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 Appropriations

BILL:	CS/CS/CS/SB 702
INTRODUCER:	Appropriations Committee; Judiciary Committee; Regulated Industries Committee; and Senator Bean and others
SUBJECT:	Pharmacy Audits
DATE:	April 14, 2014
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Peterson	Stovall	HP	**Favorable**
2.	Pringle	Imhof	RI	**Fav/CS**
3.	Munroe	Cibula	JU	**Fav/CS**
4.	Brown	Kynoch	AP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/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 in the bill are similar to the requirements currently applicable to Medicaid audits of pharmacies. The rights created in the bill do not apply to audits based on suspicion of fraud, wilful misrepresentation evidenced by a physical review, review of claims data or statements, other investigative methods; audits of claims paid for by federally funded programs; or concurrent reviews or desk audits that occur within three business days after transmission where no chargeback or recoupment is demanded.

The bill may have an indeterminate, but likely insignificant, fiscal impact.

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 of Health

[1] Other pharmacy paraprofessionals, including pharmacy interns and pharmacy technicians, are also regulated under the Act.

(DOH) to adopt rules to implement provisions of the Act and take other actions according to duties conferred on the DOH in the Act.[2]

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.[3]
- 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.[4]
- 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.[5]
- Internet pharmacy – a location not otherwise permitted under the Act, whether within or outside the state of Florida, which uses the internet to communicate with or obtain information from consumers in this state to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state.[6]
- Nonresident pharmacy – a location outside this state which ships, mails, or delivers, in any manner, a dispensed drug into this state.[7]
- Special pharmacy – a location where medicinal drugs are compounded, dispensed, stored, or sold if the location is not otherwise defined which provides miscellaneous specialized pharmacy service functions.[8]

Each pharmacy is subject to inspection by the DOH and discipline for violations of applicable state or federal law relating to pharmacy. Any pharmacy located outside of Florida 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.[9,10]

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.[11] Health plan sponsors, which include

[2] Section 465.005, F.S.
[3] *See* s. 465.018, F.S.
[4] *See* s. 465.019, F.S.
[5] *See* s. 465.0193, F.S.
[6] *See* s. 465.0197, F.S.
[7] *See* s. 465.0156, F.S.
[8] *See* s. 465.0196, F.S.
[9] Section 465.0156, F.S.
[10] However, the board may grant an exemption from the registration requirements to any nonresident pharmacy that confines its dispensing activity to isolated transactions. *See* s. 465.0156(2), F.S.
[11] 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,*

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.[12]

As expenditures for drugs have increased, health plan sponsors have looked for ways to control spending. Health plan sponsors have turned to pharmacy benefit managers (PBMs), which are third party administrators of prescription drug programs, as one method to control spending. 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.[13] Industry mergers in recent years have reduced the number of large PBMs to two, which together control 60 percent of the market and provide benefits for approximately 240 million people.[14]

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. Several different types of audits have been developed to address changes in benefit and billing processes:

- Concurrent daily review audit – 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, which can be identified according to the volume dispensed or number of days supplied.
- Retrospective audit – may be conducted as a desktop 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.
- In-pharmacy audit – most extensive type of audit 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.
- Investigative audit – occurs where there is a suspicion of fraud or abuse.

Pharmacy trade associations have increasingly complained about PBM audits. A 2011 survey conducted among members of the National Community Pharmacists Association found that

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available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/tables.pdf (last visited March 26, 2014).

[12] *Id.*

[13] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (February 2007), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 26, 2014).

[14] Office of Program Policy Analysis & Government Accountability, *Research memorandum: Pharmacy Benefit Managers* (December 2, 2013) (on file with the Senate Health Policy Committee).

pharmacy audits were focusing on trivial errors (misspelling patient names or incorrect data) rather than intentional, fraudulent acts.[15]

Organizations such as the National Community Pharmacists Association,[16] which represents independent pharmacies, have been advocating for legislation at the federal and state levels to address what they perceive as predatory practices by PBMs. As of 2013, 29 states[17] have passed fair and uniform pharmacy audit laws that regulate PBM pharmacy audit practices. Elements of these laws typically include some combination of the following:

- 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; or
- Exempting audits based on a suspicion of fraud from the auditing criteria.[18]

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 of notice prior to 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 for 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 based on the number of similar orders or refills for similar drugs.
- Each pharmacy shall be audited under the same standards and parameters.

