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 2368

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

SUBJECT: Medicaid Audits of Pharmacies

March 12, 2002 DATE: **REVISED:** ANALYST STAFF DIRECTOR REFERENCE ACTION Favorable/CS 1. Liem Wilson HC GO 2. JU 3. AHS 4. 5. AP 6.

Summary:

The Committee Substitute for Senate Bill 2368 provides additional requirements for Medicaid audits of pharmacies including: at least 2 week's prior notice of an audit; qualifications of auditors; requirements that certain errors do not constitute a willful violation and are not subject to criminal penalties without proof of intent to commit fraud; use of 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; a prohibition on the use of statistical sampling projections to a population in determining an overpayment; requirements that all pharmacies be audited under the same standards and parameters; allowing a pharmacist at least 10 days in which to produce documentation to address any discrepancy found during an audit; a limitation on the period covered by an audit to 1 calendar year; a prohibition on an audit being scheduled during the first 5 days of any month; a requirement for delivery of an audit report to a pharmacist within 90 days after conclusion of the audit; a process for a preliminary review of an audit report by peers; and a requirement for dismissal of an audit if the peer review panel finds that the pharmacist did not commit intentional fraud. The requirements of the bill do not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs.

The bill creates an undesignated section of law.

I. 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) 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 Florida Medicaid program spends nearly \$10 billion annually providing health care. The proportion of annual health care expenditures lost to fraud and abuse remains unknown because these losses are not systematically measured. However, conventional wisdom estimates that losses to fraud and abuse may exceed 10 percent of annual Medicaid spending.

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 (MFCU) of the Office of the Attorney General, and that the agency and the MFCU develop a memorandum of understanding which 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 MFCU 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 MFCU is authorized to refer any criminal violation to the appropriate prosecuting authority.

The 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 (MFCU) in the Department of Legal Affairs under the Attorney General. 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.

When MPI believes there is evidence of fraud and refers the case to MFCU, MPI ceases working on the case and collection of overpayments. If MFCU ultimately determines that the provider is not to be prosecuted for fraud, the case is referred back to MPI for recoupment. MFCU has access to the same data as MPI uses to find its cases, as well as leads from other providers, a hotline and the general public. In a few instances, the same case is identified independently by both agencies. The agencies regularly exchange lists of active cases to avoid AHCA interfering with cases being investigated by MFCU.

When AHCA identifies an overpayment to a provider in an FAL, federal law allows the state 60 days to recover the overpayment before the federal share of the overpayment is deducted from the state's federal allotment. If the provider is bankrupt or the amount is determined to be legitimately uncollectible, the state is not liable for the federal portion. The state may later reclaim the refunded amount, if the provider is bankrupt or out of business and the state documents that it has made reasonable efforts to obtain recovery.

The federal Centers for Medicare and Medicaid Services (formerly HCFA) fraud control staff report that the 60 day repayment requirement has proven to be extremely problematic for states, since states rarely are able to complete action on overpayment cases (particularly those that involve appeals hearings), attempt to collect, and determine that amounts are uncollectible within the 60 days allowed in regulations. At times this may provide an incentive for states to remove problematic providers from the Medicaid program without identifying specific overpayments, in order to side-step the issue of making federal refunds.

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 contracts with Heritage Information Systems, Inc., to conduct compliance audits of pharmacy providers. Heritage currently performs two types of on-site audits: a one day audit referred to as an "on-site audit," and a multi-day audit referred to as an "in-depth" audit.

In an on-site audit, the provider is given approximately one week prior notice and the audit lasts one day. In this audit a statistically valid random sample of paid claims are generated from the Medicaid paid claims file. The supporting documentation of each claim is reviewed at the pharmacy for compliance. During the audit and upon completion of the review, the provider is informed of the discrepancies found and is given the opportunity to address those issues and provide additional documentation. Following the conclusion of the on site audit the provider is given 5 additional days to submit additional documentation. Overpayments found in the sample are extended to the population of claims using a statistical methodology and an overpayment for the audit is determined.

In-depth audits, lasting 4 to 5 days, are ordered when, based on a preliminary review, the Agency feels that a more thorough analysis is required and it is believed that providing notice may compromise the effectiveness of the audit. Therefore, the provider is not given notice for this type of audit. This audit consists of the review of a random sample of claims and the results are extended to the population of claims being reviewed to identify the overpayment for this review. This audit also compares purchase documentation for approximately 20 drugs with claims paid by Medicaid. An overpayment for this review is computed for any purchase shortages. The provider must address both overpayments.

