HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 791 Audits of Pharmacy Records
SPONSOR(S): Diaz, Jr.
TIED BILLS: **IDEN./SIM. BILLS:** SB 1358

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Poche	Shaw
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

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 certain criteria, including, but not limited to the following provisions:

- 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.

House Bill 791 permits the application of the audit criteria and audit program contained in s. 465.188, F.S., to audits of pharmacies conducted by third-party payers or third-party administrators, such as pharmacy benefits managers, for claims filed after July 1, 2011. The bill requires third-party payers or third-party administrators to establish a process to allow a pharmacist to obtain a preview of the audit results and to allow for an appellate process, which includes establishing an ad hoc peer review counsel. If the peer review counsel finds an unfavorable to be unsubstantiated, the bill requires the third-party payer or administrator to dismiss the audit without further action.

The bill provides the audit criteria may not subject a claim to an action for financial recoupment, unless recoupment is required by law given certain circumstances. The bill provides that a clerical or recordkeeping error is not a willful violation that would subject the claim to criminal penalties without additional proof of intent to commit fraud. Lastly, the bill provides that a claim is not subject to an action for financial recoupment if it is a valid claim, but for a clerical or recordkeeping error.

The bill may have a fiscal impact on state government. See Fiscal Comments.

The bill provides an effective date upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

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, and costing nearly $20.7 billion in program expenditures.[1]

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.

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.[4]

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

[1] Office of Economic and Demographic Research, Social Services Estimating Conference, *Medicaid Caseloads and Expenditures, Executive Summary*, February 15 and 25, 2013, available at http://edr.state.fl.us/Content/conferences/Medicaid/medsummary.pdf (last viewed on March 22, 2013).
[2] S. 409.907(2), F.S.
[3] S. 409.913(7), F.S.
[4] S. 409.913(1)(e), F.S.

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.

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.[5]
- An audit must be conducted by a pharmacist licensed in Florida.[6]
- 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.[7]
- 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.[8]
- 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.[9]
- Each pharmacy shall be audited under the same standards and parameters.[10]
- A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.[11]
- The period covered by an audit may not exceed one calendar year.[12]
- An audit may not be scheduled during the first five days of any month due to the high volume of prescriptions filled during that time.[13]
- The audit report must be delivered to the pharmacist within ninety days after conclusion of the audit.[14]
- A final audit report must be delivered to the pharmacist within six months after receipt of the preliminary audit report or final appeal, whichever is later.[15]
- The agency conducting the audit may not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.[16]

The law requires the AHCA to establish a process that allows a pharmacist to obtain a preliminary review of an audit report and to appeal an unfavorable audit report without the necessity of obtaining legal counsel.[17] 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.[18] 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.[19]

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

[5] S. 465.188(1)(a), F.S.
[6] S. 465.188(1)(b), F.S.
[7] S. 465.188(1)(c), F.S.
[8] S. 465.188(1)(d), F.S.
[9] S. 465.188(1)(e), F.S.
[10] S. 465.188(1)(f), F.S.
[11] S. 465.188(1)(g), F.S.
[12] S. 465.188(1)(h), F.S.
[13] S. 465.188(1)(i), F.S.
[14] S. 465.188(1)(j), F.S.
[15] Id.
[16] S. 465.188(1)(k), F.S.
[17] S. 465.188(2), F.S.
[18] Id.
[19] Id.

reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.[20]

Medicaid Program Integrity

Medicaid Program Integrity, a unit of the AHCA, recovers overpayments, which are payments made in a manner inconsistent with Medicaid policy, through MPI-conducted audits, paid claims reversals and vendor-assisted audits.[21] MPI audits include comprehensive investigations involving reviews of professional records, generalized analyses involving computer-assisted reviews of paid claims and focused audits involving reviews of certain types of providers in specific geographic areas.[22] MPI audits utilize generally-accepted accounting principles and statistical analysis methods.[23] Paid claims reversals are effected within MPI by Florida licensed pharmacists who review pharmacy paid claims and identify apparent mis-billings.[24] The pharmacies are notified and claims corrected, resulting in recoveries of Medicaid overpayments. Vendor-assisted audits are conducted, under MPI supervision, by contracted firms who perform work that would otherwise not be possible due to staffing limitations.[25] In fiscal year 2011-2012, 44 pharmacy site visits were conducted.[26]

Third-Party Payer/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.[27] This has brought about increased scrutiny of pharmaceutical dispensing and reimbursement processes.

