

HOUSE No. 4804

The Commonwealth of Massachusetts

In the Year Two Thousand Ten

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 drug,
10 prescription device, pharmacist services or prescription drug and device and pharmacist services
11 portion of a health benefit plan on behalf of plan sponsors such as self-insured employers,
12 insurance companies, and labor unions. A health benefit plan that does not contract with a

13 pharmacy benefit manager shall be considered a pharmacy benefit manager for the purposes of
14 this chapter unless specifically exempted. The provisions of this chapter shall not apply to a
15 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
20 commissioner. (b) Any person seeking a certificate of registration shall apply to the
21 commissioner, in writing, on a form provided by the commissioner. The application form shall
22 state (1) the name, address, official position and professional qualifications of each individual
23 responsible for the conduct of the affairs of the pharmacy benefits manager, including all
24 members of the board of directors, board of trustees, executive committee, other governing board
25 or committee, the principal officers in the case of a corporation, the partners or members in the
26 case of a partnership or association and any other person who exercises control or influence over
27 the affairs of the pharmacy benefits manager, and (2) the name and address of the applicant's
28 agent for service of process in the Commonwealth.(c) Each application for a certificate of
29 registration shall be accompanied by a nonrefundable fee set by the Commissioner of no less
30 than five hundred dollars. (d) A health benefit plan that does not contract with a pharmacy
31 benefit manager shall not be required to obtain a certificate of registration. Such health benefit
32 plan shall notify the commissioner annually, in writing that it is affiliated with or operating a
33 business as a pharmacy benefits manager.(e) Any person acting as a pharmacy benefits manager
34 on January 1, 2011, and required to obtain a certificate of registration under subsection (a) of this

35 section, shall obtain a certificate of registration from the commissioner not later than April 1,
36 2011.

37 Section 3. Audit Scope and Procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

68 Section 4. Appeal Process.

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

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

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

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

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

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

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

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

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

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