



Senate

General Assembly

File No. 9

February Session, 2014

Senate Bill No. 14

Senate, March 11, 2014

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT CONCERNING PHARMACY AUDITS AND ELECTRONIC FUNDS TRANSFER PAYMENTS TO PHARMACIES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

1 Section 1. (NEW) (*Effective October 1, 2014*) (a) As used in this
2 section:

3 (1) "Extrapolation" means the practice of inferring a frequency of
4 dollar amount of overpayments, underpayments, nonvalid claims or
5 other errors on any portion of claims submitted, based on the
6 frequency or dollar amount of overpayments, underpayments,
7 nonvalid claims or other errors actually measured in a sample of
8 claims;

9 (2) "Pharmacy audit" means an audit, conducted on-site or remotely
10 by or on behalf of a pharmacy benefits manager or plan sponsor of any
11 records of a pharmacy for prescription drugs or prescription devices
12 dispensed by such pharmacy to beneficiaries of a health benefit plan.
13 "Pharmacy audit" does not include (A) a concurrent review or desk

14 audit that occurs within three business days of the pharmacy's
15 transmission of a claim to a pharmacy benefits manager or plan
16 sponsor, or (B) a concurrent review or desk audit where no charge-
17 back or recoupment is demanded by the pharmacy benefits manager
18 or plan sponsor;

19 (3) "Plan sponsor" has the same meaning as described in section 38a-
20 479aaa of the general statutes, as amended by this act.

21 (b) (1) No entity other than a pharmacy benefits manager or a plan
22 sponsor shall conduct a pharmacy audit unless such entity and
23 manager or sponsor, as applicable, have executed a written agreement
24 for the conducting of pharmacy audits. Prior to conducting a
25 pharmacy audit on behalf of such manager or sponsor, such entity
26 shall notify the pharmacy in writing that such entity and manager or
27 sponsor, as applicable, have executed such agreement.

28 (2) Any entity conducting a pharmacy audit shall have access only
29 to previous pharmacy audit reports of that particular pharmacy
30 conducted by or on behalf of such entity. Nothing in this subdivision
31 shall be construed to authorize access to any information that is
32 confidential or prohibited from disclosure by law.

33 (3) Any information collected during a pharmacy audit shall be
34 confidential by law, except that the entity conducting the pharmacy
35 audit may share such information with the pharmacy benefits manager
36 and the plan sponsor, for which such pharmacy audit is being
37 conducted.

38 (4) No entity conducting a pharmacy audit shall receive payment or
39 any other consideration on any basis that is based on the amount
40 claimed or the actual amount recouped from the pharmacy being
41 audited.

42 (c) (1) Any entity conducting a pharmacy audit shall:

43 (A) Provide the pharmacy being audited at least fourteen calendar
44 days' prior written notice before conducting a pharmacy audit;

45 (B) Not initiate or schedule a pharmacy audit during the first five
46 business days of any month, unless expressly agreed to by the
47 pharmacy being audited;

48 (C) Make all determinations regarding the validity of a prescription
49 or other record consistent with sections 20-612 to 20-623, inclusive, of
50 the general statutes;

51 (D) Accept paper or electronic signature logs that document the
52 delivery of prescription drug and device and pharmacist services to a
53 health plan beneficiary or such beneficiary's agent;

54 (E) Provide to the pharmacist in charge, prior to leaving the
55 pharmacy at the conclusion of an on-site portion of a pharmacy audit,
56 a complete list of records reviewed; and

57 (F) Establish a process for a pharmacy to appeal a final pharmacy
58 audit report, including a time period for filing such appeal that is not
59 less than thirty calendar days after a pharmacy receives such final
60 report, and disclose such procedures and time period to the pharmacy
61 being audited.

62 (2) Any pharmacy audit that involves clinical judgment shall be
63 conducted by or in consultation with a licensed pharmacist.

64 (3) No pharmacy audit shall cover a period of more than twenty-
65 four months after the date a claim was submitted by the pharmacy to
66 the pharmacy benefits manager or plan sponsor unless a longer period
67 is required by law.

