



## 98TH GENERAL ASSEMBLY

### State of Illinois

2013 and 2014

HB5987

by Rep. Brandon W. Phelps

#### SYNOPSIS AS INTRODUCED:

New Act

Creates the Audits of Pharmacy Benefits Act. Imposes a number of requirements on audits of pharmacy services conducted pursuant to a contract entered into by the pharmacy and the auditing entity on behalf of a health carrier or a pharmacy benefits manager. Requires the entity conducting a pharmacy audit to deliver a preliminary audit report to the pharmacy and to give the pharmacy an opportunity to respond to the report prior to issuing a final audit report. Provides that the entity is also required to implement a process for appealing the findings of the final audit report, and further provides that if either party is unsatisfied with the appeal, that party may seek relief under the terms of the contract. Establishes a number of requirements that the auditing entity must follow when calculating the amounts and penalties that are to be recovered from the pharmacy based on the audit report, and prohibits the entity from receiving payment on any basis tied to the amount claimed or recovered from the pharmacy. Effective immediately.

LRB098 14528 ZMM 49287 b

1 AN ACT concerning regulation.

2 **Be it enacted by the People of the State of Illinois,**  
3 **represented in the General Assembly:**

4 Section 1. Short title. This Act may be cited as the Audits  
5 of Pharmacy Benefits Act.

6 Section 5. Definitions. As used in this Act:

7 "Clerical or recordkeeping error" includes a typographical  
8 error, scrivener's error, or computer error in a required  
9 document or record.

10 "Extrapolation" means the practice of inferring a  
11 frequency or dollar amount of overpayments, underpayments,  
12 nonvalid claims, or other errors on any portion of claims  
13 submitted, based on the frequency or dollar amount of  
14 overpayments, underpayments, nonvalid claims, or other errors  
15 actually measured in a sample of claims.

16 "Health benefit plan" has the same meaning as provided in  
17 Section 5 of the Health Carrier External Review Act.

18 "Health Carrier" has the same meaning as provided in  
19 Section 5 of the Health Carrier External Review Act.

20 "Pharmacy" has the same meaning as provided in Section 3 of  
21 the Pharmacy Practice Act.

22 "Pharmacy audit" means an audit, either onsite or remotely,  
23 of any records of a pharmacy conducted by or on behalf of a

1 health carrier or a pharmacy benefits manager, or a  
2 representative thereof, for prescription drugs that were  
3 dispensed by that pharmacy to beneficiaries of a health benefit  
4 plan pursuant to a contract with the health benefit plan or  
5 issuer or administrator thereof. "Pharmacy audit" does not  
6 include a concurrent review or desk audit that occurs within 3  
7 business days of transmission of a claim or a concurrent review  
8 or desk audit where no chargeback or recoupment is demanded.

9 "Pharmacy benefit manager" means a person, business, or  
10 other entity that, pursuant to a contract or under an  
11 employment relationship with a health carrier, health benefit  
12 plan sponsor, or other third-party payer, either directly or  
13 through an intermediary, manages the prescription drug  
14 coverage provided by the health carrier, health benefit plan  
15 sponsor, or other third-party payer, including, but not limited  
16 to, the processing and payment of claims for prescription  
17 drugs, the performance of drug utilization review, the  
18 processing of drug prior authorization requests, the  
19 adjudication of appeals or grievances related to prescription  
20 drug coverage, contacting with network pharmacies, and  
21 controlling the cost of covered prescription drugs.

22 Section 10. Exemptions.

23 (a) Nothing in this Act shall apply to:

24 (1) an audit conducted because a pharmacy benefit  
25 manager, health carrier, health benefit plan sponsor, or

1 other third-party payer has indications that support a  
2 reasonable suspicion that criminal wrongdoing, willful  
3 misrepresentation, fraud, or abuse has occurred; or

4 (2) an audit conducted by, or at the direction of, the  
5 State Board of Pharmacy, the Department of Healthcare and  
6 Family Services, the Department of Public Health, or the  
7 Medicaid program.

8 Section 15. Amended or renewed contracts. Notwithstanding  
9 any other law, a contract that is issued, amended, or renewed  
10 on or after January 1, 2015, between a pharmacy and a health  
11 carrier or a pharmacy benefit manager to provide pharmacy  
12 services to beneficiaries of a health benefit plan shall comply  
13 with the provisions of this Act.