Health insurers, including Medicare and Medicaid, and other third party payers spent $208.6 billion on prescription drugs in 2011 and consumers paid $45 billion out of pocket for prescription drugs that year.[28] 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.[29]

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[20] S. 465.188(3) and (4), F.S.
[21] Florida Agency for Health Care Administration, Office of the Inspector General, *Annual Report 2011-2012*, September 2012, page 14, available at www.fdhc.fl.us/Executive/Inspector_General/docs/OIG%20Annual%20Report%20FY%202011-12[1].pdf (last viewed March 22, 2013).
[22] Id.
[23] Id.
[24] Id.
[25] Id.
[26] Florida Agency for Health Care Administration and the Office of the Attorney General, *The State's Efforts to Control Medicaid Fraud and Abuse- FY 2011-2012*, December 31, 2012, page 36, available at www.ahca.myflorida.com/docs/FinalReportSignedandCertified.pdf (last viewed on March 22, 2013) (on file with Health Innovation Subcommittee staff).
[27] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, *National Health Expenditures; Aggregate and Per Capita Amounts, Annual Percent Change and Percent Distribution, by Type of Expenditure: Selected Calendar Years 1960-2011*, Table 2, available at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NaturalHealthAccountsHistorical.html (last viewed on March 22, 2013).
[28] Id. at Table 4.
[29] National Community Pharmacists Association, *Survey: Pharmacists Say Patient Care Undermined by Auditing, Payment Practices*, available at www.ncpanet.org/index.php/new-releases/2012-news-releases/1470-survey-pharmacists-say-patient-care-undermined-by-auditing-payment-practices (last viewed on March 22, 2013).

Effect of Proposed Changes

The bill expands the application of requirements for Medicaid audits of pharmacies, contained in s. 465.188, F.S., to audits of pharmacy permittees conducted by a third-party payer or third-party administrator, such as a pharmacy benefits manager, under the third party's program. The bill creates a consistent standard for pharmacy audits under the Medicaid program and third-party payer or administrator programs.

The bill provides that any clerical or recordkeeping error, without proof of intent to commit fraud, revealed during the audit is not subject to criminal penalties. The bill also provides that a claim for payment is not subject to a recoupment action if, but for the recordkeeping or clerical error, the claim is otherwise valid under the program.

The audit criteria made applicable to third-party claims by the bill apply only to third-party claims submitted for payment after July 1, 2011. The bill prohibits the use of the accounting practice of extrapolation in calculating penalties or financial recoupment of a paid claim for the Medicaid program or a third-party payer or third-party administrator program. Also, the bill states that audit criteria may not create a claim for financial recoupment where it did not otherwise exists, unless recoupment is required by law as a result of the application of audit criteria to a claim.

Lastly, the bill requires the third-party payer or administrator contracting with the pharmacy under audit to establish a process that allows a pharmacist to obtain a preliminary review of an audit report and to appeal an unfavorable audit report without the necessity of obtaining legal counsel. The bill permits the third-party payer or administrator to appoint the ad hoc peer review counsel to conduct the preliminary review and appeal. If the ad hoc peer review counsel finds an unfavorable audit is unsubstantiated, the third-party payer or administrator must dismiss the audit report without further proceedings.

B. SECTION DIRECTORY:

Section 1: Amends s. 465.188, F.S., relating to Medicaid audits of pharmacies.
Section 2: Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   See Fiscal Comments.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill 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. This provision may 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 collecting overpayments from the Medicaid program through computer and recordkeeping errors.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not require rule-making.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES