

State of South Dakota

EIGHTY-EIGHTH SESSION
LEGISLATIVE ASSEMBLY, 2013

607U0375

SENATE HEALTH AND HUMAN SERVICES ENGROSSED NO. **SB 133** - 02/04/2013

Introduced by: Senators Rave, Holien, Lederman, Lucas, Sutton, and Tidemann and
Representatives Cronin, Bartling, Hawley, Lust, Magstadt, Munsterman,
Rounds, Solum, and Tyler

1 FOR AN ACT ENTITLED, An Act to establish a pharmacy audit integrity program.

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

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

6 Section 2. Term used in this Act mean:

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

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

13 Section 3. The pharmacy benefits manager shall disclose an amendment to the pharmacy
14 audit terms in a contract between a pharmacy and a pharmacy benefits manager to the pharmacy



1 at least sixty days prior to the effective date of the proposed change.

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

- 4 (1) Give a pharmacy a minimum fourteen days written notice before conducting initial
5 on-site audit;
- 6 (2) Conduct an audit that involves clinical or professional judgment in consultation with
7 a licensed pharmacist; and
- 8 (3) Audit each pharmacy under the same standards and parameters as other similarly
9 situated pharmacies.

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

- 12 (1) The period covered by the audit may not exceed twenty-four months from the date
13 that the claim was submitted to or adjudicated by the entity, unless a longer period
14 is required under state or federal law;
- 15 (2) If an entity uses random sampling as a method for selecting a set of claims for
16 examination, the sample size shall be appropriate for a statistically reliable sample.
17 Notwithstanding any other provision, the auditing entity shall provide the pharmacy
18 a masked list that provides a prescription number or date range that the auditing
19 entity is seeking to audit;
- 20 (3) An on-site audit may not take place during the first five business days of the months
21 of December and January unless the pharmacy consents;
- 22 (4) An auditor may not enter any portion of the pharmacy area where patient-specific
23 information is available unless escorted, and to the extent possible shall remain out
24 of sight and hearing range of the pharmacy patients;

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

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

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

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

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

12 (d) The information in subsections (a), (b), or (c) is not readily available for the
13 auditor at the time of the audit;

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

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

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

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

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

- 1 (2) A pharmacy's usual and customary price for compounded medications is considered
2 the reimbursable cost unless the pricing methodology is outlined in the provider
3 contract;
- 4 (3) A finding of overpayment or underpayment can only be based on the actual
5 overpayment or underpayment and not a projection based on the number of patients
6 served having a similar diagnosis or on the number of similar orders or refills for
7 similar drugs;
- 8 (4) The entity conducting the audit may not use extrapolation in calculating the
9 recoupment or penalties for audits unless required by state or federal law or
10 regulation;
- 11 (5) Calculations of overpayments may not include dispensing fees unless:
12 (a) A prescription was not actually dispensed;
13 (b) The prescriber denied authorization;
14 (c) The prescription dispensed was a medication error by the pharmacy; or
15 (d) The identified overpayment is solely based on an extra dispensing fee;
- 16 (6) An entity may not consider any clerical or record-keeping error, such as a
17 typographical error, scrivener's error, or computer error regarding a required
18 document or record as fraud. However, such errors may be subject to recoupment;
- 19 (7) In the case of errors that have no actual financial harm to the patient or plan, the
20 pharmacy benefits manager may not assess any chargebacks. Errors that are a result
21 of the pharmacy's failing to comply with a formal corrective action plan may be
22 subject to recovery; and
- 23 (8) Interest may not accrue during the audit period for either party. The audit period
24 begins with the notice of the audit and ends with the final audit report.

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

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

17 Section 9. The entity conducting the audit shall establish a written appeals process which
18 shall include appeals of preliminary reports and final reports.

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

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

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