14 Section 20. Payment to auditing entity; recoupment of  
15 pharmacy funds.

16 (a) An entity conducting a pharmacy audit shall not receive  
17 payment or any other consideration on any basis that is tied to  
18 the amount claimed or actual amount recovered from the pharmacy  
19 that is the subject of the audit. Nothing in this subsection  
20 shall be construed to prevent the pharmacy benefit manager or  
21 health benefit plan from charging or assessing the health  
22 benefit plan sponsor, directly or indirectly, based on amounts  
23 recouped if both of the following conditions are met:

24 (1) the health benefit plan sponsor and the pharmacy

1 benefit manager or health benefit plan have a contract that  
2 explicitly states the percentage charge or assessment to  
3 the health benefit plan sponsor; and

4 (2) no commission or financial incentive is paid to an  
5 agent or employee of the entity conducting the pharmacy  
6 audit based, directly or indirectly, on amounts recouped.

7 (b) A pharmacy shall not be subject to recoupment of funds  
8 for a clerical or recordkeeping error, unless the error  
9 resulted in actual financial harm to the pharmacy benefit  
10 manager, the health carrier, or the beneficiary of a health  
11 benefit plan.

12 Section 25. Information to be collected; disclosures.

13 (a) Except as otherwise prohibited by State or federal law,  
14 an entity conducting a pharmacy audit shall keep confidential  
15 any information collected during the course of the audit and  
16 shall not share any information with any person other than the  
17 health carrier, pharmacy benefit manager, or third-party payer  
18 for which the audit is being performed. An entity conducting a  
19 pharmacy audit shall have access to previous audit reports  
20 relating to a particular pharmacy conducted by or on behalf of  
21 the same entity. Nothing in this subsection shall be construed  
22 to authorize access to information that is otherwise prohibited  
23 by law. Nothing in this subsection shall be construed to  
24 prohibit any employer, trust fund, government agency, or any  
25 other entity for which the audit is being performed from

1 disclosing its general opinions or conclusions regarding the  
2 business practices of the pharmacy based on the audit.

3 (b) An entity that is not a health carrier or pharmacy  
4 benefit manager and that is conducting a pharmacy audit on  
5 behalf of a health carrier or pharmacy benefit manager shall,  
6 prior to conducting the audit, notify the pharmacy in writing  
7 that the entity and the health carrier or pharmacy benefit  
8 manager have executed a business associate agreement or other  
9 agreement as required under State and federal privacy laws.

10 (c) An entity conducting a pharmacy audit shall, prior to  
11 leaving a pharmacy at the end of an onsite portion of the  
12 audit, provide the pharmacist in charge with a complete list of  
13 records reviewed to allow the pharmacy to account for  
14 disclosures as required by State and federal privacy laws.

15 Section 30. Timing and notice of onsite audits.

16 (a) An entity conducting an onsite pharmacy audit shall not  
17 initiate or schedule a pharmacy audit during the first 5  
18 business days of any calendar month, unless it is expressly  
19 agreed to by the pharmacy being audited.

20 (b) An entity conducting an onsite pharmacy audit shall  
21 provide the pharmacy at least 2 weeks' prior written notice  
22 before conducting an initial audit.

23 Section 35. Audits involving clinical judgments;  
24 pharmacy's compliance with federal law; signature logs.

1 (a) A pharmacy audit that involves clinical judgment shall  
2 be conducted by, or in consultation with, a licensed  
3 pharmacist.

4 (b) An entity conducting a pharmacy audit shall make all  
5 determinations regarding the legal validity of a prescription  
6 or other record consistent with determinations made pursuant to  
7 the Pharmacy Practice Act.

8 (c) Nothing in this Section shall be construed to prohibit  
9 a pharmacy benefits manager from denying a claim, either in  
10 whole or in part, for failure to comply with federal Food and  
11 Drug Administration or manufacturer requirements, the  
12 prescription drug formulary, prior authorization requirements,  
13 days' supply requirements, or other coverage or plan design  
14 requirement, or for failure to include a National Provider  
15 Identification number.

16 (d) An entity conducting a pharmacy audit shall accept  
17 paper or electronic signature logs that document the delivery  
18 of pharmacy services to a health plan beneficiary or his or her  
19 agent.

20 Section 40. Length of time allowed for audit. The time  
21 period covered by a pharmacy audit shall not exceed 24 months  
22 from the date that the claim was submitted to, or adjudicated  
23 by, the pharmacy benefits manager, unless a longer period is  
24 required under State or federal law or unless the originating  
25 prescription is required.

