HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/HB 745	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Appropriations Committee; Cummings and others	116 **Y's**	0 **N's**
COMPANION BILLS:	CS/CS/CS/SB 702	**GOVERNOR'S ACTION:**	Approved

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SUMMARY ANALYSIS

CS/HB 745 passed the House on April 30, 2014, as CS/CS/CS/SB 702.

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. This has brought about increased scrutiny of pharmaceutical dispensing and reimbursement processes. As expenditures for drugs have increased, third-party payers have looked for ways to control that spending. Among other things, they have turned to pharmacy benefit managers (PBMs), which are third-party administrators of prescription drug programs.

PBMs process prescription drug claims for third-party payers and use claim volume to negotiate with drug makers and pharmacies. They are also responsible for maintaining the formulary of covered drugs, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers. Pharmacies have increasingly complained that these audits are onerous and burdensome. In Florida, the primary concerns of pharmacies regarding audits by PBMs are fairness and lack of consistency in many audit areas.

The bill provides certain rights in ch. 465, F.S., pertaining to a pharmacy during an audit by a third-party payer. The bill imposes notice, timing, and procedural requirements on entities conducting pharmacy audits. The bill appears to address many of the complaints expressed by pharmacies in relation to perceived inequity, unfairness, or burdensome practices of third-party payor audits or third-party administrator audits.

The provisions of the bill do not apply to audits that are based on a suspicion of fraud or wilful misrepresentation; audits of claims paid by federally funded programs; or concurrent reviews or desk audits that occur within 3 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 7-day advance notice requirement under the bill, if the pharmacy has been a member of a credentialed provider network for less than 12 months.

The bill has an indeterminate, but likely insignificant, fiscal impact on state government.

The bill was approved by the Governor on June 13, 2014, ch. 2014-85, L.O.F., and will become effective on October 1, 2014.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Background

Third-Party Payor/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 $263.3 billion in 2012.[1] Health insurers, including Medicare and Medicaid, and other third party payers spent $214 billion on prescription drugs in 2011 and consumers paid $46.8 billion out of pocket for prescription drugs that year.[2]

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 (PBMs), which are third party administrators of prescription drug programs. PBMs 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. PBMs currently administer prescription drug plans for more than 210 million people in the U.S. with employer sponsored health care coverage, individual health care coverage, health care coverage through a union, and coverage for prescription drugs through Medicare Part D.[3] Two large PBMs, Express Scripts and CVS/Caremark, control 60 percent of the market and administer prescription drug plans for approximately 240 million people.[4]

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. PBMs conduct different types of audits, depending on client and contractual requirements, including:

- Claims analyses to identify payment anomalies;
- Desk audit using documents received from a pharmacy; and
- On-site audit of a pharmacy.[5]

Audit practices, protocols, and requirements vary by PBM and by the client.

Pharmacies have increasingly complained about the perceived onerous and burdensome nature of these audits.[6] In Florida, the primary concerns of pharmacies regarding audits by PBMs are fairness

[1] 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 1960-2012*, Table 2, available at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf (last viewed on March 22, 2014).
[2] Id. at Table 4.
[3] Pharmaceutical Care Management Association, *About PCMA*, available at www.pcmanet.org/about-pcma/about-pcma (last viewed on March 19, 2014).
[4] The Florida Legislature, Office of Program Policy Analysis and Government Accountability, *Pharmacy Benefit Managers*, December 20, 2013, page 1 (on file with Health Innovation Subcommittee staff).
[5] Id. at page 2.
[6] National Community Pharmacists Association, *Survey: Pharmacists Say Patient Care Undermined by Auditing, Payment Practices*, available at www.ncpanet.org/pdf/leg/sep12/pbmsurvey0912final.pdf (last viewed on March 22, 2014).

and lack of consistency in areas such as prior notification, extrapolation,[7] and look-back period of the audit.[8]

Statewide Medicaid Managed Care

In 2011, Florida established the Statewide Medicaid Managed Care (SMMC) program as Part IV of Chapter 409, F.S. The SMMC requires the Agency for Health Care Administration (AHCA) to create an integrated managed care program for Medicaid enrollees to provide all the mandatory and optional Medicaid benefits for primary and acute care. Each Medicaid recipient will have one managed care organization to coordinate all health care services, rather than various entities as in the current Medicaid program. This comprehensive coordinated system of care was successfully implemented in a 5-county Medicaid reform pilot program which began in 2006.

The SMMC program has two components: the Long-term Care Managed Care Program and the Managed Medical Assistance (MMA) Program. The MMA program provides primary and acute medical assistance and related services, including pharmacy. On December 28, 2012, AHCA released an Invitation to Negotiate (ITN) to competitively procure managed care plans on a statewide basis for the MMA program.[9] AHCA subsequently selected health maintenance organizations and provider service networks via the competitive procurement. On February 6, 2014, AHCA executed contracts with the MMA managed care plans.[10]

AHCA began implementing the MMA program in selected regions on May 1, 2014, with the last regions being implemented on August 1, 2014. The program must be fully implemented in all regions by October, 2014, as directed in s. 409.971, F.S.

Once the MMA program is fully implemented, most Medicaid recipients will receive services through managed care rather than fee-for-service.

