By Senator Grall

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A bill to be entitled

An act relating to pharmacy audits; amending s. 624.491, F.S.; revising requirements for audits of licensed pharmacies conducted by or on behalf of pharmacy benefit plans or programs; revising audit procedures, documentation requirements, reporting and appeal requirements, and recoupment limits and procedures; prohibiting the person or entity conducting such audit from taking certain actions; requiring that an audit designated as a fraud, waste, or abuse audit be based on specified evidence or credible allegations or claims; providing requirements for the person or entity conducting such fraud, waste, or abuse audit; prohibiting a person or entity auditing the records of a licensed pharmacy from using a fraud, waste, or abuse audit designation to circumvent certain provisions; providing an exception; revising applicability; providing for enforcement; authorizing the Office of Insurance Regulation to investigate complaints of violations, issue cease and desist orders, impose fines and other administrative penalties, order restitution for improper recoupments, prohibit any person or entity from conducting audits for a specified timeframe upon certain findings, and suspend or revoke a pharmacy benefit manager's registration under certain circumstances; requiring the Financial Services Commission to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 624.491, Florida Statutes, is amended to read:

624.491 Pharmacy audits; enforcement; penalties; rulemaking.—

(1) A pharmacy benefits plan or program as defined in s. 626.8825 providing pharmacy benefits must comply with ~~the requirements of~~ this section when the pharmacy benefits plan or program or any person or entity acting on behalf of the pharmacy benefits plan or program, including, but not limited to, a pharmacy benefit manager as defined in s. 626.88, audits the records of a pharmacy licensed under chapter 465. The person or entity conducting such audit must:

(a) Apply uniform audit standards, scope, frequency, and penalty practices to all pharmacies within the pharmacy benefits plan's or program's network, including pharmacy benefit manager-owned or -affiliated pharmacies and nonaffiliated pharmacies.

(b) Not impose stricter audit methodologies, higher error thresholds, expanded documentation requirements, or more frequent audits on nonaffiliated pharmacies than on pharmacy benefit manager-owned or -affiliated pharmacies.

(c) Upon request by the office or a network pharmacy subject to audit, provide documentation demonstrating compliance with paragraph (a) or paragraph (b), including a comparison of audit frequency, scope, methodologies, and recoupment rates between pharmacy benefit manager-owned or -affiliated pharmacies and nonaffiliated pharmacies.

(d) ~~(a)~~ Except as provided in subsection (5) ~~(3)~~, notify the

pharmacy in writing at least 30 ~~7~~ calendar days before any ~~the~~ initial onsite or remote audit for each audit cycle.

(e)~~(b)~~ Not schedule an ~~onsite~~ audit during the first 7 ~~3~~ calendar days of a month unless the pharmacist consents in writing ~~otherwise~~.

(f) Not disrupt patient care or otherwise interfere with the pharmacy's daily operations.

(g)~~(c)~~ Limit the duration of the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity.

(h) Limit each audit to a random sampling of no more than 0.1 percent of prescriptions. Additional claims may be audited only if fraud, waste, or abuse is reasonably suspected and stated in writing.

(i) Use a random selection process for conducting audits. Targeted selection based on drug class, cost, or therapeutic category is prohibited unless fraud, waste, or abuse is reasonably suspected and stated in writing.

(j)~~(d)~~ In the case of an audit that requires clinical or professional judgment, conduct the audit in consultation with, or allow the audit to be conducted by, a pharmacist licensed in this state.

(k)~~(e)~~ Allow the pharmacy to use the written and verifiable records of a prescriber, hospital, physician, or other authorized practitioner, which are transmitted by any means of communication, to validate the pharmacy records in accordance with state and federal law. Electronic records and scanned prescriptions are valid.

(l)~~(f)~~ Reimburse the pharmacy for a claim that was

retroactively denied for a clerical error, typographical error, scrivener's error, or computer error or for an omission or discrepancy in documentation which does not affect the identity of the patient, the identity of the prescriber, the drug dispensed, the quantity dispensed, the date of service, or the accuracy of the amount paid under the claim, if the prescription was properly and correctly dispensed, unless a pattern of such errors exists, fraudulent billing is alleged, or the error results in actual financial loss to the entity. Such errors are not considered fraud unless there is clear and convincing evidence of intent to defraud.

(m) ~~(g)~~ Provide the pharmacy with a copy of the preliminary audit report within 30 ~~120~~ days after the conclusion of the audit.

(n) ~~(h)~~ Allow the pharmacy to produce documentation to address a discrepancy or audit finding, or to initiate an appeal, within 30 ~~10 business~~ days after the preliminary audit report is delivered to the pharmacy. A written audit appeals process is required.

(o) ~~(i)~~ Provide the pharmacy and the plan sponsor with a copy of the final audit report within 90 days ~~6 months~~ after the pharmacy's receipt of the preliminary audit report.

(p) ~~(j)~~ Calculate any recoupment or penalties based on actual overpayments. Recoupment may ~~and~~ not be calculated according to the accounting practice of extrapolation unless agreed upon in writing as part of a settlement. Recoupment is limited to the dispensing fee unless the pharmacy failed to dispense the drug or acted with willful intent to defraud. Ingredient cost recoupment is prohibited unless fraud or willful

misrepresentation is proven. All recouped funds must be returned in full to the plan sponsor. Recoupment may not occur until:

1. The pharmacy has had at least 30 days to respond;

2. All appeals are resolved; and

3. A final audit report is issued.

(q) Not be compensated based on recovery amounts.