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[15] 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 March 26, 2014).

[16] 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 February 6, 2014).

[17] 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.

[18] Office of Program Policy Analysis & Government Accountability, *supra* note 8.

- 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 one calendar year.
- An audit may not be scheduled during the first five days of any month due to the high volume of prescriptions typically 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 six 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.[19]

Current 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 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. After the preliminary review, if the AHCA or the review panel determine 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, collectively referred to as an "entity" in the bill. The rights include:

- To have at least seven days prior notice of each initial on-site audit;
- To have an on-site audit scheduled during the first three 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 written and verifiable 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;

[19] Section 465.188, F.S.

- To receive the preliminary audit report within 120 days after the audit is concluded and to receive the final audit report within six months after receiving the preliminary report;
- To have 10 business days after the preliminary audit report is delivered to produce documentation to address a discrepancy or audit finding; and
- To have recoupment or penalties based on actual overpayments, not extrapolation.[20]

The rights do not apply to audits that are based on a suspicion of fraud, wilful misrepresentation evidenced by a physical review, review of claims data or statements, or other investigative methods; audits of claims paid for by federally funded programs; or concurrent reviews or desk audits that occur within three business days after transmission where no chargeback or recoupment is demanded.

An entity that audits a pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team Task Force area designated by the United States Department of Health and Human Services and the United States Department of Justice may dispense with the seven-day advance notice requirement under the bill, if the pharmacy has been a member of a credentialed provider network for less than 12 months.

Section 2 provides an effective date of October 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/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.

[20] Extrapolation is a process whereby statistical sampling is used to calculate and project the amount of overpayment made on claims. See e.g., "Extrapolate" means to estimate (a value or values of a function) for values of the argument not used in the process of estimation; infer (a value or values) from known values. THE AMERICAN HERITAGE DICTIONARY (2nd ed. 1985)

C. Government Sector Impact:

The bill will have an indeterminate, but likely insignificant, fiscal impact on government pharmacies. These pharmacies may file claims periodically 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 AHCA, the bill will not have a direct impact on its Medicaid Program Integrity Office.[21] Under the Statewide Medicaid Managed Care program, the Medicaid Program Integrity Office will not directly audit pharmacy claims of those providers that contract with Medicaid managed care plans. The plans will submit pharmacy encounter data to the agency and the AHCA will have a third party contractor analyze the claims. This process is not affected by the bill.[22]

The AHCA noted that under the bill, audits of claims paid for by federally funded programs and investigation of potential fraudulent claims by the AHCA are specifically exempted. It is unknown whether the AHCA's ability to monitor potential abuse is affected by this bill.[23]

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/CS/CS by Appropriations on April 10, 2014:
The CS removes a redundant provision in the bill regarding audits related to fee-for-service claims under the Medicaid program. The CS also provides that an entity that audits a pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team Task Force area designated by the United States Department of Health and Human Services and the United States Department of Justice, may dispense with the seven-day advance notice requirement under the bill, if the pharmacy has been a member of a *credentialed* provider network for less than 12 months.

[21] Correspondence between the Senate Regulated Industries Committee staff and staff of the Agency for Health Care Administration (March 12, 2014) (on file with the Senate Committee on Judiciary).
[22] *Id.*
[23] *Id.*

CS/CS by Judiciary on April 1, 2014:
The CS revises the rights of a pharmacy when audited by managed care companies, insurance companies, pharmacy benefit managers, and certain other entities. Specifically, the committee substitute:

- Requires that the records of a hospital, physician, or other practitioner used to validate a pharmacy's records be written and verifiable and allows concurrent reviews or desk audits to occur within three days after the transmission of certain claims;
- Revises the exceptions to a pharmacy's rights under the bill;
- Removes from the bill a requirement for the Office of Insurance Regulation to investigate complaints alleging the violation of a pharmacy's rights; and
- Changes the effective date of the bill from July 1, 2014 to October 1, 2014.

CS by Regulated Industries 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;
- 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;
- Modifies the timeframe for a pharmacy to receive the preliminary audit report from 90 to 120 days;
- Provides that the Office of Insurance Regulation (OIR) must investigate a complaint from a pharmacy which alleges a willful violation of the provisions of the bill by an entity regulated by the OIR; and
- Provides the complaint procedure for the OIR and specifies 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.