

1.1 moves to amend H.F. No. 1236 as follows:

1.2 Delete everything after the enacting clause and insert:

1.3 "Section 1. **[151.60] PHARMACY AUDIT INTEGRITY PROGRAM.**

1.4 The pharmacy audit integrity program is established to provide standards for an
1.5 audit of pharmacy records carried out by a pharmacy benefits manager or any entity that
1.6 represents pharmacy benefits managers.

1.7 Sec. 2. **[151.61] DEFINITIONS.**

1.8 Subdivision 1. **Scope.** For the purposes of sections 151.60 to 151.66, the following
1.9 terms have the meanings given.

1.10 Subd. 2. **Entity.** "Entity" means a pharmacy benefits manager or any person or
1.11 organization that represents these companies, groups, or organizations.

1.12 Subd. 3. **Pharmacy benefits manager or PBM.** "Pharmacy benefits manager"
1.13 or "PBM" means a person, business, or other entity that performs pharmacy benefits
1.14 management. The term includes a person or entity acting for a PBM in a contractual or
1.15 employment relationship in the performance of pharmacy benefits management.

1.16 Subd. 4. **Plan sponsor.** "Plan sponsor" means the employer in the case of an
1.17 employee benefit plan established or maintained by a single employer, a group purchaser
1.18 as defined in section 62J.03, subdivision 6, or the employee organization in the case of a
1.19 plan established or maintained by an employee organization, an association, joint board of
1.20 trustees, committee, or other similar group that establishes or maintains the plan.

1.21 Sec. 3. **[151.62] PHARMACY BENEFIT MANAGER CONTRACT.**

1.22 (a) A pharmacy benefit manager (PBM) contract that is altered or amended by that
1.23 entity may be substituted for a current contract but is not effective without the written
1.24 consent of a pharmacy. The pharmacy must receive a copy of the proposed contract

2.1 changes or renewal along with a disclosure by the PBM of all material changes in terms of
2.2 the contract or methods of reimbursement from the previous contract.

2.3 (b) An amendment or change in terms of an existing contract between a PBM and a
2.4 pharmacy must be disclosed to the pharmacy at least 120 days prior to the effective date
2.5 of the proposed change. A PBM may not alter or amend a PBM contract, or impose
2.6 any additional contractual obligation on a pharmacy, unless the PBM complies with the
2.7 requirements in this section.

2.8 Sec. 4. **[151.63] PROCEDURE AND PROCESS FOR CONDUCTING AND**
2.9 **REPORTING AN AUDIT.**

2.10 Subdivision 1. **Audit procedures.** Unless otherwise prohibited by federal
2.11 requirements or regulations, any entity conducting a pharmacy audit must follow the
2.12 following procedures.

2.13 (1) A pharmacy must be given a written notice before an initial on-site audit is
2.14 conducted.

2.15 (2) An audit that involves clinical or professional judgment must be conducted by or
2.16 in consultation with a pharmacist licensed in this state or the Board of Pharmacy.

2.17 (3) Each pharmacy shall be audited under the same standards and parameters as
2.18 other similarly situated pharmacies.

2.19 (4) If copies of records are requested by the auditing entity, they will pay the cost of
2.20 copying health records allowed under section 144.292, subdivision 6, to the pharmacy.

2.21 Subd. 2. **Audit process.** Unless otherwise prohibited by federal requirements or
2.22 regulations, for any entity conducting a pharmacy audit the following audit items apply.

2.23 (1) The period covered by the audit may not exceed 24 months from the date that the
2.24 claim was submitted to or adjudicated by the entity, unless a longer period is permitted
2.25 under federal law.

2.26 (2) If an entity uses sampling as a method for selecting a set of claims for
2.27 examination, the sample size must be appropriate for a statistically reliable sample but
2.28 may not exceed 60 prescriptions.

2.29 (3) The audit may not take place during the first seven business days of the month
2.30 due to the high volume of prescriptions filled during that time unless consented to by
2.31 the pharmacy.