1 Section 45. Preliminary audit report.

2 (a) An entity conducting a pharmacy audit shall deliver a  
3 preliminary audit report to the pharmacy before issuing a final  
4 audit report. This preliminary report shall be issued no later  
5 than 60 days after conclusion of the audit.

6 (b) A pharmacy shall be provided a time period of at least  
7 30 days following receipt of the preliminary audit report under  
8 subsection (a) to respond to the findings in the report,  
9 including addressing any alleged mistakes or discrepancies and  
10 producing documentation to that effect.

11 (c) To validate the pharmacy record and delivery, the  
12 pharmacy may use authentic and verifiable statements or  
13 records, including medication administration records of a  
14 nursing home, assisted living facility, hospital, physician,  
15 surgeon, or other authorized prescriber, or additional  
16 documentation parameters located in the provider manual.

17 (d) Any legal prescription may be used to validate claims  
18 in connection with prescriptions, refills, or changes in  
19 prescriptions, including medication administration records,  
20 facsimiles, electronic prescriptions, electronically stored  
21 images of prescriptions, electronically created annotations,  
22 or documented telephone calls from the prescriber or the  
23 prescriber's agent. Unless specifically addressed in the audit  
24 policies and procedures contained in the contract or provider  
25 manual, documentation of an oral prescription order that has



1 been verified by the prescriber shall meet the requirements of  
2 this Section.

3 (e) If an entity conducting a pharmacy audit uses  
4 extrapolation to calculate penalties or amounts to be recouped,  
5 the pharmacy may present evidence to validate orders for  
6 dangerous drugs or devices that are subject to invalidation due  
7 to extrapolation.

8 (f) Prior to issuing a final audit report, an entity  
9 conducting a pharmacy audit shall take into consideration any  
10 response by the pharmacy to the preliminary audit report  
11 provided within the timeframes allowed under this Section,  
12 unless otherwise agreed to by the entity conducting the audit.

13 Section 50. Final audit report and appeal process.

14 (a) An entity conducting a pharmacy audit shall deliver a  
15 final audit report to the pharmacy no later than 120 days after  
16 receipt of a pharmacy's response to the preliminary audit  
17 report.

18 (b) An entity conducting a pharmacy audit shall establish,  
19 in the contract between the pharmacy and the contracting  
20 entity, a process for appealing the findings in a final audit  
21 report that complies with the following requirements:

22 (1) A pharmacy shall be provided a time period of at  
23 least 30 days following receipt of the final audit report  
24 to file an appeal with the entity identified in the appeal  
25 process.

1           (2) An entity conducting a pharmacy audit shall provide  
2           the pharmacy with a written determination of appeal issued  
3           by the entity identified in the appeal process, which shall  
4           be appended to the final audit report, and a copy of the  
5           determination shall be sent to the health carrier, health  
6           benefit plan sponsor, or other third-party payer.

7           (3) If, following the appeal, either party is not  
8           satisfied with the appeal, the party may seek relief under  
9           the terms of the contract.

10          Section 55. Timing of recoupment from pharmacy. An entity  
11          conducting a pharmacy audit, a health carrier, a health benefit  
12          plan sponsor, or other third-party payer, or any person acting  
13          on behalf of those entities, shall not attempt to make  
14          chargebacks or seek recoupment from a pharmacy, or assess or  
15          collect penalties from a pharmacy, until the time period for  
16          filing an appeal to a final audit report has passed or until  
17          the appeal process has been exhausted, whichever is later. If  
18          the identified discrepancy for a single audit exceeds \$30,000,  
19          future payments to the pharmacy in excess of \$30,000 may be  
20          withheld pending adjudication of an appeal.

21          Section 60. Interest. Interest shall not accrue during the  
22          audit period for either party, beginning with the notice of the  
23          audit and ending with the conclusion of the appeal process.

1           Section 65. Unsubstantiated audit reports. If, following  
2           final disposition of a pharmacy audit pursuant to this Section,  
3           an entity conducting a pharmacy audit, a health carrier, a  
4           health benefit plan sponsor, or other third-party payer, or any  
5           person acting on behalf of those entities, finds that an audit  
6           report or any portion thereof is unsubstantiated, the entity  
7           shall dismiss the audit report or the unsubstantiated portion  
8           thereof without the necessity of any further proceedings.

9           Section 70. Board of Pharmacy jurisdiction. This Act shall  
10          not be construed to suggest or imply that the State Board of  
11          Pharmacy has any jurisdiction or authority over the provisions  
12          of this Act.

13          Section 99. Effective date. This Act takes effect upon  
14          becoming law.