FISCAL IMPACT OF PROPOSED LEGISLATION **Measure: HB 2123 - A**

Seventy-Seventh Oregon Legislative Assembly – 2013 Regular Session
Legislative Fiscal Office

Only Impacts on Original or Engrossed Versions are Considered Official

Prepared by: Kim To
Reviewed by: Linda Ames, Matt Stayner
Date: 4/1/2013

Measure Description:
Requires State Board of Pharmacy to license pharmacy benefit managers.

Government Unit(s) Affected:
Oregon Health Authority (OHA), Board of Pharmacy

Local Government Mandate:
This bill does not affect local governments' service levels or shared revenues sufficient to trigger Section 15, Article XI of the Oregon Constitution.

Analysis:
House Bill 2123 A-Engrossed:

1. Requires individuals to obtain a license from the State Board of Pharmacy in order to act as a Pharmacy Benefit Manager (PBM) in Oregon. This license must be renewed annually.
2. Imposes limits on audits of pharmacies by PBMs, and other entities including insurers, third party administrators, and state agencies.
3. Requires that PBMs apply individual pharmacy reimbursement readjustments on a network-wide basis.

At this time, the fiscal impact of this bill on the State Board of Pharmacy and the Oregon Health Authority is indeterminate due to several factors discussed below.

State Board of Pharmacy
The full fiscal impact of this bill on the Board of Pharmacy is indeterminate due to the potential costs associated with compliance and enforcement. The bill requires the Board of Pharmacy to license PBMs in Oregon. If the bill passes, the Board of Pharmacy anticipates establishing one Operations Policy Analyst 2 position to oversee the licensing program. The agency estimates the Personal Services, related Services Supplies cost of the licensing program to be roughly $290,000 Other Funds and 1.00 FTE per biennium. However, note that in addition to licensing, the agency anticipates additional costs associated with modifying existing databases, changes in accounting processes, training of staff and Board members, as well as costs associated with complaints and investigations. Although at this time, these costs are indeterminate, but expected to be significant, the Board of Pharmacy provides the following information as a point of reference:

Accounting System: The bill stipulates that all moneys collected from PBM's for registration and renewal must be used only for the purpose of administering the PBM program. This mandated separation of the PBM program funds from other agency funds will require an additional layer of accounting for the agency.

Complaints and Investigations: The bill directs the agency to refuse to issue or renew, or suspend or revoke a licensee or applicant if the applicant or licensee engages in conduct likely to mislead, deceive or defraud the general public, or engages in unfair or deceptive business practices. Because these broad conditions may be subject to interpretation, the Board of Pharmacy anticipates an increase in the number of complaints, and investigations. Furthermore, if a case

results in disciplinary action, the licensee has due process rights for any disciplinary action. As a result, additional hearings and Department of Justice costs may be incurred. The Attorney General 2013-2015 proposed hourly rate for 2013-2015 is $167.00 per hour. A hearing relating to disciplinary action is estimated to require on average six hours of attorney general time. On average it takes an investigator about eight hours to conduct an investigation. If the investigation workload for the PBM program is significant, the Board of Pharmacy may need additional staffing and resources.

Inspections: At this time, it is not known whether or not inspections of PBM's will be necessary and if so, whether or not they will be conducted by the PBM Administrator or the Compliance Investigator. If the Board of Pharmacy is required to conduct inspections, affected staff members as well as Board members will require training. If the inspection workload for the PBM program is significant, the Board of Pharmacy may need additional staffing and resources.

Oregon Health Authority

The full fiscal impact of this bill on the Oregon Health Authority's Oregon Educators Benefit Board (OEBB) is indeterminate. The bill requires that PBMs apply individual pharmacy reimbursement readjustments on a network-wide basis which would inflate costs across the network especially if higher reimbursement rates provided to Critical Access Pharmacies are applied network-wide. OEBB contracts with a PBM. Inflated costs would impact OEBB through increased medical prescription drug rates. Although the exact premium increase is indeterminate at this time, according to OEBB's largest health insurer, Moda Health, the fiscal impact could range between two and three percent. A three percent increase in premium rates would result in an estimated fiscal impact of $27,560,914 Other Funds Non-Limited in the 2013-2015 biennium.

Also, note that the Oregon Educators Revolving Fund (ORS 243.884) authorizes the Oregon Health Authority's Oregon Educators Benefit Board to collect employee and employer contributions for pass-through of benefit premiums to insurance carriers for eligible members. Therefore, any proposed legislation resulting in a fiscal impact on revenues or expenditures with regard to insurance premiums provided by OEBB will impact any educational entity that has mandated or elective coverage under OEBB. This includes school districts, community colleges, education service districts and some charter schools.