(2) The person or entity conducting such audit may not:

(a) Disregard valid inventory acquired in accordance with state and federal law and legitimate business practices. All legally sourced products held by the pharmacy at the time of dispensing must count toward inventory reconciliation.

(b) Impose additional notification or approval requirements for routine pharmacy business decisions.

(c) Require sourcing from a narrower list of distributors than what is permitted under state or federal licensure standards.

(d) Impose manufacturer-driven restrictions on the source of drug products used in audit reconciliation.

(e) Reject purchases from pharmacy-to-pharmacy transfers conducted in accordance with state and federal law and accompanied by appropriate transaction documentation.

(f) Require bank statements, deposit records, including copies of the front or back of checks, and point-of-sale transaction records, or a combination of such records if any one or more of these records sufficiently demonstrates copay collection consistent with industry norms. Reasonable proof of copay collection shall be limited to standard pharmacy records, including signature logs, point-of-sale transaction records, and accounting records.

(g) Require subsequent attestations from the patient. Lack of subsequent attestation may not be used to justify claim reversal or recoupment if a pharmacy possesses valid documentation that medication was dispensed to the patient or his or her authorized representative, including, but not limited to, signature logs, electronic dispensing records, point-of-sale transaction records, or an in-person pharmacist acknowledgement of dispensing.

(h) Initiate subsequent attestations more than 180 days after the date of service.

(i) Require duplicate or extraordinary documentation beyond what is required under state and federal law in invoice audits. The following is deemed sufficient proof of lawful acquisition of products for audit reconciliation purposes:

1. Invoices from licensed wholesalers or distributors.

2. Valid documentation of pharmacy-to-pharmacy transfers conducted in accordance with state or federal law.

3. Records consistent with the Drug Supply Chain Security Act, 21 U.S.C. ss. 351 et seq., and Board of Pharmacy requirements.

Documentation may not be required unless reasonably necessary to validate lawful inventory acquisitions.

(3)(a) An audit designated as a fraud, waste, or abuse audit must be based on specific, documented evidence or a credible allegation of fraud, waste, or abuse involving the pharmacy or a specific claim or set of claims under review.

(b) The person or entity conducting a fraud, waste, or abuse audit must provide the pharmacy with, in writing, before

commencement of such audit:

1. A clear statement that the audit is designated as a fraud, waste, or abuse audit.

2. A list of the specific facts, data, or allegations forming the basis for the fraud, waste, or abuse designation.

3. Identification of the specific claims or classes of claims to which the fraud, waste, or abuse designation applies.

(c) A person or entity auditing the records of a pharmacy licensed under chapter 465 may not use a fraud, waste, or abuse audit designation to circumvent any provision of this section unless the audit complies fully with this subsection.

(4) ~~(2)~~ This section does not apply to:

(a) Audits conducted by the Medicaid Fraud Control Unit or initiated under a criminal investigation supported by probable cause;

(b) ~~(a)~~ Audits in which suspected fraudulent activity or other intentional or willful misrepresentation is evidenced by a physical review, review of claims data or statements, or other investigative methods;

(c) ~~(b)~~ Audits of claims paid for by federally funded programs; or

(d) ~~(c)~~ Concurrent reviews or desk audits that occur within 3 business days after transmission of a claim and where no chargeback or recoupment is demanded.

(5) ~~(3)~~ An entity that audits a pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team (HEAT) Task Force area designated by the United States Department of Health and Human Services and the United States Department of Justice may dispense with the notice requirements of paragraph

(1)(d) ~~(1)(a)~~ if such pharmacy has been a member of a credentialed provider network for less than 12 months.

(6)~~(4)~~ Pursuant to s. 408.7057, and after receipt of the final audit report issued under paragraph (1)(o) ~~(1)(i)~~, a pharmacy may appeal the findings of the final audit report as to whether a claim payment is due and as to the amount of a claim payment.

(7)~~(5)~~ A pharmacy benefits plan or program that, under terms of a contract, transfers to a pharmacy benefit manager the obligation to pay a pharmacy licensed under chapter 465 for any pharmacy benefit claims arising from services provided to or for the benefit of an insured or subscriber remains responsible for a violation of this section.

(8) The office shall enforce this section and may:

(a) Investigate complaints of violations of this section.

(b) Issue cease and desist orders.

(c) Impose administrative fines as follows:

1. For misuse of the fraud, waste, or abuse designation in violation of subsection (3), a fine not to exceed $100,000 per violation.

2. For a violation of paragraph (1)(a), paragraph (1)(b), or paragraph (1)(c), a fine not to exceed $50,000 per violation.

3. For any other violation of this section, a fine not to exceed $25,000 per violation.

(d) Order restitution for improper recoupments.

(e) Prohibit any person or entity from conducting audits under this section for up to 2 years upon a finding that such person or entity has committed willful abuse of the fraud, waste, or abuse designation in violation of subsection (3).

(f) Suspend or revoke a pharmacy benefit manager's registration under s. 624.490 for repeated or willful violations.

(9) The commission shall adopt rules necessary to implement this section.

Section 2. This act shall take effect July 1, 2026.