1 AN ACT concerning regulation.

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

- Section 5. The Illinois Insurance Code is amended by adding Section 513b7 as follows:
- 6 (215 ILCS 5/513b7 new)
- 7 <u>Sec. 513b7. Pharmacy audits.</u>
- 8 <u>(a) As used in this Section:</u>
- 9 "Audit" means any physical on-site, remote electronic, or
 10 concurrent review of a pharmacist service submitted to the
 11 pharmacy benefit manager or pharmacy benefit manager affiliate
- by a pharmacist or pharmacy for payment.
- "Auditing entity" means a person or company that performs
 a pharmacy audit.
- "Extrapolation" means the practice of inferring a

 frequency of dollar amount of overpayments, underpayments,

 nonvalid claims, or other errors on any portion of claims

 submitted, based on the frequency of dollar amount of

 overpayments, underpayments, nonvalid claims, or other errors

 actually measured in a sample of claims.
- 21 <u>"Misfill" means a prescription that was not dispensed; a</u>
 22 <u>prescription that was dispensed but was an incorrect dose,</u>
 23 amount, or type of medication; a prescription that was

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requested; or

1	dispensed to the wrong person; a prescription in which the
2	prescriber denied the authorization request; or a prescription
3	in which an additional dispensing fee was charged.
4	"Pharmacy audit" means an audit conducted of any records
5	of a pharmacy for prescriptions dispensed or nonproprietary
6	drugs or pharmacist services provided by a pharmacy or
7	pharmacist to a covered person.
8	"Pharmacy record" means any record stored electronically
9	or as a hard copy by a pharmacy that relates to the provision
10	of a prescription or pharmacy services or other component of
11	pharmacist care that is included in the practice of pharmacy.
12	(b) Notwithstanding any other law, when conducting a
13	pharmacy audit, an auditing entity shall:
14	(1) not conduct an on-site audit of a pharmacy at any
15	time during the first 3 business days of a month or the
16	first 2 weeks and final 2 weeks of the calendar year or
17	during a declared State or federal public health
18	<pre>emergency;</pre>
19	(2) notify the pharmacy or its contracting agent no
20	later than 14 business days before the date of initial
21	on-site audit; the notification to the pharmacy or its
22	contracting agent shall be in writing and delivered
23	either:

(A) by mail or common carrier, return receipt

(B) electronically, not including facsimilie, with

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electronic receipt confirmation and delivered during normal business hours of operation, addressed to the supervising pharmacist and pharmacy corporate office, if applicable, at least 14 business days before the date of an initial on-site audit;

- (3) limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the pharmacy benefit manager;
- (4) provide in writing the list of specific prescription numbers to be included in the audit 14 business days before the on-site audit that may or may not include the final 2 digits of the prescription numbers;
- (5) use the written and verifiable records of a hospital, physician, or other authorized practitioner that are transmitted by any means of communication to validate the pharmacy records in accordance with State and federal law;
- (6) limit the number of prescriptions audited to no more than 100 prescriptions per audit and an entity shall not audit more than 200 prescriptions in any 12-month period, except in cases of fraud, waste, or abuse; a refill shall not constitute a separate prescription and a pharmacy shall not be audited more than once every 6 months;
- (7) provide the pharmacy or its contracting agent with a copy of the preliminary audit report within 45 days

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after	the	conclusion	of	the	audit:

- (8) be allowed to conduct a follow-up audit on site if a remote or desk audit reveals the necessity for a review of additional claims;
- (9) accept invoice audits as validation invoices from any wholesaler registered with the Department of Financial and Professional Regulation from which the pharmacy has purchased prescription drugs or, in the case of durable medical equipment or sickroom supplies, invoices from an authorized distributor other than a wholesaler;
- (10) provide the pharmacy or its contracting agent with the ability to provide documentation to address a discrepancy or audit finding if the documentation is received by the pharmacy benefit manager no later than the 45th day after the preliminary audit report was provided to the pharmacy or its contracting agent; the pharmacy benefit manager shall consider a reasonable request from the pharmacy for an extension of time to submit documentation to address or correct any findings in the report;
- (11) be required to provide the pharmacy or its contracting agent with the final audit report no later than 90 days after the initial audit report was provided to the pharmacy or its contracting agent;
- (12) conduct the audit in consultation with a pharmacist in specific cases if the audit involves

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clinical	or	professional	ıudament;

- (13) not chargeback, recoup, or collect penalties from a pharmacy until the time period to file an appeal of the final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later, unless the identified discrepancy is expected to exceed \$25,000, in which case the auditing entity may withhold future payments in excess of that amount until the final resolution of the audit;
- (14) not compensate the employee or contractor conducting the audit based on a percentage of the amount claimed or recouped pursuant to the audit;
- (15) not use extrapolation to calculate penalties or amounts to be charged back or recouped unless otherwise required by federal law or regulation; any amount to be charged back or recouped due to overpayment may not exceed the amount the pharmacy was overpaid;
- (16) not include dispensing fees in the calculation of overpayments unless a prescription is considered a misfill, the medication is not delivered to the patient, the prescription is not valid, or the prescriber denies authorizing the prescription; and
- (17) conduct a pharmacy audit under the same standards and parameters as conducted for other similarly situated pharmacies audited by the auditing entity.
- (c) Except as otherwise provided by State or federal law,

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- an auditing entity conducting a pharmacy audit may have access 1 2 to a pharmacy's previous audit report only if the report was 3 prepared by that auditing entity.
 - (d) Information collected during a pharmacy audit shall be confidential by law, except that the auditing entity conducting the pharmacy audit may share the information with the health benefit plan for which a pharmacy audit is being conducted and with any regulatory agencies and law enforcement agencies as required by law.
 - (e) A pharmacy may not be subject to a chargeback or recoupment for a clerical or recordkeeping error in a required document or record, including a typographical error or computer error, unless the pharmacy benefit manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefit manager, a health plan managed by the pharmacy benefit manager, or a consumer.
 - (f) A pharmacy shall have the right to file a written appeal of a preliminary and final pharmacy audit report in accordance with the procedures established by the entity conducting the pharmacy audit.
 - (g) No interest shall accrue for any party during the audit period, beginning with the notice of the pharmacy audit and ending with the conclusion of the appeals process.
 - (h) An auditing entity must provide a copy to the plan sponsor of its claims that were included in the audit, and any

1	recouped money shall be returned to the plan sponsor, unless
2	otherwise contractually agreed upon by the plan sponsor and
3	the pharmacy benefit manager.
4	(i) The parameters of an audit must comply with
5	manufacturer listings or recommendations, unless otherwise
6	prescribed by the treating provider, and must be covered under
7	the individual's health plan, for the following:
8	(1) the day supply for eyedrops must be calculated so
9	that the consumer pays only one 30-day copayment if the
10	bottle of eyedrops is intended by the manufacturer to be a
11	30-day supply;
12	(2) the day supply for insulin must be calculated so
13	that the highest dose prescribed is used to determine the
14	day supply and consumer copayment; and
15	(3) the day supply for topical product must be
16	determined by the judgment of the pharmacist or treating
17	provider upon the treated area.
18	(j) This Section shall not apply to:
19	(1) audits in which suspected fraud, waste, or abuse
20	or other intentional or willful misrepresentation is
21	evidenced by a physical review, review of claims data or
22	statements, or other investigative methods;
23	(2) audits of claims paid for by federally funded
24	programs; or
25	(3) concurrent reviews or desk audits that occur

within 3 business days after transmission of a claim and

1 in which no chargeback or recoupment is demanded.