

**SENATE . . . . . No. 458**

---

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:
<i>Michael J. Rodrigues</i>	
<i>Susan C. Fargo</i>	
<i>Michael R. Knapik</i>	
<i>Walter F. Timilty</i>	<i>7th Norfolk</i>
<i>Kevin Aguiar</i>	<i>7th Bristol</i>
<i>F. Jay Barrows</i>	<i>1st Bristol</i>
<i>Paul A. Schmid, III</i>	<i>8th Bristol</i>

**SENATE . . . . . No. 458**

---

---

By Mr. Rodrigues, a petition (accompanied by bill, Senate, No. 458) of Michael J. Rodrigues, Susan C. Fargo, Michael R. Knapik, Walter F. Timilty and other members of the General Court for legislation to regulate pharmacy audits. Financial Services.

---

---

The Commonwealth of Massachusetts

—————  
**In the Year Two Thousand Eleven**  
—————

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 name,  
22 address, official position and professional qualifications of each individual responsible for the  
23 conduct of the affairs of the pharmacy benefits manager, including all members of the board of  
24 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, 2011, 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, 2011.

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  
42 and describe in detail the audit procedures;

43 (2) The auditor shall give the pharmacy written notice at least one week prior to  
44 conducting the initial on-site audit for each audit cycle;

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

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

50 (5) A pharmacy may use the records of a hospital, physician, or other authorized  
51 prescriber to validate the record with respect to orders or refills of prescription drugs or devices.

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

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

57 (12) 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 unless  
59 otherwise consented to by the pharmacy;

60 (b) The auditor shall provide the pharmacy with a written report of the audit.

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

63 (11) A pharmacy benefit manager shall not withhold payment to a pharmacy for  
64 reimbursement claims as a means to recoup money owed to the pharmacy benefit manager by  
65 said pharmacy as a result of an audit unless an identified discrepancy for a preliminary audit  
66 exceeds \$25,000.

67 (12) The auditor shall provide a copy of the final audit report, after completion of any  
68 review process, to the plan sponsor.

69 Section 4. Appeal Process.

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

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

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

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

82 Section 6. The commissioner may promulgate regulations to enforce the provisions of  
83 this chapter including, but not limited to, oversight of the following audit practices:

84 (a) The number of days by which a preliminary audit report shall be delivered to the  
85 pharmacy after conclusion of the audit.

86 (b) The number of days by which a pharmacy shall be allowed to address any  
87 discrepancy found during the preliminary audit;

88 (c) The number of days by which a final audit report shall be delivered to the pharmacy  
89 after receipt of the preliminary audit report or final appeal, as provided for in section 4,  
90 whichever is later;

91 (d) The means by which a pharmacy benefit manager may request information from a  
92 pharmacy.

93 SECTION 3. The audit criteria set forth in this chapter shall apply only to audits of  
94 claims for services provided and claims submitted for payment after April 1, 2011.