SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

BILL: CS/SB 1428

SPONSOR: Health, Aging, and Long-Term Care Committee and Senator Peaden

SUBJECT: Medicaid Audits of Pharmacies

March 25, 2003 DATE: **REVISED**: ANALYST STAFF DIRECTOR REFERENCE ACTION Favorable/CS 1. Wilson Wilson HC 2. AHS AP 3. _____ 4. 5. 6.

I. Summary:

The bill establishes requirements for audits of the Medicaid-related records of a pharmacy licensed in Florida. The Agency for Health Care Administration must establish a process for a preliminary review and appeal of an audit report. Investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs are excluded from these requirements.

This bill creates one unnumbered section of law.

II. Present Situation:

Medicaid

Medicaid is a medical assistance program that pays for health care for the poor and disabled. The program is jointly funded by the federal government, the state, and the counties. The federal government, through law and regulations, has established extensive requirements for the Medicaid program. Under s. 409.902, F.S., the Agency for Health Care Administration (AHCA or agency) is the single state agency responsible for the Florida Medicaid Program. The statutory provisions for the Medicaid program appear in ss. 409.901 through 409.9205, F.S.

The Medicaid Estimating Conference estimates that the Florida Medicaid program will spend nearly \$12 billion on Medicaid services next year. Over \$2 billion will be spent on pharmacy services. Pharmacy services account for 18.2 percent of the Medicaid services budget. The pharmacy component of the Medicaid services budget is second only to the nursing home component.

Section 409.907, F.S., establishes requirements for Medicaid provider agreements. The agency may make payments for medical assistance and related services rendered to Medicaid recipients

only to an individual or entity who has a provider agreement in effect with the agency. Section 409.908, F.S., specifies conditions under which Medicaid providers may be reimbursed for Medicaid compensable services made on behalf of Medicaid eligible persons.

Sections 409.913 and 409.9131, F.S., prescribe the activities of the agency related to oversight of the integrity of the Medicaid program. Staff of the Medicaid Program Integrity section develop and use statistical methodologies to identify providers who exhibit aberrant billing patterns, conduct investigations and audits of these providers, calculate provider overpayments, initiate recovery of overpayments in instances of provider abuse, and recommend administrative sanctions for providers who have abused or defrauded Medicaid. The section requires that any suspected criminal violation identified by the agency be referred to the Medicaid Fraud Control Unit of the Office of the Attorney General, and that the agency and the Medicaid Fraud Control Unit develop a memorandum of understanding that includes protocols for referral of cases of suspected criminal fraud and return of these cases where investigation determines that administrative action by the agency is appropriate.

Section 409.920, F.S., contains provisions related to Medicaid provider fraud, and requires the Attorney General to conduct a statewide program of Medicaid fraud control. The duties of the program include investigation of possible criminal violations pertaining to the administration of the Medicaid program, in the provision of medical assistance, or in the activities of Medicaid providers. The Attorney General is to investigate alleged abuse or neglect of patients in health care facilities receiving Medicaid payments, and misappropriation of patient's private funds in facilities receiving Medicaid payments, in coordination with the agency. The Attorney General is required to refer all suspected abusive activities not of a criminal nature to the agency, as well as each instance of overpayment which is discovered during the course of an investigation.

Medicaid Fraud Control Unit

Section 16.59, F.S., creates the Medicaid Fraud Control Unit within the Department of Legal Affairs. The unit is authorized to investigate all violations of s. 409.920, F.S., relating to Medicaid provider fraud, and any criminal violations discovered during the course of those investigations. The unit is authorized to refer any criminal violation to the appropriate prosecuting authority.

Medicaid Overpayment Recovery Processes

Overpayments by Medicaid are often lumped into the generic category of "Medicaid fraud," however, Medicaid fraud is a subset of the larger category of "Medicaid overpayments." Medicaid overpayments may result from a host of problems, including provider billing errors, confusion about Medicaid policy requirements, poor medical practice, poor business practices, or fraud. If an overpayment is the result of an intentional action on the part of the provider, in order to gain an unauthorized benefit, it becomes "fraud."

Although the Medicaid Program Integrity (MPI) Office within AHCA searches for, identifies, and investigates overpayments, MPI does not investigate, prosecute or recover in the case of fraud. If MPI staff, in their investigation, suspect that the provider's billings are due to intentional fraud, MPI staff are required by federal and state law to refer the case to the Medicaid

Fraud Control Unit. At this point Medicaid stops all action on the case, including recovery activity. Medicaid Program Integrity, therefore, investigates and initiates recovery of those overpayments that are not fraudulent in nature.

