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# HOUSE . . . . . No. 2111

## The Commonwealth of Massachusetts

**In the Year Two Thousand Nine**

An Act regulating pharmacy audits..

*Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:*

SECTION 1. The purpose of this Act is to establish minimum and uniform standards and criteria for the audit of pharmacy records by or on behalf of certain entities.

SECTION 2. The General Laws are hereby amended by inserting after chapter 93I the following chapter:-

Chapter 93J

Regulation of Pharmacy Audits

Section 1. Definitions.

For purposes of this chapter the following terms shall have the following meanings:

"Pharmacy Benefits Manager" or "PBM" means a person, business or other entity that performs pharmacy benefits management. The term includes a person or entity acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a managed care company, non-profit hospital or medical service organization,

insurance company, third party payor, or a health program administered by an entity of the Commonwealth.

Section 2. Audit Scope and Procedures.

(a) Notwithstanding any general or special law to the contrary, an audit of the records of a pharmacy conducted by a managed care company, non profit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by any department of the commonwealth or any entity that represents such companies, groups, or department, hereafter referred to as the entity, shall follow these procedures:

(1) The pharmacy contract must identify and describe in detail the audit procedures;

(2) The entity conducting the on-site audit must give the pharmacy written notice at least two weeks prior to conducting the initial on-site audit for each audit cycle;

(3) The entity conducting the on-site audit shall not interfere with the delivery of pharmacist services to a patient and shall utilize every effort to minimize inconvenience and disruption to pharmacy operations during the audit process;

(4) Any audit which involves clinical or professional judgment must be conducted by or in consultation with a pharmacist licensed in the state;

(5) Any clerical or record-keeping error, such as a typographical error, scrivener's error, or computer error, regarding a required document or record shall not in and of itself constitute fraud; and no such claim shall be subject to criminal penalties without proof of intent to commit fraud; however, such claims may be subject to recoupment;

(6) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of the healing arts for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug;

(7) A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be 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;

(8) The entity shall not estimate audit results for unaudited prescription drug benefit claims based on a sample of such claims submitted by a pharmacy.

(9) A finding of an overpayment shall not include the dispensing fee amount;

(10) Each pharmacy shall be audited under the same standards and parameters as other similarly situated pharmacies audited by the entity;

(11) The period covered by an audit may not exceed one year from the date the claim was submitted to or adjudicated by a managed care company, non profit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a Department of the State or any entity that represents such companies, groups, or department;

(12) An audit may not be initiated or scheduled during the first seven calendar days of any month due to the high volume of prescriptions filled in the pharmacy during that time unless otherwise consented to by the pharmacy;

(13) The entity may request additional information on particular prescriptions only in person or by certified U.S. mail; and such requests shall not be made for prescriptions that have been previously audited or approved via prior authorization unless said prescription has been changed; and

(14) The auditing entity may not receive payment based on a percentage of the amount recovered.

(b) The entity must provide the pharmacy with a written report of the audit and comply with the following requirements:

(1) The preliminary audit report must be delivered to the pharmacy within 90 days after conclusion of the audit;

(2) A pharmacy shall be allowed at least 60 days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit;

(3) A final audit report shall be delivered to the pharmacy within 120 days after receipt of the preliminary audit report or final appeal, as provided for in Section 6 of this Code section, whichever is later;

(4) The audit report must be signed and include the signature of any pharmacist participating in the audit;

(5) Any recoupment of disputed funds shall only occur after final internal disposition of the audit, including the appeals process as set forth in Section 6 of this Code section;

(6) Interest shall not accrue during the audit period;

(7) A PBM shall not withhold payment to a pharmacy for reimbursement claims as a means to recoup money owed to the PBM by said pharmacy as a result of an audit; and

(8) Each entity conducting an audit shall provide a copy of the final audit report, after completion of any review process, to the plan sponsor.

Section 3. Appeal Process.

(a) Each entity conducting an audit shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(b) The National Council for Prescription Drug Programs ("NCPDP") or any other recognized national industry standard shall be used to evaluate claims submission and product size disputes.

(c) If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or said portion without the necessity of any further action.

Section 4. The provisions of this chapter shall not apply to any audit or investigation that involves alleged fraud, willful misrepresentation, or abuse, including without limitation investigative audits or any other statutory provision that authorizes investigations relating to insurance fraud.

SECTION 3. The audit criteria set forth in this Act shall apply only to audits of claims for services provided and claims submitted for payment after August 31, 2009.