The Audit Process

The agency determines and directs Heritage to perform audits of selected pharmacies. Auditors arrive at the pharmacy and conduct an entrance interview. The auditor describes the audit process, including, but 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 claims to be reviewed is presented during the entrance interview.

Auditors conduct the review of records. In addition, auditors review shelf stock, conduct a brief analysis of the pharmacy's usual and customary pricing, conduct interviews, obtain a list of pharmacy employees, and copy documentation. Auditors also request financial documentation. During the review of the prescription sample, the auditor documents discrepancies in Heritage's computer system. Throughout the multi-day audit, the provider is given multiple opportunities to provide required documentation.

After receipt and review of all documentation, Heritage processes the audit findings and an audit report is generated. The report may include independent findings on specific drugs and extension of overpayments found in the random sample to the population of claims in the review period using generally accepted statistical formulas and methods. The report is sent to AHCA.

At the conclusion of the review, the auditor prints a copy of the exit interview report and reviews the report with the pharmacist. At this time, the pharmacist is again given the opportunity to provide essential documentation. Should the pharmacist produce additional documentation, the auditor reviews the documentation and modifies the audit findings. If a random sample was used in this audit, findings may be extrapolated.

The pharmacist is provided instructions on sending documentation that could not be found during the audit but was on site during the audit. The pharmacist may send the located documentation to Heritage postmarked no later than 5 days from delivery of the exit interview report. The pharmacist must furnish a written and signed statement to the effect that the documentation was on site at the time of the audit.

The agency reviews the findings of the audit report and takes appropriate actions. These actions may include, but are not limited to, sending a notice with rights to the provider regarding the overpayment due, sending an educational letter, and making referrals to the Medicaid Fraud Control Unit.

Common Violations

The most common violations found in the review of the prescription records are:

- Cannot find an original hard copy prescription document;
- Failure to document additional refills;
- Wrong prescriber on claim; and
- Overbilled quantity.

The original prescription or physician's order must be maintained in its original paper form or as an exact front and back scanned image of the original prescription or physician's order. The original prescription or physician's order paper document is required to be physically filed stored, readily retrievable, and furnished as needed or requested. The existence of or storing of data regarding the original prescription, physician's order, or dispensing information in a computer database or reports generated is not sufficient for compliance.

Additional refill authorization must be documented by either creating a new original prescription, or adding the additional authorized refills to the original prescription or physician's order by noting at least the date, number of additional refills, and the prescriber or prescriber's agent authorizing the refills. This notation must be retained on the original prescription document (paper form) or in the computer database and readily retrievable. Adding additional refills without documenting the above information is not sufficient for compliance.

II. Effect of Proposed Changes:

Section 1. Requires that:

- notwithstanding any other law, an audit of the Medicaid related records of a pharmacy must be conducted as provided in this section;
- requires the agency to provide at least 2 week's prior notice of an audit;
- requires that an audit must be conducted by a pharmacist licensed in this state;
- provides that certain errors (any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error) do not constitute a willful violation and are not subject to criminal penalties without proof of intent to commit fraud;
- allows a pharmacist to 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 drug or narcotic drug;
- prohibits the agency from using any statistical sampling and extending the results to the population in determining the overpayment;
- requires that all pharmacies be audited under the same standards and parameters;
- provides that a pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit;
- limits the period covered by an audit to 1 calendar year;
- prohibits an audit from being scheduled during the first 5 days of any month; and
- requires that the audit report must be delivered to the pharmacist within 90 days after conclusion of the audit.

The bill requires AHCA to establish a process under which a pharmacist may obtain a preliminary review of an audit report and may 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 consisting of pharmacists in active practice appointed by the agency.

The bill requires that the agency dismiss the audit report without the necessity of any further proceedings if the peer review panel finds that the pharmacist did not commit intentional fraud.

The requirements of the bill do not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs.

Section 2. Provides an effective date of upon becoming a law.

III. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Art. VII, s. 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 Art. III, s. 19(f) of the Florida Constitution.

IV. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Under state law, different types of pharmacies have different record requirements. The requirement that all pharmacies be audited under the same standards and parameters would force the agency to conduct the most comprehensive audit in all cases.

C. Government Sector Impact:

The agency believes that the bill will substantially reduce the ability of the state to recover Medicaid overpayments to pharmacies.

V. Technical Deficiencies:

Federal regulations require that states recover overpayments to providers, regardless of whether the overpayment was the result of fraud of 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 federal compliance in 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. The bill uses the term "special pharmacy", but does not define the term.

VI. Related Issues:

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

VII. Amendments:

None.

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