The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	SB 1602
INTRODUCER:	Senator Latvala
SUBJECT:	Pharmacies
DATE:	February 14, 2012
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Wilson	Stovall	HR	**Pre-meeting**
2.			BC	
3.				
4.				
5.				
6.				

I. Summary:

The bill makes the pharmacy audit requirements contained in s. 465.188, F.S., which currently apply only to audits of Medicaid-related pharmacy records, applicable to third-party payor and third-party administrator audits of pharmacy records. In addition, the bill specifies that a claim is not subject to financial recoupment if the claim, except for typographical, computer, clerical, or recordkeeping errors, is a valid claim. The audit criteria may not subject a claim to financial recoupment except when recoupment is required by law. The audit criteria apply to third-party claims submitted for payment after July 1, 2011.

The bill also prohibits a third-party payor or state agency from requiring the delivery of pharmacy provider services and prescription drugs by mail. However, a third-party payor or state agency may offer an incentive program for the delivery of prescription drugs by mail.

This bill substantially amends s. 465.188, F.S., and creates one undesignated section of law.

II. Present Situation:

Medicaid

Medicaid is the medical assistance program that provides access to health care for low-income families and individuals. Medicaid also assists aged and disabled people with the costs of nursing facility care and other medical expenses. The Agency for Health Care Administration (AHCA) is responsible for administering the Medicaid program. Medicaid serves approximately 3.19 million people in Florida.

Medicaid reimburses health care providers that have a provider agreement with the AHCA only for goods and services that are covered by the Medicaid program and only for individuals who are eligible for medical assistance from Medicaid. Each provider agreement is a voluntary contract between the AHCA and the provider, in which the provider agrees to comply with all laws and rules pertaining to the Medicaid program.[1] A Medicaid provider has a contractual obligation to comply with Medicaid policy which requires that a claim must be true and correct or payments may be recouped.[2]

Section 409.906, F.S., identifies the services for which Florida has, at its option, decided to make payments under the Medicaid program. Prescribed drug services are optional services under the Medicaid program. Under s. 409.906(20), F.S., the AHCA may pay for medications that are prescribed for a recipient by a physician or other licensed practitioner of the healing arts authorized to prescribe medication and that are dispensed to the recipient by a licensed pharmacist or physician in accordance with applicable state and federal law.

Section 409.908(14), F.S., establishes policies regarding Medicaid reimbursement of providers of prescribed drugs. Section 409.912(37), F.S., requires the AHCA to implement a Medicaid prescribed-drug spending-control program that includes several specified components.

Section 409.913, F.S., provides for the oversight of the integrity of the Medicaid program to ensure that fraudulent and abusive behavior occur to the minimum extent possible, and to recover overpayments and impose sanctions as appropriate. Overpayment is defined to include any amount that is not authorized to be paid by the Medicaid program whether paid as a result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse, or mistake.[3]

Under s. 409.913(2), F.S., the AHCA is required to conduct, or cause to be conducted by contract or otherwise, reviews, investigations, analyses, audits, or any combination of these, to determine possible fraud, abuse, overpayment, or recipient neglect in the Medicaid program and to report the findings of any overpayments in audit reports as appropriate.

Section 409.913(32), F.S., authorizes agents and employees of the AHCA to inspect, during normal business hours, the records of any pharmacy, wholesale establishment or manufacturer, or any other place in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold or kept for sale, for the purpose of verifying the amount of drugs and medical supplies ordered, delivered, or purchased by a Medicaid provider. The AHCA must provide at least 2 business days' prior notice of an inspection. The notice must identify the provider whose records will be inspected, and the inspection shall include only records specifically related to that provider.

[1] *See* s. 409.907(2), F.S.
[22] *See* s. 409.913(7), F.S.
[3] *See* s. 409.913(1)(e), F.S.

Medicaid Pharmacy Audits

Section 465.188, F.S., establishes requirements for the conduct of an audit of the Medicaid-related records of a pharmacy licensed under ch. 465, F.S. The audit must meet the following requirements.

- The agency conducting the audit must give the pharmacist at least 1 week's prior notice of the initial audit for each audit cycle.
- An audit must be conducted by a pharmacist licensed in Florida.
- Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error regarding a document or record required under the Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud.
- A pharmacist may use the physician's record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.
- A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.
- Each pharmacy shall be audited under the same standards and parameters.
- A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.
- The period covered by an audit may not exceed 1 calendar year.
- An audit may not be scheduled during the first 5 days of any month due to the high volume of prescriptions filled during that time.
- The audit report must be delivered to the pharmacist within 90 days after conclusion of the audit. A final audit report must be delivered to the pharmacist within 6 months after receipt of the preliminary audit report or final appeal, whichever is later.
- The agency conducting the audit may not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.