68 (d) (1) (A) Not later than sixty calendar days after an entity
69 concludes a pharmacy audit and before such entity issues a final
70 pharmacy audit report, such entity shall provide a preliminary
71 pharmacy audit report to the pharmacy. Such entity shall provide such
72 pharmacy with not less than thirty calendar days after such pharmacy
73 receives such preliminary report to respond to the findings in such
74 report, including addressing any alleged mistakes or discrepancies and
75 producing documentation to that effect.

76 (B) To validate the pharmacy record and delivery, a pharmacy may
77 use authentic and verifiable statements or records, including, but not
78 limited to, medication administration records of a nursing home,
79 assisted living facility, hospital or health care provider with
80 prescriptive authority.

81 (C) To validate claims in connection with prescriptions or changes
82 in prescriptions, or refills of prescription drugs, a pharmacy may use
83 any valid prescription, including, but not limited to, medication
84 administration records, facsimiles, electronic prescriptions,
85 electronically stored images of prescriptions, electronically created
86 annotations or documented telephone calls from the prescribing health
87 care provider or such provider's agent. Documentation of an oral
88 prescription order that has been verified by the prescribing health care
89 provider shall meet the provisions of this subparagraph.

90 (D) If an entity conducting a pharmacy audit uses extrapolation to
91 calculate penalties or amounts to be charged back or recouped, the
92 pharmacy may present evidence to validate orders for prescription
93 drugs or prescription devices that are subject to invalidation due to
94 extrapolation.

95 (2) (A) Not later than one hundred twenty calendar days after any
96 responses from the pharmacy under subdivision (1) of this subsection
97 are received by the entity conducting the pharmacy audit or, if no such
98 responses are received, after the entity concludes a pharmacy audit,
99 such entity shall issue a final pharmacy audit report that takes into
100 consideration any responses provided to such entity by the pharmacy.

101 (B) A pharmacy may appeal a final pharmacy audit report in
102 accordance with the procedures established by the entity conducting
103 the pharmacy audit.

104 (C) After an appeal under subparagraph (B) of this subdivision has
105 been decided, the entity that issued the final pharmacy audit report
106 shall provide a written determination of the appeal together with the
107 final pharmacy audit report to the pharmacy and, if applicable, the

108 pharmacy benefits manager and the plan sponsor. If the pharmacy,
109 pharmacy benefits manager or plan sponsor is not satisfied with such
110 determination, such pharmacy, manager or sponsor may seek relief
111 pursuant to the terms of the contract between such pharmacy and such
112 manager or sponsor.

113 (e) (1) No pharmacy shall be subject to charge-back or recoupment
114 for a clerical or recordkeeping error in a required document or record,
115 including a typographical error, scrivener's error or computer error,
116 unless such error resulted in actual financial harm to the pharmacy
117 benefits manager, plan sponsor or a plan beneficiary.

118 (2) No entity conducting a pharmacy audit or person acting on
119 behalf of such entity shall charge-back or recoup, attempt to charge-
120 back or recoup, or assess or collect penalties from a pharmacy until the
121 time period to file an appeal of a final pharmacy audit report has
122 passed or the appeals process has been exhausted, whichever is later. If
123 an identified discrepancy in a pharmacy audit exceeds thirty thousand
124 dollars, future payments to the pharmacy in excess of such amount
125 may be withheld pending adjudication of an appeal. No interest shall
126 accrue for any party during the audit period, beginning with the notice
127 of the pharmacy audit and ending with the conclusion of the appeals
128 process.

129 (f) The provisions of this section shall not apply to a pharmacy audit
130 conducted because a pharmacy benefits manager, a plan sponsor, an
131 entity acting on behalf of such manager or sponsor or an employer
132 covered under a health benefit plan has indications that support a
133 reasonable suspicion that the pharmacy being audited is or has been
134 engaged in criminal wrongdoing, wilful misrepresentation or fraud.

