

HOUSE No.

The Commonwealth of Massachusetts

PRESENTED BY:

Peter J. Koutoujian

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act regulating pharmacy audits.

PETITION OF:

NAME:

Peter J. Koutoujian

DISTRICT/ADDRESS:

10th Middlesex

The Commonwealth of Massachusetts

In the Year Two Thousand and 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:

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

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

Chapter 93J

Regulation of Pharmacy Audits

7 Section 1. Definitions.

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

9 “Pharmacy Benefits Manager” or “PBM” means a person, business or other entity that performs
10 pharmacy benefits management. The term includes a person or entity acting for a PBM in a
11 contractual or employment relationship in the performance of pharmacy benefits management
12 for a managed care company, non-profit hospital or medical service organization, insurance
13 company, third party payor, or a health program administered by an entity of the
14 Commonwealth.

15 Section 2. Audit Scope and Procedures.

16 (a) Notwithstanding any general or special law to the contrary, an audit of the records of a
17 pharmacy conducted by a managed care company, non profit hospital or medical service
18 organization, insurance company, third-party payor, pharmacy benefit manager, a health program

19 administered by any department of the commonwealth or any entity that represents such
20 companies, groups, or department, hereafter referred to as the entity, shall follow these
21 procedures:

- 22 (1) The pharmacy contract must identify and describe in detail the audit procedures;
- 23 (2) The entity conducting the on-site audit must give the pharmacy written notice at least two
24 weeks prior to conducting the initial on-site audit for each audit cycle;
- 25 (3) The entity conducting the on-site audit shall not interfere with the delivery of pharmacist
26 services to a patient and shall utilize every effort to minimize inconvenience and disruption to
27 pharmacy operations during the audit process;
- 28 (4) Any audit which involves clinical or professional judgment must be conducted by or in
29 consultation with a pharmacist licensed in the state;
- 30 (5) Any clerical or record-keeping error, such as a typographical error, scrivener's error, or
31 computer error, regarding a required document or record shall not in and of itself constitute
32 fraud; and no such claim shall be subject to criminal penalties without proof of intent to commit
33 fraud; however, such claims may be subject to recoupment;
- 34 (6) A pharmacy may use the records of a hospital, physician, or other authorized practitioner of
35 the healing arts for drugs or medicinal supplies written or transmitted by any means of
36 communication for purposes of validating the pharmacy record with respect to orders or refills of
37 a legend or narcotic drug;
- 38 (7) A finding of an overpayment or underpayment must be based on the actual overpayment or
39 underpayment and may not be a projection based on the number of patients served having a
40 similar diagnosis or on the number of similar orders or refills for similar drugs;
- 41 (8) The entity shall not estimate audit results for unaudited prescription drug benefit claims based
42 on a sample of such claims submitted by a pharmacy.
- 43 (9) A finding of an overpayment shall not include the dispensing fee amount;
- 44 (10) Each pharmacy shall be audited under the same standards and parameters as other similarly
45 situated pharmacies audited by the entity;
- 46 (11) The period covered by an audit may not exceed one year from the date the claim was
47 submitted to or adjudicated by a managed care company, non profit hospital or medical service
48 organization, insurance company, third-party payor, pharmacy benefit manager, a health program
49 administered by a Department of the State or any entity that represents such companies, groups,
50 or department;

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

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

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

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

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

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

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

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

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

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

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

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

78 Section 3. Appeal Process.

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

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

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

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

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