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 Regulated Industries

BILL:	CS/SB 702
INTRODUCER:	Regulated Industries Committee and Senators Bean and Sobel
SUBJECT:	Pharmacy Audits
DATE:	March 13, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Petersen	Stovall	HP	**Favorable**
2.	Pringle	Imhof	RI	**Fav/CS**
3.			JU	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 702 establishes the rights of a pharmacy when it is audited directly or indirectly by a managed care company, insurance company, third-party payor, pharmacy benefit manager, or an entity that represents responsible parties, such as companies or groups that self-insure. The rights created are largely the same as the requirements currently applicable to Medicaid audits of pharmacies. The rights do not apply to audits based on a suspicion of fraud or audits of Medicaid fee-for-service claims.

The bill requires the Office of Insurance Regulation to investigate a complaint from a pharmacy that alleges a willful violation provisions of the bill by an entity regulated by the office. It provides for the complaint procedure and that a violation is an unfair claim settlement practice under s. 641.3903(5)(c)1. and 4., F.S., and enforceable as provided in part I, ch. 641, F.S., and s. 626.9521, F.S.

II. Present Situation:

Pharmacy Regulation

Pharmacies and pharmacists are regulated under the Florida Pharmacy Act (the Act) found in ch. 465, F.S.[1] The Board of Pharmacy (the board) is created within the department to adopt rules to implement provisions of the Act and take other actions according to duties conferred on it in the Act.[2]

[1] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.
[2] Section 465.005, F.S.

Several pharmacy types are specified in law and are required to be permitted or registered under the Act:

- Community pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.
- Institutional pharmacy – a location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility where medical drugs are compounded, dispensed, stored, or sold. The Act further classifies institutional pharmacies according to the type of facility or activities with respect to the handling of drugs within the facility.
- Nuclear pharmacy – a location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold, excluding hospitals or the nuclear medicine facilities of such hospitals.
- Internet pharmacy – a location not otherwise permitted under the Act, whether within or outside the state, which uses the internet to communicate with or obtain information from consumers in this state in order to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.
- Non-resident pharmacy – a location outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state.
- Special pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold if such location is not otherwise defined which provides miscellaneous specialized pharmacy service functions.

Each pharmacy is subject to inspection by the Department of Health and discipline for violations of applicable state or federal law relating to pharmacy. Any pharmacy located outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state is considered a nonresident pharmacy, and must register with the board as a nonresident pharmacy.[3,4]

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 263.3 billion in 2012.[5] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $216.5 billion on prescription drugs in 2012 and consumers paid $46.8 billion out of pocket for prescription drugs that year.[6]

As expenditures for drugs have increased, health plan sponsors have looked for ways to control that spending. Among other things, they have turned to pharmacy benefit managers (PBMs),

[3] Section 465.0156, F.S.
[4] However, the board may grant an exemption from the registration requirements to any nonresident pharmacy which confines its dispensing activity to isolated transactions. *See* s. 465.0156(2), F.S.
[5] 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 1970-2012, available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/tables.pdf (last visited Feb. 6, 2014).
[6] *Id.*

which are third party administrators of prescription drug programs. PBMs initially emerged in the 1980s as prescription drug claims processors. PBMs now provide a range of services including developing and managing pharmacy networks, developing drug formularies, providing mail order services, and processing and auditing claims.

In 2007, there were approximately 70 PBMs operating in the United States and managing prescription drug benefits for an estimated 95 percent of health beneficiaries nationwide.[7] Industry mergers in recent years have cut the number of large PBMs to two which together control 60 percent of the market and provide benefits for approximately 240 million people.[8]

The audit process is one means used by PBMs and health plan sponsors to review pharmacy programs. The audits are designed to ensure that procedures and reimbursement mechanisms are consistent with contractual and regulatory requirements. Over the years, different types of audits have been developed to address changes in benefit and billing processes. A concurrent daily review audit is intended to make immediate changes to a claim before payment is made and is triggered when a PBM or health plan sponsor's computer systems identify an unusual prescription, e.g. by volume dispensed, number of days supplied. A retrospective audit may be conducted as a desk top audit or an in-pharmacy audit. PBM or health plan sponsor staff conduct a desk audit remotely by contacting pharmacies to obtain supporting documentation, such as the written prescription, for a claim the staff are reviewing. An in-pharmacy audit is the most extensive and can last for days or weeks. During an in-pharmacy audit, audit staff require pharmacies to provide documentation for prescriptions dispensed during a specified time period. When the auditors identify errors or lack of documentation to support the claim, they notify the pharmacy and request repayment of all or a portion of the prescription cost. The last form of audit is an investigative audit which occurs where there is a suspicion of fraud or abuse.