135 Sec. 2. Section 38a-479aaa of the general statutes is repealed and the
136 following is substituted in lieu thereof (*Effective October 1, 2014*):

137 As used in this section and sections 38a-479bbb to 38a-479hhh,
138 inclusive, as amended by this act, and section 1 of this act:

- 139 (1) "Commissioner" means the Insurance Commissioner;
- 140 (2) "Department" means the Insurance Department;
- 141 (3) "Drug" means drug, as defined in section 21a-92;
- 142 (4) "Person" means person, as defined in section 38a-1;
- 143 (5) "Pharmacist services" includes (A) drug therapy and other
144 patient care services provided by a licensed pharmacist intended to
145 achieve outcomes related to the cure or prevention of a disease,
146 elimination or reduction of a patient's symptoms, and (B) education or
147 intervention by a licensed pharmacist intended to arrest or slow a
148 disease process;
- 149 (6) "Pharmacist" means an individual licensed to practice pharmacy
150 under section 20-590, 20-591, 20-592 or 20-593, and who is thereby
151 recognized as a health care provider by the state of Connecticut;
- 152 (7) "Pharmacy" means a place of business where drugs may be sold
153 at retail and for which a pharmacy license has been issued to an
154 applicant pursuant to section 20-594; and
- 155 (8) "Pharmacy benefits manager" or "manager" means any person
156 that administers the prescription drug, prescription device, pharmacist
157 services or prescription drug and device and pharmacist services
158 portion of a health benefit plan on behalf of plan sponsors such as self-
159 insured employers, insurance companies, labor unions and health care
160 centers.
- 161 Sec. 3. Section 38a-479bbb of the general statutes is repealed and the
162 following is substituted in lieu thereof (*Effective October 1, 2014*):
- 163 (a) Except as provided in subsection (d) of this section, no person
164 shall act as a pharmacy benefits manager in this state without first
165 obtaining a certificate of registration from the commissioner.
- 166 (b) Any person seeking a certificate of registration shall apply to the
167 commissioner, in writing, on a form provided by the commissioner.

168 The application form shall state (1) the name, address, official position
169 and professional qualifications of each individual responsible for the
170 conduct of the affairs of the pharmacy benefits manager, including all
171 members of the board of directors, board of trustees, executive
172 committee, other governing board or committee, the principal officers
173 in the case of a corporation, the partners or members in the case of a
174 partnership or association and any other person who exercises control
175 or influence over the affairs of the pharmacy benefits manager, and (2)
176 the name and address of the applicant's agent for service of process in
177 this state.

178 (c) Each application for a certificate of registration shall be
179 accompanied by (1) a nonrefundable fee of fifty dollars, and (2)
180 evidence of a surety bond in an amount equivalent to ten per cent of
181 one month of claims in this state over a twelve-month average, except
182 that such bond shall not be less than twenty-five thousand dollars or
183 more than one million dollars.

184 (d) Any pharmacy benefits manager operating as a line of business
185 or affiliate of a health insurer, health care center, hospital service
186 corporation, medical service corporation or fraternal benefit society
187 licensed in this state or any affiliate of such health insurer, health care
188 center, hospital service corporation, medical service corporation or
189 fraternal benefit society shall not be required to obtain a certificate of
190 registration. Such health insurer, health care center, hospital service
191 corporation, medical service corporation or fraternal benefit society
192 shall notify the commissioner annually, in writing, on a form provided
193 by the commissioner, that it is affiliated with or operating a business as
194 a pharmacy benefits manager.

195 [(e) Any person acting as a pharmacy benefits manager on January
196 1, 2008, and required to obtain a certificate of registration under
197 subsection (a) of this section, shall obtain a certificate of registration
198 from the commissioner not later than April 1, 2008, in order to
199 continue to do business in this state.]

200 Sec. 4. Section 38a-479eee of the general statutes is repealed and the

201 following is substituted in lieu thereof (*Effective October 1, 2014*):

202 [The commissioner may conduct investigations and hold hearings
203 on any matter under the provisions of sections 38a-479aaa to 38a-
204 479hhh, inclusive. The commissioner may issue subpoenas, administer
205 oaths, compel testimony and order the production of books, records
206 and documents. If any person refuses to appear, to testify or to
207 produce any book, record, paper or document when so ordered, upon
208 application of the commissioner, a judge of the Superior Court may
209 make such order as may be appropriate to aid in the enforcement of
210 this section.] Upon written request from a pharmacy, a pharmacy
211 benefits manager shall pay claims to such pharmacy by electronic
212 funds transfer. Any such payments shall be made within the time
213 periods specified under subparagraph (B) of subdivision (15) of section
214 38a-816.

