Rep. Freeman

FULL COMMITTEE PONY

HB 2123
Relating prescription drugs

Pharmacy benefit managers (or PBMs) are companies that contract with insurance companies, managed-care organizations, self-insured employers, as well as unions and government programs to manage prescription drug benefits. Some 95% of all patients with drug coverage receive benefits through PBMs. Further, PBMs have expanded their services to include programs such as disease and drug therapy management.

House Bill 2123 modifies the Insurance Code to provide the Insurance Division of the Department of Consumer Business Services (DCBS) with regulatory oversight of PBMs conducting business in Oregon.

In addition, the bill establishes parameters to ensure fair and uniform audits of pharmacies by a PBM, insurer, or state agency.

The bill also imposes requirements on PBMs relating to their list of drugs for which maximum allowable costs (or MAC) reimbursement rates have been established; and requires PMBs to establish an appeals process for when disputes arise between a network pharmacy and a PMB regarding a drug subject to MAC pricing.

The Joint Subcommittee on Human Services recommends HB 2123 be amended and reported out “do pass” as amended.

77th OREGON LEGISLATIVE ASSEMBLY – 2013 Session **MEASURE: HB 2123-B**
STAFF MEASURE SUMMARY

Joint Committee on Ways and Means **Carrier – House: Rep. Bailey**
Carrier – Senate: Sen. Steiner Hayward

Revenue:
Fiscal: Fiscal statement issued

Action: Do Pass the A-Engrossed Measure as Amended and be Printed B-Engrossed
Vote:
House
Yeas:
Nays:
Exc:
Senate
Yeas:
Nays:
Exc:
Prepared By: Kim To, Legislative Fiscal Office
Meeting Date: June 12, 2013

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:
- Indeterminate Other Funds fiscal impact

EFFECT OF COMMITTEE AMENDMENT: Replaces the bill. Requires a pharmacy benefit manager (PBM) to register with the Department of Consumer and Business Services, and to annually renew the registration. Establishes limitations and requirements for an audit of a pharmacy by a PBM, an insurer, a third party administrator, a state agency or a person that represents or is employed by one of those entities. Imposes requirements on a PBM relating to their list of drugs for which maximum allowable costs have been established.

BACKGROUND: 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-A10 requires PBMs to register with DCBS, establishes regulations for audits of pharmacies and creates regulations around maximum allowable cost (MAC) pricing lists used by PBMs.

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

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, Susie Jordan
Date: 6/6/2013

Measure Description:
Requires Department of Consumer and Business Services to register pharmacy benefit managers.

Government Unit(s) Affected:
Oregon Health Authority (OHA), Department of Consumer and Business Services (DCBS)

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 B-Engrossed modifies the Insurance Code. The measure:

- Defines claim, insurer, pharmacist, pharmacy, third party administrator, and pharmacy benefit manager.
- Requires a pharmacy benefit manager (PBM) to register with the Department of Consumer and Business Services, and to annually renew the registration. The bill provides that the registration fee and renewal does not exceed $50, and allows DCBS to adopt fees by rule.
- Establishes limitations and requirements for an audit of a pharmacy by a PBM, an insurer, a third party administrator, a state agency or a person that represents or is employed by one of those entities. The audit limitations and requirements in the bill apply to contracts between pharmacies and PBMs that are entered into, renewed or extended on or after the effective date of the bill.
- Imposes requirements on a PBM relating to their list of drugs for which maximum allowable costs have been established. The requirements related to the list of drugs for which maximum allowable costs have been established become operative on January 1, 2015. Limits the applicability of an adjustment made in response to a critical access pharmacy when a critical access pharmacy appeal of a reimbursement determination is upheld. Allows a network pharmacy to appeal a maximum allowable cost only if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the drug supplier.

Oregon Health Authority (OHA)
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. OEBB contracts with a PBM. According to OEBB's largest health insurer, Moda Health, this requirement has the potential of inflating costs across the network. Inflated costs would impact OEBB through increased medical prescription drug rates. Although the exact premium increase is indeterminate at this time, Moda Health predicts the fiscal impact could result in a 0.5% increase in rates. Based on January 2013 premium costs and 2012 enrollment over three month period, OEBB calculates that a 0.5% increase in premium rates would result in an estimated fiscal impact of roughly $542,777 Other Funds Non-Limited in the 2013-2015 biennium.

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.

Department of Consumer and Business Services (DCBS)

The fiscal impact of this bill on the Department of Consumer and Business Services is indeterminate, but anticipated to be absorbable. The department reports that existing law requires a person who transacts business as a third party administrator (TPA) to be licensed through DCBS. A third party administrator is defined as a person who directly or indirectly solicits or effects coverage of, underwrites, collects charges or premiums from, or adjusts or settles claims on, residents of this state or residents of another state from offices in this state, in connection with life insurance or health insurance coverage. Therefore some TPAs also conduct pharmacy benefit manager activities. Currently DCBS licenses 296 TPAs. It is unknown how many of these existing TPAs will register as PBMs, or how many other PBMs will be subject to registration.

