LEGISLATURE OF THE STATE OF IDAHO

Sixty-third Legislature First Regular Session - 2015

IN THE HOUSE OF REPRESENTATIVES

HOUSE BILL NO. 188

BY HEALTH AND WELFARE COMMITTEE

AN ACT

RELATING TO PHARMACIES; AMENDING TITLE 41, IDAHO CODE, BY THE ADDITION OF A NEW CHAPTER 62, TITLE 41, IDAHO CODE, TO PROVIDE A SHORT TITLE, TO STATE THE PURPOSE AND INTENT, TO DEFINE TERMS, TO PROVIDE APPLICABILITY AND SCOPE, TO PROVIDE PROCEDURES FOR CONDUCTING AND REPORTING AN AUDIT, TO PROVIDE FOR AN APPEAL PROCESS AND TO PROHIBIT THE PRACTICE OF EXTRAPOLATION; AMENDING TITLE 41, IDAHO CODE, BY THE ADDITION OF A NEW CHAPTER 63, TITLE 41, IDAHO CODE, TO PROVIDE A SHORT TITLE, TO DEFINE TERMS, TO PROVIDE APPLICABILITY, TO PROVIDE REQUIRED PRACTICES FOR PHARMACY BENEFIT MANAGERS, TO PROVIDE FOR REGISTRATION OF PHARMACY BENEFIT MANAGERS, TO PROVIDE THAT WAIVERS BY COVERED ENTITIES ARE AGAINST PUBLIC POLICY, TO PROVIDE FOR ENFORCEMENT AND TO PROVIDE FOR RULEMAKING AUTHORITY; AMENDING CHAPTER 18, TITLE 41, IDAHO CODE, BY THE ADDITION OF A NEW SECTION 41-1852, IDAHO CODE, TO DEFINE TERMS, TO PROVIDE REQUIREMENTS FOR A PHARMACY BENEFIT MANAGER, TO PROVIDE FOR APPEALS, TO PROVIDE THE REQUIREMENTS FOR AN APPEAL, TO PROVIDE FOR ADJUSTMENTS IF AN APPEAL IS UPHELD AND TO PROVIDE AN EXCEPTION; AND PROVIDING SEVERABILITY.

Be It Enacted by the Legislature of the State of Idaho:

SECTION 1. That Title 41, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW CHAPTER, to be known and designated as Chapter 62, Title 41, Idaho Code, and to read as follows:

CHAPTER 62

PHARMACY AUDIT INTEGRITY ACT

41-6201. SHORT TITLE. This chapter shall be known and may be cited as the "Pharmacy Audit Integrity Act."

41-6202. PURPOSE AND INTENT. The purpose of this chapter is to establish minimum and uniform standards and criteria for the audit of pharmacy records by or on behalf of certain entities.

41-6203. DEFINITIONS. For purposes of this chapter:

(1) "Generic prescription medication" means a chemically equivalent copy of a brand-name medication with an expired patent.

(2) "Pharmacist" and "pharmacy" are as defined in section 54-1705, Idaho Code.

(3) "Pharmacy benefit management" means the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, or any of the following services provided with regard to the administration of pharmacy benefits:

(a) Mail order pharmacy;
(b) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;
(c) Clinical formulary development and management services;
(d) Rebate contracting and administration;
(e) Certain patient compliance, therapeutic intervention and generic substitution programs; and
(f) Disease management programs.

"Pharmacy benefit management" does not include activities of retail, community, long-term care or hospital pharmacies licensed under chapter 17, title 54, Idaho Code, that are not carried out as part of a contract entered into by that pharmacy with a covered entity to administer and manage payment for pharmacy benefits for covered individuals.

(4) "Pharmacy benefit manager" means an entity that performs pharmacy benefits management. "Pharmacy benefit manager" includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefits management for a covered entity.

41-6204. APPLICABILITY AND SCOPE. (1) This chapter shall apply to any audit of the records of a pharmacy conducted by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a department of the state, or any entity that represents those companies, groups or department.

(2) This chapter shall not apply to any investigative audit conducted that involves fraud, willful misrepresentation or abuse including, without limitation, investigative audits or any other statutory provision that authorizes investigations relating to insurance fraud or to medical assistance as defined in chapter 2, title 56, Idaho Code.

41-6205. PROCEDURES FOR CONDUCTING AND REPORTING AN AUDIT. (1) Any entity conducting an audit of a pharmacy shall follow these procedures:
(a) Any audit conducted pursuant to the provisions of this chapter shall be performed by a person or firm licensed under chapter 2, title 54, Idaho Code;
(b) The pharmacy contract must identify and describe in detail the audit procedures;
(c) The entity conducting the on-site audit must give the pharmacy written notice at least two (2) weeks before conducting the initial on-site audit for each audit cycle. Audits shall commence on the date and time specified in the written notice;
(d) The entity conducting the on-site audit shall not interfere with the delivery of pharmacist services to a patient and shall make every effort to minimize inconvenience and disruption to pharmacy operations during the audit process;
(e) Any audit that involves clinical or professional judgment must be conducted by or in consultation with a licensed pharmacist;
(f) Any clerical or recordkeeping error, such as a typographical error, scrivener's error or computer error, regarding a required document or

record does not constitute fraud and shall not be subject to recoupment costs;