77th OREGON LEGISLATIVE ASSEMBLY – 2013 Regular Session **MEASURE: HB 2123 A**
STAFF MEASURE SUMMARY **CARRIER:**
House Committee on Health Care

REVENUE: No revenue impact
FISCAL: Fiscal statement issued

Action:		Do Pass as Amended and Be Printed Engrossed and Be Referred to the Committee on Ways and Means by Prior Reference
Vote:		8 - 1 - 0
	Yeas:	Clem, Conger, Harker, Kennemer, Keny-Guyer, Lively, Thompson, Greenlick
	Nays:	Weidner
	Exc.:	0
Prepared By:		Tyler Larson, Administrator
Meeting Dates:		3/15, 4/1

WHAT THE MEASURE DOES: Requires licensure from State Board of Pharmacy to act as pharmacy benefit manager (PBM). Requires board establish rules for obtaining and renewing license. Allows board to refuse to issue or renew, suspend or revoke PBM license for specified conduct. Imposes limits on audits of pharmacies. Limits drugs be placed on maximum allowable cost (MAC) list. Requires PBMs disclose sources informing MAC list to network pharmacies and establish process for network pharmacy to request adjustment of MAC price.

ISSUES DISCUSSED:
- Work group history
- Impact of PBMs on local pharmacies
- PBM regulations in other states
- PBM audit procedures
- State Board of Pharmacy authority to license PBMs
- MAC pricing

EFFECT OF COMMITTEE AMENDMENT: Replaces the measure.

BACKGROUND: The Oregon State Board of Pharmacy (OSBP) regulates the practice of Pharmacy and enforces laws regarding pharmacists, drug outlets and the sale of drugs in Oregon. OSBP licenses pharmacists, registers and inspects retail and hospital pharmacies and stores that sell over the counter drugs, registers and inspects drug wholesalers and manufacturers and regulates the quality and distribution of drugs in Oregon.

A pharmacy benefit manager (PBM) is a third party administrator of prescription drug programs, and are primarily responsible for processing and paying prescription drug claims. Proponents assert that PBMs are profitable at the expense of pharmacies, and that audit procedures based on technicalities and undisclosed pricing practices endanger small pharmacies in Oregon.

House Bill 2123-A requires PBMs to be licensed by the OSBP, establishes regulations for audits of pharmacies and creates regulations around maximum allowable cost (MAC) pricing lists used by PBMs.

A-Engrossed
House Bill 2123

Ordered by the House April 3
Including House Amendments dated April 3

Introduced and printed pursuant to House Rule 12.00. Presession filed (at the request of House Interim Committee on Health Care)

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Requires State Board of Pharmacy to license pharmacy benefit managers.

Imposes limits on audits of pharmacies by pharmacy benefit managers and other entities.

[*Requires pharmacy benefit managers that have contracted with provider of health care plan or that are under control of provider of health care plan to permit covered individuals to fill mail order prescriptions at retail community pharmacy in same manner and at similar price that individuals fill orders at mail order pharmacies.*]

Places restrictions on use of maximum allowable cost pricing index by pharmacy benefit managers.

A BILL FOR AN ACT

Relating to prescription drugs.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 to 4 of this 2013 Act are added to and made a part of ORS chapter 689.

SECTION 2. (1) As used in this section and sections 3 and 4 of this 2013 Act:

(a) "Insurer" has the meaning given that term in ORS 731.106.

(b)(A) "Pharmacy benefit manager" means a person that contracts with pharmacies on behalf of an insurer, a third party administrator or the Oregon Prescription Drug Program established in ORS 414.312 to:

(i) Process claims for prescription drugs or medical supplies or provide retail network management for pharmacies or pharmacists;

(ii) Pay pharmacies or pharmacists for prescription drugs or medical supplies;

(iii) Contract with pharmacies or pharmacists for the procurement of prescription drugs or medical supplies; or

(iv) Negotiate rebates with manufacturers for drugs paid for or procured as described in this paragraph.

(B) "Pharmacy benefit manager" does not include a health care service contractor as defined in ORS 750.005.

(c) "Third party administrator" means a person licensed under ORS 744.702.

(2) A person must obtain a license from the State Board of Pharmacy in order to act as a pharmacy benefit manager in this state. The license must be renewed annually. The board shall establish by rule the procedure and qualifications for obtaining and renewing a license under this section. The procedure must include a requirement to:

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

(a) Submit an application, in a form prescribed by the board, that contains the name and address of an agent for the service of process;

(b) Pay a fee established by the board; and

(c) Verify that the applicant has obtained a surety bond.