Should this bill become law, DCBS will be required to: (1) conduct rulemaking to develop the registration form and set fees; (2) create and maintain the registration system; (3) assure that all PBMs are registered and that registrations are renewed; and (4) monitor and carry out compliance and enforcement activities. Extrapolating from historical enforcement data on TPAs, DCBS assumes that its Insurance Division can perform these duties using existing staff and resources. However, if the enforcement activities of this bill or if the cumulative impact of legislation affecting the enforcement of the Insurance Code is greater than anticipated, DCBS may need to return to seek additional resources in the event that reprioritization of duties and responsibilities of existing staff is not feasible.

HB 2123-A10
(LC 935)
5/17/13 (MBM/ps)

PROPOSED AMENDMENTS TO
A-ENGROSSED HOUSE BILL 2123

On page 1 of the printed A-engrossed bill, delete lines 4 through 24 and delete pages 2 through 5 and insert:

"SECTION 1. Sections 2 to 11 of this 2013 Act are added to and made a part of the Insurance Code.

"SECTION 2. As used in sections 2 to 11 of this 2013 Act:

"(1) '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.

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

"(3) 'Pharmacist' has the meaning given that term in ORS 689.005.

"(4) 'Pharmacy' has the meaning given that term in ORS 689.005.

"(5)(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:

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

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

"(C) 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.

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

"SECTION 3. (1) To conduct business in this state, a pharmacy benefit manager must register with the Department of Consumer and Business Services and annually renew the registration.

"(2) To register under this section, a pharmacy benefit manager must:

"(a) Submit an application to the department on a form prescribed by the department by rule.

"(b) Pay a registration fee, not to exceed $50, adopted by the department by rule.

"(3) To renew a registration under this section, a pharmacy benefit manager must pay a renewal fee, not to exceed $50, adopted by the department by rule.

"(4) The department shall deposit all moneys collected under this section into the Consumer and Business Services Fund created in ORS 705.145.

"SECTION 4. As used in sections 4 to 10 of this 2013 Act:

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

"(2) '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.

"(3) '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 subsection.

"(4) '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.

"SECTION 5. An entity that audits claims or an independent third party that contracts with an entity to audit claims:

"(1) 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;

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

"(3) Must give at least 15 days' advance written notice of an on-site audit to the pharmacy or corporate headquarters of the pharmacy;

"(4) May not conduct an on-site audit during the first five days of any month without the pharmacy's consent;

"(5) Must conduct the audit in consultation with a pharmacist who is licensed by this or another state if the audit involves clinical or professional judgment;

"(6) May not conduct an on-site audit of more than 250 unique prescriptions of a pharmacy in any 12-month period except in cases of alleged fraud;

"(7) May not conduct more than one on-site audit of a pharmacy

in any 12-month period;

"(8) Must audit each pharmacy under the same standards and parameters that the entity uses to audit other similarly situated pharmacies;

"(9) 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 section 9 (3) of this 2013 Act;

"(10) 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;

"(11) 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; and

"(12) May not charge a pharmacy for a denied or disputed claim until the audit and the appeals procedure established under subsection (1) of this section are final.

"SECTION 6. 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.

"SECTION 7. An entity that contracts with an independent third party to conduct audits may not:

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

"(2) 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.

"SECTION 8. For purposes of sections 4 to 10 of this 2013 Act, an

entity, or an independent third party that contracts with an entity to conduct audits, must allow as evidence of validation of a claim:

"(1) An electronic or physical copy of a prescription that complies with ORS chapter 689 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;

"(2) 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

"(3) 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.

"SECTION 9. (1)(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 45 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 appeals procedure established under section 5 (1) of this 2013 Act and to provide additional documentation in support of the claim.

The entity shall consider a reasonable request for an extension of time to submit documentation to contest the report or any findings in the report.

"(2) If an audit results in the dispute or denial of a claim, the entity conducting the audit shall allow the pharmacy to resubmit the claim using any commercially reasonable method, including facsimile, mail or electronic mail.

"(3) 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 appeals procedure established under section 5 (1) of this 2013 Act. The final report must include a final accounting of all moneys to be recovered by the entity.

"(4) Recoupment of disputed funds from a pharmacy by an entity or repayment of funds to an entity by a pharmacy, unless otherwise agreed to by the entity and the pharmacy, shall occur after the audit and the appeals procedure established under section 5 (1) of this 2013 Act are final. If the identified discrepancy for an individual audit exceeds $40,000, any future payments to the pharmacy may be withheld by the entity until the audit and the appeals procedure established under section 5 (1) of this 2013 Act are final.

