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 Committee on Health Policy

BILL:	SB 1358
INTRODUCER:	Senators Flores and Sobel
SUBJECT:	Audits of Pharmacy Records
DATE:	March 29, 2013
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	McElheney	Stovall	HP	**Favorable**
2.			AHS	
3.			AP	
4.				
5.				
6.				

I. Summary:

SB 1358 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. Extrapolation may not be used for calculating recoupment in pharmacy audits and 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.

This bill substantially amends section 465.188 of the Florida Statutes.

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 3.3 million people in Florida.[1]

[1] Social Services Estimating Conference Medicaid Caseloads, February 2013 forecast, available at: http://edr.state.fl.us/content/conferences/medicaid/medcases.pdf (Last visited on March 28, 2013).

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.[2] 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.[3]

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. The estimated Medicaid prescribed drug services for state fiscal year 2012-2013 is $1,890.4 million.[4]

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.[5]

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.

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[2] *See* s. 409.907(2), F.S.
[3] *See* s. 409.913(7), F.S.
[4] Social Services Estimating Conference Medicaid Services Expenditures, February 25, 2013, available at: http://edr.state.fl.us/content/conferences/medicaid/medhistory.pdf (Last visited on March 28, 2013).
[5] *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 one 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 one 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 263 billion in 2011.[6] This has brought about increased scrutiny of pharmaceutical dispensing and reimbursement processes.

Health insurers, including Medicare and Medicaid, and other third party payers spent $214.3 billion on prescription drugs in 2011 and consumers paid $45 billion out of pocket for prescription drugs that year.[7] 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[8] and the Independent Pharmacy Cooperative,[9] 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.

A 2011 survey conducted among members of the National Community Pharmacists Association. found that pharmacy audits were focusing on trivial errors (misspelling patient names or incorrect data) rather than intentional, fraudulent acts.[10]

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[6] Centers for Medicare and Medicaid Services, *National Health Expenditures Web Tables, Table 16, Retail Prescription Drugs Aggregate, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2011*. Found at: <https://www.cms.gov/NationalHealthExpendData/downloads/tables.pdf> (Last visited on March 22, 2013).

[7] *Id.*

[8] National Community Pharmacists Association, NCPA to Medicare: Rein in Egregious Pharmacy Audits; Reform Preferred Networks; and Curb Mail Order Waste in 2014 Prescription Drug Plans. Found at: <http://www.ncpanet.org/index.php/news-releases/1593-ncpa-to-medicare-rein-in-egregious-pharmacy-audits-reform-preferred-networks-and-curb-mail-order-waste-in-2014-prescription-drug-plans> (Last visited on March 29, 2013).

[9] 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 March 22, 2013).

[10] 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 March 22, 2013).

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.

Similar to Medicaid audits, audits by third-party payors or third-party administrators must provide a pharmacist with at least one week's notice prior to the audit. The bill provides that a claim is not subject to financial recoupment if the claim is a valid claim other than typographical, scrivener's, computer, clerical, or recordkeeping errors. Extrapolation, which is an accounting practice, may not be used for calculating recoupment and audit criteria may not subject a claim for financial recoupment unless recoupment is required by law. The audit criteria apply to third-party claims submitted for payment after July 1, 2011.

The bill does not modify the existing provision that the audit criteria in this section of law apply to Medicaid claims submitted for payment after July 11, 2003. Therefore, the new audit criteria affecting Medicaid claims will have a retroactive application to Medicaid claims submitted for payment after July 11, 2003. These new audit criteria for Medicaid claims include:

- A claim is not subject to financial recoupment if, except for typographical, scrivener's, computer, or other clerical or recordkeeping error, the claim is an otherwise valid claim.
- The agency or other entity conducting an audit may not use extrapolation in calculating recoupment for Medicaid.
- The audit criteria may not subject a claim to recoupment except 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. Members of the ad hoc peer review panel for preliminary review and appeal of third-party payor or third-party administrator audit reports are appointed by the third-party payor or third-party administrator contracting with the pharmacy.

Section 2 provides that the bill will take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

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:

SB 1358 will have an indeterminate fiscal impact on the private insurance sector through potential modifications in pharmacy auditing methodologies and limitations on recoupment of claims.

Due to the prior notification requirement before third-party payor or third-party administrator audits may get underway, pharmacies may be better able to manage workload responsibilities. Pharmacies may also benefit due to less frequent recoupment of claims.

C. Government Sector Impact:

The AHCA reports that it could nullify the effect of compliance audits on providers who may not be committing fraud, but are committing abuse and being overpaid by the Medicaid program through computer and recordkeeping errors. In addition, this bill could affect capitation rates for Medicaid managed care by restricting the managed care organization's ability to recoup for erroneous payments. The fiscal impact to the AHCA is indeterminate.[11]

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.

[11] AHCA Bill Analysis for SB 1358 and HB 791 (2013) on file with the Senate Health Policy Committee.

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.