Medicaid Program Integrity finds its cases via peer review organization audits, referrals from Medicaid policy staff, reports from other providers, as well as reports from Medicaid recipients. MPI uses a variety of data mining techniques to identify suspicious provider billing patterns. Once a suspicious billing pattern is identified, MPI reviews the provider's records to determine if the provider's payment was inappropriate. Using statistical methodologies such as sampling to determine error rates and then applying error rates to a provider's universe of claims, MPI computes an amount that it believes the provider has been overpaid and sends the provider a "preliminary audit letter" (PAL).

The provider is allowed to dispute the findings in the PAL by submitting additional information, such as additional documentation that a service was actually rendered or was medically necessary. After considering the information the provider has submitted, MPI makes its final determination of the actual Medicaid overpayment and sends the provider a "final audit letter" (FAL), which is the agency's determination of the amount due to and collectible by Medicaid.

If the provider feels the agency is incorrect in this determination, the provider has a right to appeal the decision to the Division of Administrative Hearings (DOAH), in which case the agency's position is defended by the AHCA Office of the General Counsel (OGC). Depending on the circumstances of the overpayment, Medicaid program policy staff, medical consultants, or MPI staff may be called on to testify at these hearings to support the agency's position.

If the provider agrees to the FAL determination, or if the agency prevails at a hearing, the provider's payback amount is collected by the Accounts Receivable section of AHCA. In addition to recovery of amounts overpaid, a variety of other sanctions are available to the agency, such as suspension or termination of the provider from the Medicaid program and fines.

Medicaid Pharmacy Audits

Section 409.913(2), F.S., requires the agency to conduct, or cause to be conducted audits to determine possible fraud or abuse in the Medicaid program. The agency currently contracts for audits of pharmacies to determine compliance with Medicaid policy, rules and regulations. Under this contract, all audits are conducted or supervised by a pharmacist licensed in the State of Florida. In most cases, pharmacies are provided approximately 5 days' notice. According to AHCA, the following is a brief description of the audit process:

(a) Auditors arrive at the pharmacy and conduct an "entrance interview." The auditor describes the audit process, which includes, but is not limited to, reviewing a sample of prescription records, signature logs, data in the pharmacy computer, scanning prescription hard copies, reviewing business records, and obtaining information on how the pharmacy operates and the location of documentation. A list of sample claims to be reviewed is presented during the entrance interview. The pharmacist is informed that they may provide essential documentation at any point during the audit process.

- (b) Auditors conduct the review of records, review shelf stock, conduct a analysis of the pharmacy's usual and customary pricing, conduct interviews, obtain a list of pharmacy employees for the record, and copy documentation. Auditors also request financial documentation.
- (c) While onsite and after review of all documentation, the auditor provides the pharmacist with a list of any discrepancies, prints a copy of the "exit interview report" and reviews the report with the pharmacist. Throughout the audit and again at this time, the pharmacist is given the opportunity to provide essential documentation. Should the pharmacist produce additional documentation, the auditor reviews the documentation and adjusts the findings, as appropriate. The pharmacist is provided instructions on sending documentation that could not be found while the auditor was onsite. The pharmacist is allowed an additional 5 days from delivery of the "exit interview report" to mail additional documentation to the auditor.
- (d) After receipt and review of all documentation, the auditor processes the findings and generates a report. If a random sample was used in the audit, findings may be extrapolated. The report is sent to AHCA.
- (e) The agency reviews the findings of the audit report and notifies the pharmacy of the results. If an overpayment is identified, a preliminary audit letter is sent allowing the provider 30 days to provide additional documentation.
- (f) After consideration of all documentation provided, if an overpayment is due, a final audit letter is sent, with proper notice of rights regarding the overpayment due. This letter includes notification of administrative rights to challenge the agency action. At that time a hearing, informal or formal, may be requested. Legal counsel is an option for the pharmacist at the DOAH hearing but is not required.

Medicaid Claims Payment Accuracy Study

In July 2002, AHCA entered into a contract with Tucker Alan, Inc., to conduct a study of the accuracy of Medicaid claims payment in order to determine error rates in Medicaid claims payments. The study was designed to answer three questions:

- Was the claim submitted by the provider processed and paid correctly by Florida Medicaid?
- Were the services billed to and paid by Medicaid for services that were properly documented and medically necessary?
- Did the recipient receive the services that were billed to and paid by Medicaid?