"SECTION 10. Sections 4 to 10 of this 2013 Act do not:

"(1) Preclude an entity from instituting an action for fraud against a pharmacy;

"(2) Apply to an audit of pharmacy records when fraud or other intentional and willful misrepresentation is evidenced by physical review, review of claims data or statements or other investigative methods; or

"(3) 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 11. (1) As used in this section:

"(a) 'List' means the list of drugs for which maximum allowable costs have been established.

"(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:

"(a) May not place a drug on a list unless 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.

"(b) Shall ensure that all drugs on a list are generally available for purchase by pharmacies in this state from national or regional wholesalers.

"(c) Shall ensure that all drugs on a list are not obsolete.

"(d) Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager.

"(e) Shall make a list available to a network pharmacy upon request in a format that is readily accessible to and usable by the network

pharmacy.

"(f) Shall update each list maintained by the pharmacy benefit manager every seven business days and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format.

"(g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable cost.

"(3) A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. An appeal requested under this section must be completed within 30 calendar days of the pharmacy making the claim for which appeal has been requested.

"(4) A pharmacy benefit manager must provide as part of the appeals process established under subsection (3) of this section:

"(a) A telephone number at which a network pharmacy may contact the pharmacy benefit manager and speak with an individual who is responsible for processing appeals;

"(b) A final response to an appeal of a maximum allowable cost within seven business days; and

"(c) If the appeal is denied, the reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost.

"(5)(a) If an appeal is upheld under this section, the pharmacy benefit manager shall make an adjustment on the date that the pharmacy benefit manager makes the determination. The pharmacy benefit manager shall make the adjustment effective for all similarly situated

pharmacies in this state that are within the network.

"(b) If the request for an adjustment has come from a critical access pharmacy, as defined by the Oregon Health Authority by rule for purposes related to the Oregon Prescription Drug Program, the adjustment approved under paragraph (a) of this subsection shall apply only to critical access pharmacies.

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

"SECTION 12. The amendments to section 11 of this 2013 Act by section 13 of this 2013 Act become operative on January 1, 2015.

"SECTION 13. Section 11 of this 2013 Act is amended to read:

"**Sec. 11.** (1) As used in this section:

"(a) 'List' means the list of drugs for which maximum allowable costs have been established.

"(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:

"(a) May not place a drug on a list unless 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.

"(b) Shall ensure that all drugs on a list are generally available for purchase by pharmacies in this state from national or regional wholesalers.

"(c) Shall ensure that all drugs on a list are not obsolete.

"(d) Shall make available to each network pharmacy at the beginning of the term of a contract, and upon renewal of a contract, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefit manager.

"(e) Shall make a list available to a network pharmacy upon request in a format that is readily accessible to and usable by the network pharmacy.

"(f) Shall update each list maintained by the pharmacy benefit manager every seven business days and make the updated lists, including all changes in the price of drugs, available to network pharmacies in a readily accessible and usable format.

"(g) Shall ensure that dispensing fees are not included in the calculation of maximum allowable cost.

"(3) A pharmacy benefit manager must establish a process by which a network pharmacy may appeal its reimbursement for a drug subject to maximum allowable cost pricing. A network pharmacy may appeal a maximum allowable cost if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the supplier of the drug. An appeal requested under this section must be completed within 30 calendar days of the pharmacy making the claim for which appeal has been requested.

"(4) A pharmacy benefit manager must provide as part of the appeals process established under subsection (3) of this section:

"(a) A telephone number at which a network pharmacy may contact the pharmacy benefit manager and speak with an individual who is responsible for processing appeals;

"(b) A final response to an appeal of a maximum allowable cost within seven business days; and

"(c) If the appeal is denied, the reason for the denial and the national drug code of a drug that may be purchased by similarly situated pharmacies at a price that is equal to or less than the maximum allowable cost.

"(5)(a) If an appeal is upheld under this section, the pharmacy benefit

manager shall make an adjustment [*on the date that the pharmacy benefit manager makes the determination. The pharmacy benefit manager shall make the adjustment effective for all similarly situated pharmacies in this state that are within the network.*] **for the pharmacy that requested the appeal from the date of initial adjudication forward.**

"(b) If the request for an adjustment has come from a critical access pharmacy, as defined by the Oregon Health Authority by rule for purposes related to the Oregon Prescription Drug Program, the adjustment approved under paragraph (a) of this subsection shall apply only to critical access pharmacies.

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

"SECTION 14. (1) Section 11 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.

"(2) The amendments to section 11 of this 2013 Act by section 13 of this 2013 Act apply to contracts between pharmacies and pharmacy benefit managers that are entered into, renewed or extended on or after the operative date specified in section 12 of this 2013 Act.".
