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# Notice of Rulemaking Hearing

*Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.*

<b>Agency/Board/Commission:</b>	Department of Commerce and Insurance
<b>Division:</b>	Division of Insurance
<b>Contact Person:</b>	Will Kerby
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*Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:*

<b>ADA Contact:</b>	Don Coleman
<b>Address:</b>	500 James Robertson Parkway, Nashville, TN 37243
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**Hearing Location(s)** (for additional locations, copy and paste table)

Address 1:	500 James Robertson Parkway			
Address 2:	Conference Room 1-A			
City:	Nashville			
Zip:	37243			
Hearing Date:	February 9, 2024			
Hearing Time:	10:00 am	<input checked="" type="checkbox"/> CST/CDT	<input type="checkbox"/> EST/EDT	

**Additional Hearing Information:**

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**Revision Type (check all that apply):**

☒ Amendment

☒ New

☐ 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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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; 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.

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 each MAC list used by the PBM 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. The unique identifier of the MAC list used by the PBM for internal distribution and identification;
  2. 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.;
  3. The policies, procedures, or criteria used to determine which prescription drugs or devices are placed on the MAC list; and
  4. 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 (h), 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, 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.

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: December 20, 2023

Signature: *Will Kerby*

Name of Officer: Will Kerby

Title of Officer: Chief Counsel for Insurance and TennCare Oversight

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Filed with the Department of State on: 12/20/2023

*Tre Hargett*

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Secretary of State

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