharmacies are the types of small businesses that would directly benefit from the rules being proposed. The Department does not know the number of small pharmacies currently operating in Tennessee. Of the 55 PBMs currently licensed by the Department, to the best of the Department's knowledge, none are small businesses.

- 2. The projected reporting, recordkeeping and other administrative costs required for compliance with the rule being proposed, including the type of professional skills necessary for preparation of the report or record;**

The Department is unable to estimate the costs that will be imposed on pharmacy benefit managers (PBMs) as a result of these rules. However, the types of skills necessary for preparation of the reports, forms, and records needed to comply with these rules are not significantly different than the types of skills and records currently utilized by PBMs in their day-to-day operations.

- 3. A statement of the probable effect on impacted small businesses and consumers;**

The rules will have very little direct impact on small businesses in Tennessee. The rules will have an indirect impact by allowing the Department to ensure that PBMs are reimbursing Tennessee pharmacies at least their actual cost for any prescription drug or device dispensed.

- 4. A description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and objectives of the rule being proposed that may exist, and to what extent the alternative means might be less burdensome to small business;**

These rules represent the least burdensome option to accomplish the purposes of 2022 Pub. Ch. 1070 and 2022 Pub. Ch. 998.

- 5. A comparison of the rule being proposed with any federal or state counterparts; and**

While there are regulations, both federal and state, that affect PBMs, most other states' regulations are not as detailed as these rules. However, a growing number of states are expanding their regulation of PBMs in a similar manner to these rules.

- 6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the rule being proposed.**

Exempting small pharmacies from any part of the rules would undermine their effectiveness and remove many protections for small pharmacies.

- 7. The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs:**

To the extent the rules set up entry barriers, stifle entrepreneurial activity, curb innovation, or increase costs, it is only to the most limited extent necessary to carry out the Department's mandate to promulgate rules in Tenn. Code Ann. § 56-7-3101.

### **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 provide additional licensing criteria PBMs must meet when seeking and renewing licensure with the Department. The rules also outline the Department’s ability to audit PBMs to ensure compliance with Tenn. Code Ann. Title 56, Chapter 7, Parts 31 and 32. Additionally, the rules outline the types of information that PBMs must submit to the Department as part of an annual report. Finally, the rules edit existing rules in chapter 0780-01-95 to refine existing processes in response to feedback from stakeholders.

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. 998 and 1070 require the Department promulgate rules to effectuate the requirements in the public chapters. 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;

Tenn. Op. Atty. Gen. No. 16-42  
*Gobeille v. Liberty Mutual Insurance Company*, 577 U.S. 312 (2016)  
*Ky. Ass'n of Health Plans, Inc. v. Nichols*, 227 F.3d 352 (6th Cir. 2000)  
*Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80 (2020)

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 allow the Department to assess fees intended to offset the Department’s costs stemming from administration. Further, the Department does not have sufficient information to determine the financial impact to state or local governments but expects it will be minimal.

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

Jud Jones, Director of PBM Compliance, Scott McAnally, Director of Insurance, 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;

Jud Jones, Director of PBM Compliance, Scott McAnally, Director of Insurance, 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

Jud Jones  
500 James Robertson Pkwy, 10th Floor



Nashville, TN 37243  
615-532-0413  
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Any additional information relevant to the rule proposed for continuation that the committee requests;

None

**COMMERCE AND INSURANCE  
INSURANCE DIVISION**

**CHAPTER 0780-01-95  
PHARMACY BENEFITS MANAGERS**

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**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-.17(1)(g).
  - (b)(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.
  - (c)(b) "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)(c) "Department" means the department of commerce and insurance.

~~(f)(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.

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

~~(h)(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.

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

~~(j)(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.

#### **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; ~~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 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;~~
  - ~~(d)(e) If applicable, written notification the PBM has issued payment to the pharmacy showing the exact amount of the payment detailed instructions for how to reverse and rebill the claim upon which the initial appeal is based;~~ and
  - ~~(e)(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)

- ~~(a)(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 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-.16 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 an a departmental 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) 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.~~

~~(11)~~ (11.2) 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.

#### **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) Each A PBM shall make its initial appeal process or covered entity shall make available on its secure website. The PBM's secure website must include all deadlines applicable to its information about the initial appeal process, a description of the steps contained within its initial appeal process, and 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.~~
- ~~(6)(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.

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

#### **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-.15(5): \$250.00~~
- ~~(5) Review of an annual report under Rule 0780-01-95-.17: \$2,000.00~~

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

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

#### **~~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: 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 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 refile 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.

#### **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.

#### **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.
  - (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.

#### **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.

**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;
  - (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 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 list; and
    3. The policies, procedures, or criteria used when updating the 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;

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).
  - (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 pursuant to subparagraph (a) as confidential or proprietary information or trade secrets from annual reports 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.

#### 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.

#### **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.