Medicaid Pharmacy Audits

Section 465.188, F.S., establishes requirements for AHCA and other state agencies when conducting 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.[11]
- An audit must be conducted by a pharmacist licensed in Florida.[12]
- 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.[13]
- 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.[14]

[7] A PBM audit usually looks at a small sample of the large volume of prescriptions filled by a pharmacy during a certain time period. Some audit practices allow the PBM to apply the error rate found in the sample to the entire volume of prescriptions in order to calculate the repayment.
[8] See supra, FN 4 at page 3.
[9] Id.
[10] AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, *Addendum 2* Solicitations Number: AHCA ITN 017-12/13; Feb. 26, 2013, available at: http://myflorida.com/apps/vbs/vbs_www.ad.view_ad?advertisement_key_num=105774 (last visited March 22, 2014); AHCA Invitation to Negotiate, *Statewide Medicaid Managed Care*, Solicitation Number: AHCA ITN 017-12/13, Dec. 28, 2012, available at: http://myflorida.com/apps/vbs/vbs_www.ad.view_ad?advertisement_key_num=105774 (last visited March 22, 2014).
[11] S. 465.188(1)(a), F.S.
[12] S. 465.188(1)(b), F.S.
[13] S. 465.188(1)(c), F.S.
[14] S. 465.188(1)(d), F.S.

- 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.[15]
- Each pharmacy shall be audited under the same standards and parameters.[16]
- A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.[17]
- The period covered by an audit may not exceed one calendar year.[18]
- 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.[19]
- The audit report must be delivered to the pharmacist within ninety days after conclusion of the audit.[20]
- 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.[21]
- The agency conducting the audit may not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.[22]

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.[23] 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.[24] 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.[25]

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 that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.[26]

Effect of Proposed Changes

CS/HB 745 creates certain rights in ch. 465, F.S., which pertain to a pharmacy during an audit by a third-party payer. These rights address many of the complaints expressed by pharmacies in relation to perceived inequity, unfairness, or burdensome practices of third-party payor audits or third-party administrator audits.

The bill provides the following rights to a pharmacy regarding an audit:

- To be given 7 days of notice prior to the initial onsite audit of each audit cycle.
- To have an onsite audit scheduled after the first 3 calendar days of the month, unless the pharmacist consents to an earlier audit date.
- To limit the audit period to 24 months from the date a claim was submitted to or adjudicated by the entity conducting the audit.

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[15] S. 465.188(1)(e), F.S.
[16] S. 465.188(1)(f), F.S.
[17] S. 465.188(1)(g), F.S.
[18] S. 465.188(1)(h), F.S.
[19] S. 465.188(1)(i), F.S.
[20] S. 465.188(1)(j), F.S.
[21] Id.
[22] S. 465.188(1)(k), F.S.
[23] S. 465.188(2), F.S.
[24] Id.
[25] Id.
[26] S. 465.188(3) and (4), F.S.

- To have an audit which requires clinical or professional judgment conducted by or in consultation with a pharmacist.
- To use the written and verifiable records of a hospital or authorized practitioner to validate a pharmacy record in accordance with state and federal law.
- To be reimbursed for a claim that was retroactively denied for a clerical, scrivener's, typographical, or computer error if the patient received the correct medication, dose, and instructions for administration, unless a pattern of errors exists or fraud is alleged, or the error results in actual financial loss to the entity.
- To receive a preliminary audit report within 120 days after conclusion of the audit.
- To produce documentation to challenge a discrepancy or finding within 10 days after the preliminary audit report is delivered to the pharmacy.
- To receive the final audit report within 6 months of receiving the preliminary audit report.
- To have penalties and recoupments based on actual overpayments and not according to accounting principles of extrapolation.

The rights do not apply to audits that are based on a suspicion of fraud or 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 3 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 7-day advance notice requirement under the bill, if the pharmacy has been a member of a credentialed provider network for less than 12 months.

The bill has an indeterminate, but likely insignificant fiscal impact on state government.

Subject to the Governor's veto powers, the effective date of this bill is October 1, 2014.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to AHCA, the bill will not have a direct impact on the Medicaid Program Integrity (MPI) office within AHCA. Under the Statewide Medicaid Managed Care (SMMC) program, MPI will not directly audit pharmacy claims of those providers that contract with MMA plans. In addition, the Medicaid audits or investigation of potential fraudulent claims by the agency is specifically exempted, as Medicaid is a federally funded program.[27]

   AHCA is required to pay actuarially sound, risk-adjusted rates to managed care plans participating in the MMA program. The bill may impact the prescription drug benefit offered by the MMA plans; however, the impact is indeterminate, but likely insignificant.

[27] HB 745, Agency Legislative Bill Analysis, Agency for Health Care Administration, February 10, 2014 (on file with Health Care Appropriations Subcommittee).

As part of the State Group Insurance Program, the Department of Management Services contracts with a PBM for the State Employees' Prescription Drug Plan. Limiting the audit to a 24-month look back period could result in a loss of recouped claims for the trust fund; however, this would have an insignificant, negative, indeterminate impact to the State Employees' Health Insurance Trust Fund.[28]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill may limit the ability of managed care organizations, insurance companies, and other third party payors to recoup funds that may have been paid in error to pharmacies.

D. FISCAL COMMENTS:

None.

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[28] Agency Legislative Bill Analysis, Department of Management Services, March 27, 2014 (on file with Health Care Appropriations Subcommittee).