215 Sec. 5. Section 38a-479hhh of the general statutes is repealed and the
216 following is substituted in lieu thereof (*Effective October 1, 2014*):

217 (a) The commissioner may conduct investigations and hold hearings
218 on any matter under the provisions of sections 38a-479aaa to 38a-
219 479hhh, inclusive, as amended by this act, and section 1 of this act. The
220 commissioner may issue subpoenas, administer oaths, compel
221 testimony and order the production of books, records and documents.
222 If any person refuses to appear, to testify or to produce any book,
223 record, paper or document when so ordered, upon application of the
224 commissioner, a judge of the Superior Court may make such order as
225 may be appropriate to aid in the enforcement of this section.

226 (b) Any person aggrieved by an order or decision of the
227 commissioner under sections 38a-479aaa to 38a-479hhh, inclusive, as
228 amended by this act, or section 1 of this act may appeal therefrom in
229 accordance with the provisions of section 4-183.

This act shall take effect as follows and shall amend the following sections:

| | | |
|-----------|------------------------|-------------|
| Section 1 | <i>October 1, 2014</i> | New section |
| Sec. 2 | <i>October 1, 2014</i> | 38a-479aaa |
| Sec. 3 | <i>October 1, 2014</i> | 38a-479bbb |
| Sec. 4 | <i>October 1, 2014</i> | 38a-479eee |
| Sec. 5 | <i>October 1, 2014</i> | 38a-479hhh |

INS *Joint Favorable*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note**State Impact:** None**Municipal Impact:** None**Explanation**

This bill concerns the auditing and methods of payment of pharmacies. As this concerns the relations between private payers, auditing entities and private pharmacies, there is no state or municipal impact.

The Out Years**State Impact:** None**Municipal Impact:** None

OLR Bill Analysis**SB 14*****AN ACT CONCERNING PHARMACY AUDITS AND ELECTRONIC FUNDS TRANSFER PAYMENTS TO PHARMACIES.*****SUMMARY:**

This bill prescribes how and by whom pharmacy audits can be conducted. It specifies the duties of the auditing entity and how pharmacies can validate their records. It requires the auditing entity to give the audited pharmacy preliminary and final reports, and allows the pharmacy to appeal the final report. It limits when a pharmacy can be subjected to a charge-back or recoupment.

Under the bill, any information collected during an audit is confidential, but the auditing entity may share it with the pharmacy benefits manager (PBM) and the health insurance plan sponsor (e.g., an insurer or self-insured employer) for whom the audit is conducted. It bars the auditing entity from receiving payment or other consideration based on the amount claimed or actually recouped from the audited pharmacy.

The bill does not apply to audits conducted because a PBM, plan sponsor, an entity acting on their behalf, or an employer covered under a health benefit plan has indications that support a reasonable suspicion that a pharmacy being audited is or has been engaged in criminal wrongdoing, willful misrepresentation, or fraud.

The bill allows the insurance commissioner to conduct investigations and hold hearings in connection with pharmacy audits. He may issue subpoenas, administer oaths, compel testimony, and order production of books, records, and documents. If any person refuses to appear, testify, or produce any book, record, paper or document when ordered, a Superior Court judge may make

appropriate orders upon the commissioner's application.

The bill allows anyone aggrieved by the commissioner's order or decision to appeal to the courts and makes related minor and technical changes.

The bill also requires a PBM, upon a pharmacy's written request, to pay claims to the pharmacy by electronic funds transfer. The payment must be made within 20 days if the claim was filed electronically and within 60 days if it was filed on paper.

EFFECTIVE DATE: October 1, 2014

PHARMACY AUDITS

Under the bill, a pharmacy audit is one conducted of any pharmacy's records for prescription drugs or prescription devices it dispenses to a health insurance plan's beneficiaries. The audit can be conducted on-site or remotely by, or on behalf of, a PBM or health insurance plan sponsor.

The bill does not apply to a concurrent review or desk audit (1) that occurs within three business days of the pharmacy's transmitting a claim to a PBM or plan sponsor or (2) where the PBM or plan sponsor does not demand a charge-back or recoupment. The scope of a pharmacy audit is limited to the 24-month period after the date the pharmacy submitted claim to the PBM or plan sponsor, unless a longer period is required by law.