(3) The board may refuse to issue or renew, or may suspend or revoke, a pharmacy benefit manager license if the applicant or licensee:

(a) Fails to comply with this section or section 3 or 4 of this 2013 Act;

(b) Engages in conduct likely to mislead, deceive or defraud the general public or the board;

(c) Engages in unfair or deceptive business practices; or

(d) Fails to pay fees or fines.

(4) The board shall deposit all moneys collected under this section into the State Board of Pharmacy Account established in ORS 689.139. Moneys collected under this section may be used only for the purpose of administering this section and sections 3 and 4 of this 2013 Act.

SECTION 3. (1) As used in this section:

(a) "Audit" means an on-site or remote review of the records of a pharmacy by or on behalf of an entity.

(b) "Claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or service.

(c) "Clerical error" means a minor error:

(A) In the keeping, recording or transcribing of records or documents or in the handling of electronic or hard copies of correspondence;

(B) That does not result in financial harm to an entity; and

(C) That does not involve dispensing an incorrect dose, amount or type of medication or dispensing a prescription drug to the wrong person.

(d) "Entity" includes:

(A) A pharmacy benefit manager;

(B) An insurer;

(C) A third party administrator;

(D) A state agency; or

(E) A person that represents or is employed by one of the entities described in this paragraph.

(e) "Fraud" means knowingly and willfully executing or attempting to execute a scheme, in connection with the delivery of or payment for health care benefits, items or services, that uses false or misleading pretenses, representations or promises to obtain any money or property owned by or under the custody or control of any person.

(2) An entity that audits claims:

(a) Must establish, in writing, a procedure for a pharmacy to appeal the entity's findings with respect to a claim and must provide a pharmacy with a notice regarding the procedure, in writing or electronically, prior to conducting an audit of the pharmacy's claims;

(b) Must give at least 15 days' advance written notice of an audit to the pharmacy or corporate headquarters of the pharmacy;

(c) Must conduct the audit in consultation with a pharmacist if the audit involves clinical

or professional judgment;

(d) May not conduct an audit of a claim more than 24 months after the date the claim was adjudicated by the entity;

(e) May not conduct the audit during the first five days of any month without the pharmacy's consent;

(f) May not review more than 200 claims of a pharmacy in any 12-month period except in cases of alleged fraud;

(g) May not conduct more than one on-site audit of a pharmacy in any 12-month period;

(h) Must use the same standards and procedures for all pharmacies of a similar size and doing a similar volume of business;

(i) Must pay any outstanding claims of a pharmacy no more than 45 days after the earlier of the date all appeals are concluded or the date a final report is issued under subsection (8) of this section;

(j) May not include dispensing fees or interest in the amount of any overpayment assessed on a claim unless the overpaid claim was for a prescription that was not filled correctly;

(k) May not recoup costs associated with:

(A) Clerical errors; or

(B) Other errors that do not result in financial harm to the entity or a consumer;

(L) May not charge a pharmacy for a denied or disputed claim until the audit and the appeals procedure established in paragraph (a) of this subsection are final;

(m) May not offset the amount of an overpayment against future remittances; and

(n) Must bill a pharmacy separately for the amount of the overpayment.

(3) An entity's finding that a claim was incorrectly presented or paid must be based on identified transactions and not based on probability sampling, extrapolation or other means that project an error using the number of patients served who have a similar diagnosis or the number of similar prescriptions or refills for similar drugs.

(4) An entity that contracts with an independent third party to conduct audits may not:

(a) Agree to compensate the independent third party based on a percentage of the amount of overpayments recovered; or

(b) Disclose information obtained during an audit except to the contracting entity, the pharmacy subject to the audit or the holder of the policy or certificate of insurance that paid the claim.

(5) For purposes of this section, an entity, or an independent third party that contracts with an entity to conduct audits, must accept as validation of a claim:

(a) An electronic or physical copy of a prescription that complies with this chapter if the prescribed drug was, within 14 days of the dispensing date:

(A) Picked up by the patient or the patient's designee;

(B) Delivered by the pharmacy to the patient; or

(C) Sent by the pharmacy to the patient using the United States Postal Service or other common carrier;

(b) Point of sale electronic register data showing purchase of the prescribed drug, medical supply or service by the patient or the patient's designee; or

(c) Electronic records, including electronic beneficiary signature logs, electronically scanned and stored patient records maintained at or accessible to the audited pharmacy's

central operations and any other reasonably clear and accurate electronic documentation that corresponds to a claim.