The law requires the AHCA to establish a process that allows a pharmacist to obtain a preliminary review of an audit report and the ability to appeal an unfavorable audit report without the necessity of obtaining legal counsel. The preliminary review and appeal may be conducted by an ad hoc peer review panel, appointed by the AHCA, which consists of pharmacists who maintain an active practice. If, following the preliminary review, the AHCA or the review panel finds that an unfavorable audit report is unsubstantiated, the AHCA must dismiss the audit report without the necessity of any further proceedings.

These requirements do not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs or to investigative audits conducted by the AHCA when there is reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.

Third-party Payor/Third-party Administrator Pharmacy Audits

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively for years through the use of prescription drugs. As a result, national expenditures for retail prescription drugs have grown from $120.9 billion in 2000 to $259.1 billion in 2010.[4] This has brought about increased scrutiny of pharmaceutical dispensing and reimbursement processes.

Health insurers, including Medicare and Medicaid, and other third party payers spent $210.3 billion on prescription drugs in 2010 and consumers paid $48.8 billion out of pocket for prescription drugs that year.[5] As expenditures for drugs have increased, insurers have looked for ways to control that spending. Among other things, they have turned to pharmacy benefit managers, which are third party administrators of prescription drug programs. Pharmacy benefit managers process prescriptions for the groups that pay for drugs, usually insurance companies or corporations, and use their size to negotiate with drug makers and pharmacies. They are primarily responsible for processing and paying prescription drug claims. They are also responsible for maintaining the formulary of covered drugs, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers.

Pharmacy benefit managers build networks of retail pharmacies to provide consumers convenient access to prescriptions at discounted rates. The audit process is one means used by pharmacy benefit managers and third-party payors to review pharmacy programs. The audits ensure that procedures and reimbursement mechanisms are consistent with contractual and regulatory requirements.

Pharmacies have increasingly complained about the onerous and burdensome nature of these audits. Organizations such as the National Community Pharmacists Association[6] and the Independent Pharmacy Cooperative,[7] which both represent independent pharmacies, have been advocating for legislation at the federal and state levels to address what they perceive as predatory practices by pharmacy benefit managers.

III. Effect of Proposed Changes:

Section 1 amends s. 465.188, F.S., relating to Medicaid audits of pharmacies, to make the provisions of the section applicable to an audit of Medicaid-related, third-party payor, or third-party administrator records of a pharmacy permittee. The bill provides that a claim is not subject to financial recoupment if the claim is a valid claim other than typographical, scrivener's,

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[4] Centers for Medicare and Medicaid Services, *National Health Expenditures Web Tables, Table 11, Retail Prescription Drugs Aggregate, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2010*. Found at: <https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf> (Last visited on February 14, 2012).
[5] *Id.*
[6] National Community Pharmacists Association, *New Survey Reveals Pharmacists are Increasingly Struggling to Care for Patients Amid Predatory Audits, Unfair Reimbursement Practices*. Found at: < http://www.ncpanet.org/index.php/news-releases/1062-new-survey-reveals-pharmacists-are-increasingly-struggling-to-care-for-patients-amid-predatory-audits-unfair-reimbursement-practices> (Last visited on February 14, 2012).
[7] Independent Pharmacy Cooperative, *IPC Introduces Pharmacy Audit Legislation in Florida*. Found at: <https://www.ipcrx.com/Public/Govt%20Affairs/GA_December_22_2011.aspx> (Last visited on February 14, 2012).

computer, clerical, or recordkeeping errors. The audit criteria contained in the bill apply to third-party claims submitted for payment after July 1, 2011.

The bill specifies that the audit criteria may not subject a claim to financial recoupment except in those circumstances when recoupment is required by law. The process for appealing audit reports is amended to conform to the addition of third-party payors and third-party administrators to the provisions of s. 465.188, F.S.

Section 2 provides that, notwithstanding any other provision of law, a third-party payor or state agency may not require, by contract, administrative rule, or condition of participation in a pharmacy provider network, the delivery of pharmacy provider services and prescription drugs by mail. A third-party payor or state agency may offer an incentive program for the delivery of drugs by mail.

Section 3 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

The bill may raise concerns due to impairment of contracts.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The bill will have an indeterminate fiscal impact on the private insurance sector through requirements for third-party payor auditing methodologies, limitations on financial recoupment of claims, and restrictions on the use of mail order pharmacies.

C. Government Sector Impact:

The bill will limit the AHCA's ability to recoup Medicaid overpayments that result from providers' computer and recordkeeping errors. Also, pharmacy service providers will likely dispute regular fee-for-service audits by Medicaid due to more restrictive language regarding what claims may be subject to financial recoupment, thus leading to more administrative hearings for the AHCA.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The provision of the bill that states that a claim is not subject to financial recoupment if, except for typographical, scrivener's, computer, clerical, or recordkeeping error, the claim is an otherwise valid claim will have a negative impact on the AHCA's ability to combat fraud and abuse in the Florida Medicaid program. Although providers may not be committing fraud, they may be committing abuse and may be collecting overpayments from the Medicaid program through computer and recordkeeping errors. This provision will also affect managed care organizations that currently provide services to Medicaid enrollees.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.