AN ACT

ENTITLED, An Act to establish a pharmacy audit integrity program.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. The pharmacy audit integrity program is hereby established to provide standards for an audit of pharmacy records carried out by a pharmacy benefits manager or any entity that represents the pharmacy benefits manager.

Section 2. Term used in this Act mean:

(1) "Entity," a pharmacy benefits manager or any person or organization that represents these companies, groups, or organizations in any capacity;

(2) "Plan sponsor," the employer in the case of an employee benefit plan established or maintained by a single employer or the employee organization in the case of a plan established or maintained by an employee organization, an association, joint board, trustee, committee, or other similar group that establishes or maintains the plan.

Section 3. The pharmacy benefits manager shall disclose an amendment to the pharmacy audit terms in a contract between a pharmacy and a pharmacy benefits manager to the pharmacy at least sixty days prior to the effective date of the proposed change.

Section 4. Unless otherwise prohibited by federal statutes or regulations, any entity conducting a pharmacy audit shall:

(1) Give a pharmacy a minimum fourteen days written notice before conducting initial on-site audit;

(2) Conduct an audit that involves clinical or professional judgment in consultation with a licensed pharmacist; and

(3) Audit each pharmacy under the same standards and parameters as other similarly situated pharmacies.

Section 5. Unless otherwise prohibited by federal statutes or regulations, for any entity conducting a pharmacy audit the following audit items apply:

(1) The period covered by the audit may not exceed twenty-four months from the date that the claim was submitted to or adjudicated by the entity, unless a longer period is required under state or federal law;

(2) If an entity uses random sampling as a method for selecting a set of claims for examination, the sample size shall be appropriate for a statistically reliable sample. Notwithstanding any other provision, the auditing entity shall provide the pharmacy a masked list that provides a prescription number or date range that the auditing entity is seeking to audit;

(3) An on-site audit may not take place during the first five business days of the months of December and January unless the pharmacy consents;

(4) An auditor may not enter any portion of the pharmacy area where patient-specific information is available unless escorted, and to the extent possible shall remain out of sight and hearing range of the pharmacy patients;

(5) Any recoupment may not be deducted against future remittances until final completion of any appeals process and both parties have received the results of the final audit;

(6) A pharmacy benefits manager may not require information to be written on a prescription unless the information is required to be written on the prescription by state or federal law. Recoupment may be assessed for items not written on the prescription if:

(a) Additional information is required in the provider manual; or

(b) The information is required by the Food and Drug Administration; or

(c) The information is required by the drug manufacturer's product safety program; and

(d) The information in subsections (a), (b), or (c) is not readily available for the auditor

at the time of the audit;

(7) The auditing company or agent may not receive payment based on a percentage of the amount recovered. This section does not prevent the entity conducting the audit from charging or assessing the responsible party, directly or indirectly, based on amounts recouped if:

(a) The plan sponsor and the entity conducting the audit have a contract that explicitly states the percentage charge or assessment to the plan sponsor; and

(b) A commission to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

Section 6. For recoupment or chargeback, the following criteria apply:

(1) Audit parameters shall consider consumer-oriented parameters based on manufacturer listings;

(2) A pharmacy's usual and customary price for compounded medications is considered the reimbursable cost unless the pricing methodology is outlined in the provider contract;

(3) A finding of overpayment or underpayment can only be based on the actual overpayment or underpayment and not a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs;

(4) The entity conducting the audit may not use extrapolation in calculating the recoupment or penalties for audits unless required by state or federal law or regulation;

(5) Calculations of overpayments may not include dispensing fees unless:

(a) A prescription was not actually dispensed;

(b) The prescriber denied authorization;

(c) The prescription dispensed was a medication error by the pharmacy; or

(d) The identified overpayment is solely based on an extra dispensing fee;

(6) An entity may not consider any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error regarding a required document or record as fraud. However, such errors may be subject to recoupment;

(7) In the case of errors that have no actual financial harm to the patient or plan, the pharmacy benefits manager may not assess any chargebacks. Errors that are a result of the pharmacy's failing to comply with a formal corrective action plan may be subject to recovery; and

(8) Interest may not accrue during the audit period for either party. The audit period begins with the notice of the audit and ends with the final audit report.

Section 7. To validate the pharmacy record and delivery, the pharmacy may use authentic and verifiable statements or record including medication administration records of a nursing home, assisted living facility, hospital, physician, or other authorized practitioner or additional audit documentation parameters located in the provider manual. Any legal prescription that meets the requirements in this chapter may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions, including medication administration records, faxes, e-prescriptions, or documented telephone calls from the prescriber or the prescriber's agents.

Section 8. A preliminary audit report shall be delivered to the pharmacy within sixty days after the conclusion of the audit. A pharmacy shall be allowed at least forty-five days following receipt of the preliminary audit, to provide documentation to address any discrepancy found in the audit. A final audit report shall be delivered to the pharmacy within one hundred twenty days after receipt of the preliminary audit report or final appeal, whichever is later. An entity shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within forty-five days after the appeals process has been exhausted and the final audit report has been issued.

Section 9. The entity conducting the audit shall establish a written appeals process which shall

include appeals of preliminary reports and final reports.

Section 10. If contractually required, an auditing entity shall provide a copy of the claims included in the audit to the plan sponsor, and any recouped money shall be returned to the plan sponsor.

Section 11. The provisions of this Act do not apply to any investigative audit that involves fraud, willful misrepresentation, or on any audit completed by the State of South Dakota on health care programs operated by the state.

Section 12. In addition to the remedies otherwise provided for in this Act, in chapter 58-29E, or under general South Dakota law, any pharmacy subject to an audit procedure may bring a civil action to enforce the provisions of this Act and to seek damages from the pharmacy benefits manager and any person or organization representing the entity during the audit process for the violation of the provisions of this Act.

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I certify that the attached Act originated in the

SENATE as Bill No. 133

_____
Secretary of the Senate

_____
President of the Senate

Attest:

_____
Secretary of the Senate

_____
Speaker of the House

Attest:

_____
Chief Clerk

Senate Bill No. 133
File No. ____
Chapter No. _____

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Received at this Executive Office this _____ day of _____ ,

20____ at _____ M.

By _____
for the Governor

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The attached Act is hereby approved this _____ day of _____ , A.D., 20___

_____
Governor

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STATE OF SOUTH DAKOTA,
ss.
Office of the Secretary of State

Filed _____ , 20___
at _____ o'clock __ M.

_____
Secretary of State

By _____
Asst. Secretary of State