2.32 (4) Auditors may not enter the pharmacy area where patient-specific information is
2.33 available and must be out of sight and hearing range of the pharmacy customers.

2.34 (5) Any recoupment will not be deducted against future remittances and shall be
2.35 invoiced to the pharmacy for payment.

3.1 (6) Recoupment may not be assessed for items on the face of a prescription not
3.2 required by the Board of Pharmacy.

3.3 (7) The auditing company or agent may not receive payment based on a percentage
3.4 of the amount recovered.

3.5 **Sec. 5. [151.64] REQUIREMENTS FOR RECOUPMENT OR CHARGEBACK.**

3.6 For recoupment or chargeback, the following criteria apply.

3.7 (1) Audit parameters must consider consumer-oriented parameters based on
3.8 manufacturer listings.

3.9 (2) A pharmacy's usual and customary price for compounded medications is
3.10 considered the reimbursable cost unless an alternate price is published in the provider
3.11 contract and signed by both parties.

3.12 (3) A finding of overpayment or underpayment must be based on the actual
3.13 overpayment or underpayment and not a projection based on the number of patients served
3.14 having a similar diagnosis or on the number of similar orders or refills for similar drugs.

3.15 (4) The entity conducting the audit shall not use extrapolation in calculating the
3.16 recoupment or penalties for audits.

3.17 (5) Calculations of overpayments must not include dispensing fees unless a
3.18 prescription was not actually dispensed or the prescriber denied authorization.

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

3.22 (7) In the case of errors that have no financial harm to the patient or plan, the PBM
3.23 must not assess any chargebacks.

3.24 (8) Interest may not accrue during the audit period, beginning with the notice of the
3.25 audit and ending with the final audit report.

3.26 **Sec. 6. [151.65] DOCUMENTATION.**

3.27 (a) The pharmacy may use the records including medication administration records
3.28 of a hospital, physician, or other authorized practitioner to validate the pharmacy record
3.29 and delivery.

3.30 (b) Any legal prescription that meets the requirements in this chapter may be used
3.31 to validate claims in connection with prescriptions, refills, or changes in prescriptions,
3.32 including medication administration records, faxes, e-prescriptions, or documented
3.33 telephone calls from the prescriber or the prescriber's agents.

4.1 Sec. 7. **[151.66] APPEALS PROCESS.**

4.2 The entity conducting the audit must establish a written appeals process which must
4.3 include appeals of preliminary reports and final reports. If either party is not satisfied with
4.4 the appeal, that party may seek mediation.

4.5 Sec. 8. **[151.67] AUDIT INFORMATION AND REPORTS.**

4.6 (a) A preliminary audit report must be delivered to the pharmacy within 30 days
4.7 after the conclusion of the audit.

4.8 (b) A pharmacy must be allowed at least 30 days following receipt of the preliminary
4.9 audit to provide documentation to address any discrepancy found in the audit.

4.10 (c) A final audit report must be delivered to the pharmacy within 90 days after
4.11 receipt of the preliminary audit report or final appeal, whichever is later.

4.12 (d) No chargeback, recoupment, or other penalties may be assessed until the appeals
4.13 process has been exhausted and the final report issued.

4.14 (e) An entity shall remit any money due to a pharmacy or pharmacist as a result of
4.15 an underpayment of a claim within 30 days after the appeals process has been exhausted
4.16 and the final audit report has been issued.

4.17 (f) Where not superseded by state or federal law, audit information may not be
4.18 shared. Auditors shall only have access to previous audit reports on a particular pharmacy
4.19 conducted by that same auditing entity.

4.20 Sec. 9. **[151.68] DISCLOSURES TO PLAN SPONSOR.**

4.21 An auditing entity must provide a copy of the final report to the plan sponsor whose
4.22 claims were included in the audit, and any recouped money shall be returned to the plan
4.23 sponsor.

4.24 Sec. 10. **[151.69] APPLICABILITY OF OTHER LAWS AND REGULATIONS.**

4.25 Sections 151.60 to 151.68 do not apply to any investigative audit that involves
4.26 fraud, willful misrepresentation, or abuse."