The study examined a sample of paid claims for acute care, prescribed medicines, and long-term care. Preliminary results from the study indicate that 4.85 percent of claim expenditures for prescribed medicines were in error, meaning that Medicaid should not have paid. If this error rate is applied to the \$2 billion pharmacy services component of the Medicaid budget, \$97 million of pharmacy expenditures may be improperly paid out by the Medicaid program.

Pharmacy Regulation

Pursuant to ch. 465, F.S., the Florida Board of Pharmacy regulates the practice of pharmacy in Florida. "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, and a special pharmacy. "Community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. "Institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medicinal drugs are compounded, dispensed, stored, or sold. "Nuclear pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold. "Nuclear pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold. "Nuclear pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in ch. 465, F.S.

Every pharmacy must be permitted and each pharmacy is subject to discipline for violations of applicable state or federal law relating to pharmacy.¹ Pharmacies are subject to inspection by the Department of Health. Any pharmacy that is located outside of Florida and that ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state is considered a nonresident pharmacy, and must register with the Florida Board of Pharmacy and make specified disclosures to the board. Such disclosures include: the location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to Florida residents.

III. Effect of Proposed Changes:

The bill states that, notwithstanding any other law, when an audit of the Medicaid-related records of a pharmacy licensed under ch. 465, Florida Statutes, is conducted, the audit must be conducted according to the following requirements:

- The pharmacist must be given at least 2 weeks' prior notice of the audit;
- Audits must be conducted by a Florida licensed pharmacist;
- Clerical, recordkeeping, or computer errors regarding records required by Medicaid must not be considered a willful violation and such errors must not be subject to criminal penalties without proof of intent to commit fraud;
- A pharmacist is permitted to use documentation written or transmitted by any means of communication for purposes of validating records with respect to orders or refills of a legend or narcotic drug;
- Findings of overpayment or underpayment must be based on actual overpayment or underpayment, not on projections based on the number of patients with a similar diagnosis or the number of similar orders or refills for similar drugs;
- All types of pharmacies must be audited under the same standards and parameters;
- A pharmacist must be allowed at least 10 days to produce documentation to address any discrepancy found during an audit;
- The period covered by an audit may not exceed 1 calendar year;

¹ See ss. 465.018, 465.022, 465.196, and 465. 023, F.S.

- An audit may not be scheduled during the first 5 days of any month; and
- The audit report must be delivered to the pharmacist within 90 days after conclusion of the audit.

The Agency for Health Care Administration is required to establish a process for a pharmacist to obtain a preliminary review of an audit report and to appeal an unfavorable audit report without the need to obtain legal counsel. The preliminary review and appeal may be conducted by an ad hoc peer-review panel made up of actively practicing pharmacists, appointed by AHCA. If, after the preliminary review, AHCA or the review panel finds that the unfavorable audit report lacks merit and that the pharmacist did not commit intentional fraud, AHCA must dismiss the report.

The bill specifies that these audit requirements do not apply to investigative audits conducted by the Medicaid Fraud Control Unit.

The bill will take effect upon becoming a law.

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 this bill have no impact on public records or open meetings issues under the requirements of Art. I, s. 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 requires AHCA to give a pharmacist 2 weeks' prior notice of the audit. Current statute provides for 24-hour notice for audits of physicians. With the exception of physician audits, no notice is required for any other provider types. This may raise equal protection challenges by non-pharmacy providers.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

If AHCA is unable to extend findings from a sample to the universe of claims paid, the agency may need to audit more pharmacy claims, which would place a greater burden on the pharmacy.

C. Government Sector Impact:

The Agency for Health Care Administration indicates that the fiscal impact is indeterminable. However, without the authority to extend findings from a sample to the universe of claims paid, audits may take more time as more claims may need to be reviewed. Audits would be more expensive to conduct. If the bill reduces the ability of AHCA to recover overpayments, there will be a negative fiscal impact on the Medicaid program.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Federal regulations require states to recover overpayments to providers, regardless of whether the overpayment was the result of fraud or simply the result of an error. The requirement in the bill that the state dismiss audit reports in which intentional fraud was not committed will place Florida out of compliance with federal requirements for the administration of its Medicaid program.

Florida's use of sampling and extension of sampling errors to a like population is the same methodology used by the federal Department of Health and Human Services and has been approved by the federal government as a tool to detect overpayments.

Giving notice allows a provider the opportunity to fabricate or create records and may allow fraudulent providers to elude Medicaid auditors by closing the business or moving.

AHCA notes that some pharmacy audits are financial in nature; and therefore the requirement that audits be conducted by pharmacists may hinder conducting financial audits that require the expertise of other types of professionals such as accountants.

VIII. Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.