GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2011

HOUSE BILL 644
Committee Substitute Favorable 5/31/11
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Short Title: Establish Pharmacy Audit Rights. (Public)

Sponsors:

Referred to:

April 6, 2011

A BILL TO BE ENTITLED

AN ACT TO ESTABLISH PHARMACY AUDIT RIGHTS AND TO ESTABLISH STANDARDS FOR RECOUPMENT OF CLAIMS AND AUTHORIZING A THIRTY-DAY PERIOD TO SUBMIT A WRITTEN REQUEST FOR A RECONSIDERATION REVIEW TO THE DIVISION OF MEDICAL ASSISTANCE.

The General Assembly of North Carolina enacts:

SECTION 1. Chapter 90 of the General Statutes is amended by adding a new Article to read:

"Article 4C.

"Pharmacy Audit Rights.

"**§ 90-85.50. Declaration of pharmacy rights during audit.**

(a) The following definitions apply in this Article:

(1) "Pharmacy" means a person or entity holding a valid pharmacy permit pursuant to G.S. 90-85.21 or G.S. 90-85.21A.

(2) "Responsible party" means the entity responsible for payment of claims for health care services other than (i) the individual to whom the health care services were rendered or (ii) that individual's guardian or legal representative.

(b) Notwithstanding any other provision of law, whenever a managed care company, insurance company, third-party payer, or any entity that represents a responsible party conducts an audit of the records of a pharmacy, the pharmacy has a right to all of the following:

(1) To have at least 21 days' advance notice of the initial on-site audit for each audit cycle.

(2) To have any audit that involves clinical judgment be done with a pharmacist who is licensed in the state in which that pharmacist is located, and is employed or working under contract with the auditing entity.

(3) Not to have clerical or record-keeping errors, including typographical errors, scrivener's errors, and computer errors, on a required document or record, in the absence of any other evidence, deemed fraudulent. This subdivision does not prohibit recoupment of fraudulent payments.

(3a) If required under the terms of the contract, to have the auditing entity provide a pharmacy, upon request, all records related to the audit in an electronic format or contained in digital media.

(4) To have the properly documented records of a hospital or any person authorized to prescribe controlled substances for the purpose of providing

medical or pharmaceutical care for their patients transmitted by any means of communication in order to validate a pharmacy record with respect to a prescription or refill for a controlled substance or narcotic drug.

(5) To have a projection of an overpayment or underpayment based on either the number of patients served with a similar diagnosis or the number of similar prescription orders or refills for similar drugs. This subdivision does not prohibit recoupments of actual overpayments, unless the projection for overpayment or underpayment is part of a settlement by the pharmacy.

(6) Prior to the initiation of an audit, if the audit is conducted for an identified problem, the audit is limited to claims that are identified by prescription number.

(7) If an audit is conducted for a reason other than described in subdivision (6) of this subsection, the audit is limited to 40 selected prescriptions.

(8) If an audit reveals the necessity for a review of additional claims, to have the audit conducted on site.

(9) Except for audits initiated for the reason described in subdivision (6) of this subsection, to be subject to no more than one audit in one calendar year.

(10) Except for cases of Food and Drug Administration regulation or drug manufacturer safety programs, to be free of recoupments based on any of the following unless defined within the billing requirements set forth in the pharmacy provider manual not inconsistent with current North Carolina Board of Pharmacy Regulations:

a. Documentation requirements in addition to or exceeding requirements for creating or maintaining documentation prescribed by the State Board of Pharmacy.

b. A requirement that a pharmacy or pharmacist perform a professional duty in addition to or exceeding professional duties prescribed by the State Board of Pharmacy.

(11) To be subject to recoupment only following the correction of a claim and to have recoupment limited to amounts paid in excess of amounts payable under the corrected claim.

(12) Except for Medicare claims, to be subject to reversals of approval for drug, prescriber, or patient eligibility upon adjudication of a claim only in cases in which the pharmacy obtained the adjudication by fraud or misrepresentation of claim elements.

(13) To be audited under the same standards and parameters as other similarly situated pharmacies audited by the same entity.

(14) To have at least 30 days following receipt of the preliminary audit report to produce documentation to address any discrepancy found during an audit.

(15) To have the period covered by an audit limited to 24 months from the date a claim was submitted to, or adjudicated by, a managed care company, an insurance company, a third-party payer, or any entity that represents responsible parties, unless a longer period is permitted by a federal plan under federal law.

(16) Not to be subject to the initiation or scheduling of audits during the first five calendar days of any month due to the high volume of prescriptions filled during that time, without the express consent of the pharmacy. The pharmacy shall cooperate with the auditor to establish an alternate date should the audit fall within the days excluded.

(17) To have the preliminary audit report delivered to the pharmacy within 120 days after conclusion of the audit.

(18) To have a final audit report delivered to the pharmacy within 90 days after the end of the appeals period, as provided for in G.S. 90-85.51.

(19) Not to have the accounting practice of extrapolation used in calculating recoupments or penalties for audits, unless otherwise required by federal requirements or federal plans.

"**§ 90-85.51. Mandatory appeals process.**

(a) Each entity that conducts an audit of a pharmacy shall establish an appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(b) If, following the appeal, the entity finds that an unfavorable audit report or any portion of the unfavorable audit report is unsubstantiated, the entity shall dismiss the unsubstantiated portion of the audit report without any further proceedings.

(c) Each entity conducting an audit shall provide a copy, if required under contractual terms, of the audit findings to the plan sponsor after completion of any appeals process.

"**§ 90-85.52. Pharmacy audit recoupments.**

(a) Recoupments of any disputed funds shall occur only after final internal disposition of an audit, including the appeals process as set forth in G.S. 90-85.51.

(b) Recoupment on an audit shall be refunded to the responsible party as contractually agreed upon by the parties.

(c) The entity conducting the audit may charge or assess the responsible party, directly or indirectly, based on amounts recouped if both of the following conditions are met:

(1) The responsible party and the entity conducting the audit have entered into a contract that explicitly states the percentage charge or assessment to the responsible party.

(2) A commission or other payment to an agent or employee of the entity conducting the audit is not based, directly or indirectly, on amounts recouped.

"**§ 90-85.53. Applicability.**

This Article does not apply to any audit, review, or investigation that involves alleged Medicaid fraud, Medicaid abuse, insurance fraud, or other criminal fraud or misrepresentation."

SECTION 2. Notwithstanding 10A NCAC 22F .0402, a provider shall submit to the Division of Medical Assistance a written request for a Reconsideration Review within 30 working days from the date of the receipt of notice of tentative decision. Failure to request a Reconsideration Review in the specified time shall result in the implementation of the tentative decision as the Division's final decision. Any provider who had received notice of a tentative decision under 10A NCAC 22F .0402 on or after March 1, 2011, shall be eligible to resubmit a written request for Reconsideration Review within 30 working days of this act becoming law. The Department of Health and Human Services shall amend any rule in conflict with this provision.

SECTION 3. Section 1 of this act becomes effective October 1, 2011, and applies to audits of pharmacies conducted on or after that date. The remaining sections of this act are effective when they become law.