Pharmacies have increasingly complained about the onerous and burdensome nature of these audits. 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.[9]

Organizations such as the National Community Pharmacists Association,[10] which represents 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. As of 2013, 29

[7] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited Feb. 6, 2014).
[8] Office of Program Policy Analysis & Government Accountability, *Research memorandum: Pharmacy Benefit Managers* (December 2, 2013) (on file with the Senate Health Policy Committee).
[9] National Community Pharmacists Association, *New Survey Reveals Pharmacists are Increasingly Struggling to Care for Patients Amid Predatory Audits, Unfair Reimbursement Practices*, 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 Feb. 6, 2014).
[10] 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 Feb. 6, 2014).

states[11] have passed fair and uniform pharmacy audit laws that regulate PBM pharmacy audit practices. Elements of these laws typically include:

- Prior notification.
- Limiting the audit timeframe to not more than 24 months.
- Recoupment based on direct evidence and not extrapolation.
- Prohibiting recoupment or penalties for clerical errors.
- Requiring the availability of a consulting pharmacist if the audit involves clinical judgment.
- Providing a timeframe for receiving results and the opportunity to appeal.
- Exempting audits based on a suspicion of fraud from the auditing criteria.[12]

Medicaid Pharmacy Audits

In 2003, the Legislature established requirements for Medicaid audits of pharmacies. The requirements are as follows:

- 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.[13]

The law requires the Agency for Health Care Administration (AHCA) to establish a process that allows a pharmacist to obtain a preliminary review of an audit report and the ability to appeal an

[11] Alabama, Arizona, California, Colorado, Florida (Medicaid, only), Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Minnesota, Mississippi, Missouri, Montana, New Hampshire, New Mexico, North Carolina, North Dakota, Oklahoma, Oregon, South Carolina, South Dakota, Tennessee, Texas, Utah, and Vermont.
[12] Office of Program Policy Analysis & Government Accountability, *supra* note 8.
[13] Section 465.188, F.S.

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 which is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.

III. Effect of Proposed Changes:

Section 1 establishes the rights of a pharmacy when it is audited directly or indirectly by a managed care company, insurance company, third-party payor, pharmacy benefit manager, or an entity that represents responsible parties such as companies or groups, referred to in the bill as "entity." The rights include:

- To have at least 7 days prior notice of each initial on-site audit;
- To have an on-site audit scheduled during the first 5 days of the month, only by consent of the pharmacist;
- To limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity;
- To have an audit that requires clinical or professional judgment conducted by or in consultation with a pharmacist;
- To use the records of a hospital, physician, or other authorized practitioner to validate the pharmacy records in accordance with state and federal law;
- To be reimbursed for a claim that was retroactively denied for a clerical, typographical, scrivener's, or computer error, if the prescription was properly dispensed, unless the pharmacy has a pattern of such errors or fraudulent billing is alleged or the error results in actual financial loss to the entity;
- To receive the preliminary audit report within 120 days after the audit is concluded and the final audit report within 6 months after receiving the preliminary report;
- To have 10 days after the preliminary audit report is delivered in which to produce documentation to address a discrepancy or audit finding; and
- To have recoupment or penalties based on actual overpayments, not extrapolation.[14]

The rights do not apply to audits that are based on a suspicion of fraud or audits for Medicaid fee-for-service claims. The Office of Insurance Regulation is required to investigate a complaint from a pharmacy that alleges a willful violation of the bill by an entity conducting an audit of the pharmacy on behalf of a managed care company or insurance company regulated by the office. The complaint must be in writing, signed by the authorized pharmacy representative and contain facts that demonstrate a violation of the bill's provisions.

[14] Extrapolation is a process whereby statistical sampling is used to calculate and project the amount of overpayment made on claims.

A violation is an unfair claim settlement practice under s. 641.3903(5)(c)1. and 4., F.S., and is enforceable against the entity as provided in part I, ch. 641, F.S., and s. 626.9521, F.S.

Section 2 provides an effective date of July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

CS/SB 702 will have an indeterminate fiscal impact on the private health sponsors through potential modifications in pharmacy auditing methodologies and limitations on recoupment of claims.

The prior notification requirement and limitation on audits during the first 5 days of the month may allow pharmacies to manage workload more efficiently.

C. Government Sector Impact:

CS/SB 702 will have an indeterminate, but likely insignificant, fiscal impact on government pharmacies, e.g. public health departments. These pharmacies may file claims from time-to-time with private health sponsors and are subject to random audits, but the substantial majority of their claims are paid by Medicaid.

VI. Technical Deficiencies:

None.

VII. Related Issues:

According to the Agency for Health Care Administration, the bill will not have a direct impact on the Medicaid Program Integrity Office within the Agency for Health Care Administration.

Under the Statewide Medicaid Managed Care program, the Medicaid Program Integrity Office will not directly audit pharmacy claims of those providers that contract with Florida Managed Medical Assistance plans. The plans will submit pharmacy encounter data to the agency and the agency will have a third party contractor analyze the claims. This process is not affected by the bill.

The agency noted that under the bill, fee-for-service Medicaid audits or investigation of potential fraudulent claims by the agency is specifically exempted. There is a remaining question as to whether the agency's ability to look at potential abuse is affected by this bill. Agency staff is reviewing this further.

VIII. Statutes Affected:

This bill creates section 465.1885 of the Florida Statutes.

IX. Additional Information:

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

CS by Regulated Industries Committee on March 13, 2014
The CS provides that the additional records used to validate the pharmacy's records will be in accordance with state and federal law.

The CS provides that a pharmacy will not be reimbursed for an erroneous claim if it causes actual loss to an entity covered by the bill. It also defines what a "properly and dispensed" prescription means.

The CS changes the timeframe for a pharmacy to receive the preliminary audit report from 90 to 120 days.

The CS provides that the Office of Insurance Regulation must investigate a complaint from a pharmacy which alleges a willful violation of the provisions of the bill by an entity regulated by the office. It provides for the complaint procedure and that a violation is an unfair claim settlement practice under s. 641.3903(5)(c)1. and 4., F.S., and enforceable as provided in part I, ch. 641, F.S., and s. 626.9521, F.S.

B. Amendments:

None.