(6)(a) After conducting an audit, an entity must provide the pharmacy that is the subject of the audit with a preliminary report of the audit. The preliminary report must be received by the pharmacy no later than 30 days after the date on which the audit was completed and must be sent:

(A) By mail or common carrier with a return receipt requested; or

(B) Electronically with electronic receipt confirmation.

(b) An entity shall provide a pharmacy receiving a preliminary report under this subsection no fewer than 45 days after receiving the report to contest the report or any findings in the report in accordance with the procedure established in subsection (2)(a) of this section and to provide additional documentation in support of the claim. The entity shall approve a reasonable request for an extension of time to submit documentation to contest the report or any findings in the report.

(7) If an audit results in a full or partial denial of a claim, the entity conducting the audit shall allow the pharmacy to resubmit the claim using any commercially reasonable method.

(8) An entity must provide a pharmacy that is the subject of an audit with a final report of the audit no later than 60 days after the later of the date the preliminary report was received or the date the pharmacy contested the report using the procedure established in subsection (2)(a) of this section. The final report must include a final accounting of all moneys to be recovered by the entity.

(9) This section does not preclude an entity from instituting an action for fraud against a pharmacy.

(10) This section does not apply to any audit or investigation that follows a finding:

(a) Of fraud;

(b) That a claim was submitted for an item or service that was not provided;

(c) That a pharmacy deliberately submitted duplicate claims for an item or service and the duplicate claims did not result from a clerical error;

(d) That a pharmacy altered claim forms, electronic claim records or medical documentation for the purpose of receiving a greater amount of reimbursement;

(e) Of soliciting, offering or receiving a kickback or bribe;

(f) Of collusion between a pharmacy or pharmacist and a patient to defraud the entity;

(g) That a pharmacy misrepresented a date or description of items or services furnished or the identity of the provider or recipient of items or services;

(h) That a claim for a prescription was submitted without a prescription's being on file or was submitted for an over-the-counter item;

(i) That a pharmacy filled a prescription using an expired product;

(j) That a claim was submitted using an incorrect national drug code number or claiming reimbursement for a brand name drug when a generic drug was dispensed;

(k) That a pharmacy failed to credit the entity for a prescription or a portion of a prescription that was obtained by a patient more than 14 days after the drug was dispensed, unless good cause exists for the delay; or

(L) That a pharmacy submitted a claim without proof that the item or service was purchased.

(11) This section does not apply to a state agency that is conducting audits or a person

that has contracted with a state agency to conduct audits of pharmacy records for prescription drugs paid for by the state medical assistance program.

SECTION 4. (1) As used in this section:

(a) "List" means the list of drugs for which a third party administrator has established maximum allowable costs.

(b) "Maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a drug.

(c) "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.

(d) "Network pharmacy" means a retail drug outlet registered under ORS 689.305 that contracts with a pharmacy benefit manager.

(e) "Therapeutically equivalent" has the meaning given that term in ORS 689.515.

(2) A pharmacy benefit manager may not place a drug on a list unless:

(a) There are at least two therapeutically equivalent, multiple source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers; and

(b) The drug is not obsolete.

(3) A pharmacy benefit manager:

(a) Shall provide to each network pharmacy at the beginning of the term of the contract, and upon each renewal of the contract, notice of the sources used by the pharmacy benefit manager to determine maximum allowable costs and the lists that apply to the network pharmacy;

(b) Shall make its lists available to a network pharmacy in a format that is readily accessible to and usable by the pharmacy;

(c) Shall update the lists at least once every seven business days and promptly notify network pharmacies of any changes;

(d) May not set a maximum allowable cost below the cost set by the sources described in paragraph (a) of this subsection; and

(e) May not include dispensing fees in the calculation of the maximum allowable cost.

(4)(a) A pharmacy benefit manager must establish a reasonable administrative process for a network pharmacy to request an adjustment of a maximum allowable cost.

(b) A pharmacy benefit manager must make a determination on a request for adjustment no later than seven business days after the pharmacy makes the request.

(c) If the pharmacy benefit manager makes an adjustment in response to a request by a network pharmacy under this subsection, the pharmacy benefit manager shall apply the adjustment to all network pharmacies retroactive to the date of the determination under paragraph (b) of this subsection.

(5) This section does not apply to the state medical assistance program.

SECTION 5. Section 4 of this 2013 Act applies to contracts between pharmacies and pharmacy benefit managers that are entered into, renewed or extended on or after the effective date of this 2013 Act.