

**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 passage of the accompanying bill:

An Act regulating pharmacy audits.

PETITION OF:

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

<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>

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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.

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

The Commonwealth of Massachusetts

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**In the Year Two Thousand Thirteen**  
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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.