

SENATE No. 483

The Commonwealth of Massachusetts

PRESENTED BY:

Michael J. Rodrigues

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 adoption of the accompanying bill:

An Act regulating pharmacy audits.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Michael J. Rodrigues	First Bristol and Plymouth
Bruce E. Tarr	First Essex and Middlesex
Gale D. Candaras	First Hampden and Hampshire
Robert M. Koczera	11th Bristol
Paul A. Schmid, III	8th Bristol
Alan Silvia	7th Bristol
Paul McMurtry	11th Norfolk
Thomas J. Calter	12th Plymouth
James J. Lyons, Jr.	18th Essex
Kimberly N. Ferguson	1st Worcester
James M. Murphy	4th Norfolk
William N. Brownsberger	Second Suffolk and Middlesex
Antonio F. D. Cabral	13th Bristol
Frank I. Smizik	15th Norfolk
Carolyn C. Dykema	8th Middlesex
Timothy R. Madden	Barnstable, Dukes and Nantucket
Kevin J. Murphy	18th Middlesex
Eileen M. Donoghue	First Middlesex

<i>Michael O. Moore</i>	<i>Second Worcester</i>
<i>Thomas M. McGee</i>	<i>Third Essex</i>
<i>Patricia A. Haddad</i>	<i>5th Bristol</i>
<i>Bradley H. Jones, Jr.</i>	<i>20th Middlesex</i>
<i>Sheila C. Harrington</i>	<i>1st Middlesex</i>
<i>Alice Hanlon Peisch</i>	<i>14th Norfolk</i>
<i>Kay Khan</i>	<i>11th Middlesex</i>
<i>Thomas A. Golden, Jr.</i>	<i>16th Middlesex</i>

SENATE No. 483

By Mr. Rodrigues, a petition (accompanied by bill, Senate, No. 483) of Michael J. Rodrigues, Bruce E. Tarr, Gale D. Candaras, Robert M. Koczera and other members of the General Court for legislation to regulate pharmacy audits. Financial Services.

[SIMILAR MATTER FILED IN PREVIOUS SESSION
SEE SENATE, NO. 458 OF 2011-2012.]

The Commonwealth of Massachusetts

In the Year Two Thousand Thirteen

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
2 criteria 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 175K the
4 following chapter:-

5 Chapter 175L

6 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", any person or entity that administers the prescription
10 drug, prescription device, pharmacist services or prescription drug and device and pharmacist
11 services portion of a health benefit plan on behalf of plan sponsors such as self-insured
12 employers, insurance companies, and labor unions. A health benefit plan that does not contract
13 with a pharmacy benefit manager shall be considered a pharmacy benefit manager for the

14 purposes of this chapter unless specifically exempted. The provisions of this chapter shall not
15 apply to a public health care payer as defined in section 1 of chapter 118G.

16 "Commissioner", the commissioner of insurance or his designee.

17 Section 2. Certification of Pharmacy Benefits Managers

18 (a) Except as provided in subsection (d) of this section, no person shall act as a pharmacy
19 benefits manager without first obtaining a certificate of registration from the commissioner.

20 (b) Any person seeking a certificate of registration shall apply to the commissioner, in
21 writing, on a form provided by the commissioner. The application form shall state (1) the
22 name, address, official position and professional qualifications of each individual responsible for
23 the conduct of the affairs of the pharmacy benefits manager, including all members of the board
24 of directors, board of trustees, executive committee, other governing board or committee, the
25 principal officers in the case of a corporation, the partners or members in the case of a
26 partnership or association and any other person who exercises control or influence over the
27 affairs of the pharmacy benefits manager, and (2) the name and address of the applicant's agent
28 for service of process in the Commonwealth.

29 (c) Each application for a certificate of registration shall be accompanied by a
30 nonrefundable fee set by the Commissioner of no less than five hundred dollars.

31 (d) A health benefit plan that does not contract with a pharmacy benefit manager shall not
32 be required to obtain a certificate of registration. Such health benefit plan shall notify the
33 commissioner annually, in writing that it is affiliated with or operating a business as a pharmacy
34 benefits manager.

35 (e) Any person acting as a pharmacy benefits manager on January 1, 2014, and required
36 to obtain a certificate of registration under subsection (a) of this section, shall obtain a certificate
37 of registration from the commissioner not later than April 1, 2014.

38 Section 3. Audit Scope and Procedures.

39 (a) Notwithstanding any general or special law to the contrary, an audit of the records of
40 a pharmacy conducted by a pharmacy benefit manager shall follow these procedures:

41 (1) The contract between a pharmacy and a pharmacy benefit manager shall identify and
42 describe in detail the audit procedures.

43 (2) With the exception of an investigative fraud audit, the auditor shall give the pharmacy
44 written notice at least two weeks prior to conducting the initial on-site audit for each audit cycle.

45 (3) A PBM cannot audit claims beyond 2 years prior to the date of audit.

46 (4) The auditor shall not interfere with the delivery of pharmacist services to a patient and
47 shall make a reasonable effort to minimize the inconvenience and disruption to the pharmacy
48 operations during the audit process.

49 (5) Any audit which involves clinical or professional judgment shall be conducted by or
50 in consultation with a licensed pharmacist from any state.

51 (6) A finding of an overpayment or underpayment shall be based on the actual
52 overpayment or underpayment. A statistically sound extrapolation for overpayment or
53 underpayment may be used to determine recoupment as part of a settlement as agreed to by the
54 pharmacy.

55 (7) Each pharmacy shall be audited under the same standards and parameters as other
56 similarly situated pharmacies audited by the entity.

57 (8) An audit may not be initiated or scheduled during the first five calendar days of
58 any month due to the high volume of prescriptions filled in the pharmacy during that time
59 unless otherwise consented to by the pharmacy.

60 (9) A preliminary audit report shall be delivered to the pharmacy no later than 45 days
61 after the conclusion of the audit.

62 (10) The audit report shall be signed and shall include the signature of any pharmacist
63 participating in the audit.

64 (11) A pharmacy benefit manager shall not withhold payment to a pharmacy for
65 reimbursement claims as a means to recoup money owed to the pharmacy benefit manager as a
66 result of an audit.

67 (12) The auditor shall provide a copy of the final audit report within 30 days following
68 the receipt of the signed preliminary audit report or the completion of the appeals process, as
69 provided for in section 4, whichever is later, to the pharmacy and plan sponsor.

70 Section 4. Appeal Process.

71 (a) Each auditor shall establish an appeals process under which a pharmacy may appeal
72 findings in a preliminary audit;

73 (b) To appeal a finding, a pharmacy may use the records of a hospital, physician, or other
74 authorized prescriber to validate the record with respect to orders or refills of prescription drugs
75 or devices;

76 (c) A pharmacy shall have 30 days to address any discrepancy found during the
77 preliminary audit.

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

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

84 Section 5. The provisions of this chapter shall not apply to any audit or investigation that
85 involves potential fraud, willful misrepresentation, or abuse, including, but not limited to,
86 investigative audits or any other statutory or regulatory provision that authorizes
87 investigations relating to insurance fraud.

88 Section 6. The commissioner may promulgate regulations to enforce the provisions of
89 this chapter.

90 SECTION 3. The audit criteria set forth in this chapter shall apply only to conducted after
91 January 1, 2014.