The bill bars any entity other than a PBM or a plan sponsor from conducting a pharmacy audit unless the auditing entity and manager or sponsor, as applicable, have a written agreement on how the audits will be conducted. Before conducting an audit on the manager's or sponsor's behalf, the entity must notify the pharmacy in writing that it and the manager or sponsor have executed the agreement.

DUTIES OF AUDITING ENTITY

Under the bill, an auditing entity must:

1. give a pharmacy at least 14 calendar days' written notice before conducting an audit;
2. initiate or schedule an audit during the first five business days of any month only if the audited pharmacy expressly agrees;
3. determine the validity of a prescription or other record according to the laws governing the dispensing of prescriptions;
4. accept paper or electronic signature logs documenting delivery of prescription drugs, devices, and pharmacist services to a health plan beneficiary or his or her agent;
5. give the pharmacist in charge a complete list of records reviewed before leaving the pharmacy at the end of an on-site portion of an audit; and
6. establish a process for a pharmacy to appeal the final audit report and disclose the appeal process and time limits to the audited pharmacy.

In addition, a licensed pharmacist must conduct or be consulted in conducting any audit that involves clinical judgment. Under the bill, an auditing entity may access only previous audit reports of the audited pharmacy conducted by or on behalf of the same entity. The bill does not authorize access to any information that is confidential or prohibited from disclosure by law.

VALIDATING RECORDS

Under the bill, a pharmacy may use authentic and verifiable statements or records to validate the pharmacy record and delivery. These records can include, among other things, medication administration records of a nursing home, assisted living facility, hospital, or a health care provider authorized to write prescriptions.

A pharmacy may use any valid prescription to validate claims in connection with prescriptions, changes in prescriptions, or refills of prescription drugs. These can include, among other things, medication

administration records, faxes, electronic prescriptions, electronically stored images of prescriptions, electronically created annotations, or documented telephone calls from the prescribing health care provider or his or her agent. The pharmacy may also use documentation of an oral prescription order if the documentation is verified by the prescribing health care provider.

If an entity conducting an audit uses extrapolation (sampling records) to calculate penalties or amounts to be charged back or recouped, the pharmacy may present evidence to validate orders for prescription drugs or prescription devices subject to invalidation due to this method. Under the bill, “extrapolation” is the practice of inferring a frequency or dollar amounts of overpayments, underpayments, nonvalid claims, or other errors on any portion of claims submitted, based on the frequency or dollar amount actually measured in a sample of claims.

REPORTS AND APPEAL

The auditing entity must give the pharmacy a preliminary report within 60 calendar days after it concludes a pharmacy audit and before it issues a final audit report. The entity must give the pharmacy at least 30 calendar days after it receives the preliminary report to respond to the auditing entity’s findings, including any alleged mistakes or discrepancies, and produce documentation to that effect.

The entity must issue a final audit report that considers any responses the pharmacy provides, within either 120 calendar days after it receives any pharmacy response or, if none is received, after the entity concludes the audit. A pharmacy may appeal a final audit report according to procedures established by the entity.

After an appeal is decided, the entity that issued the final audit report must provide a written determination of the appeal together with the final audit report to the pharmacy and, if applicable, the PBM and the plan sponsor. If the pharmacy, PBM, or plan sponsor is not satisfied with the determination, it can seek relief under the terms of

the contract between the pharmacy and the PBM or sponsor.

CHARGE-BACKS AND RECOUPMENT

The bill bars the auditing entity or a person acting on its behalf from (1) imposing a charge-back or recoupment, (2) attempting to charge back or recoup, or (3) assessing or collecting penalties from a pharmacy until the deadline for appealing a final audit report has passed or the appeals process is exhausted, whichever is later. If an identified discrepancy in an audit exceeds \$30,000, a provider may withhold future payments to the pharmacy in excess of that amount pending adjudication of an appeal. No interest may accrue for any party during the audit period, beginning with the notice of the audit and ending with the conclusion of the appeals process.

The bill also bars a charge-back or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical, scrivener's, or computer error, unless the error causes financial harm to the PBM, plan sponsor, or a plan beneficiary.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable

Yea 16 Nay 3 (02/25/2014)