(g) A pharmacy may use the records of a hospital, physician or other authorized practitioner of medicine 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 drug;

(h) 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;

(i) A finding of an overpayment shall not include the dispensing fee amount;

(j) Each pharmacy shall be audited under the same standards as other similarly situated pharmacies audited by the entity;

(k) The period covered by an audit may not exceed one (1) year from the date the claim was submitted to or adjudicated by a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payor, pharmacy benefit manager, a health program administered by a department of the state, or any entity that represents those companies, groups or department;

(l) An audit may not be initiated or scheduled during the first seven (7) calendar days of any month due to the high volume of prescriptions filled, unless otherwise consented to by the pharmacy;

(m) An auditing entity may not receive payment based on a percentage of the amount recovered;

(n) An audit shall include an equal number of generic and nongeneric prescription medications; and

(o) An auditing entity shall audit not more than two hundred fifty (250) prescriptions in a twelve (12) month period.

(2) An auditing entity must provide the pharmacy with a written report of the audit and comply with the following requirements:

(a) The preliminary audit report must be delivered to the pharmacy within ninety (90) days after conclusion of the audit;

(b) A pharmacy shall be allowed at least sixty (60) days following receipt of the preliminary audit report in which to produce documentation to address any discrepancy found during the audit;

(c) A final audit report shall be delivered to the pharmacy within one hundred twenty (120) days after receipt of the preliminary audit report or final appeal, as provided for in section 41-6206, Idaho Code, whichever is later;

(d) The audit report must be signed and include the signature of any pharmacist participating in the audit;

(e) Any recoupments of disputed funds shall occur only after final internal disposition of the audit, including the appeals process as set forth in section 41-6206, Idaho Code;

(f) Interest shall not accrue during the audit period; and

(g) After completion of any review process, each entity conducting an audit shall provide a copy of the final audit report to the plan sponsor.

41-6206. APPEAL PROCESS. (1) The Idaho department of insurance shall evaluate and resolve any disputes between a pharmacy and a pharmacy benefits manager.

(2) Each entity conducting an audit shall establish a written appeals process under which a pharmacy may appeal an unfavorable preliminary audit report to the entity.

(3) If, following the appeal, the entity finds that an unfavorable audit report or any portion thereof is unsubstantiated, the entity shall dismiss the audit report or that portion without the necessity of any further action.

41-6207. EXTRAPOLATION AUDITS. Notwithstanding any other provision in this act, the entity conducting the audit shall not use the accounting practice of extrapolation in calculating recoupments or penalties for audits. As used in this section, "extrapolation" means an audit of a sample of prescription drug benefit claims submitted by a pharmacy to the entity conducting the audit that is then used to estimate audit results for a larger batch or group of claims not reviewed by the auditor.

SECTION 2. That Title 41, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW CHAPTER, to be known and designated as Chapter 63, Title 41, Idaho Code, and to read as follows:

CHAPTER 63
PHARMACY BENEFIT MANAGER TRANSPARENCY ACT

41-6301. SHORT TITLE. This chapter shall be known and may be cited as the "Pharmacy Benefit Manager Transparency Act."

41-6302. DEFINITIONS. For purposes of this chapter:

(1) "Covered entity" means a health benefit plan as defined in section 41-4703, Idaho Code, a health carrier as defined in section 41-5903, Idaho Code, group disability insurance for state officers or employees as provided in section 67-5762, Idaho Code, or an employer, labor union or other group of persons organized in this state that provides health coverage to covered individuals who are employed or reside in this state.

(2) "Covered individual" means a member, participant, enrollee, contract holder or policyholder or beneficiary of a covered entity who is provided health coverage by the covered entity. "Covered individual" includes a dependent or other person provided health coverage through a contract or health plan for a covered individual.

(3) "Generic drug" means a chemically equivalent copy of a brand-name drug with an expired patent.

(4) "Labeler" means an entity or person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and that has a labeler code from the federal food and drug administration under 21 CFR 270.20. "Labeler" does not mean a person or entity that repackages drugs for use of its participants, members or enrollees or pharmacy operations of any integrated delivery system undertaken for the benefit of patients obtaining care through that system.

(5) "Pharmacy benefit management" means the procurement of prescription drugs at a negotiated rate for dispensation within this state to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals, or any of the following services provided with regard to the administration of pharmacy benefits:

(a) Mail order pharmacy;

(b) Claims processing, retail network management and payment of claims to pharmacies for prescription drugs dispensed to covered individuals;

(c) Clinical formulary development and management services;

(d) Rebate contracting and administration;

(e) Certain patient compliance, therapeutic intervention and generic substitution programs; and

(f) Disease management programs.

"Pharmacy benefit management" does not include activities of retail, community, long-term care or hospital pharmacies licensed under chapter 17, title 54, Idaho Code, that are not carried out as part of a contract entered into by that pharmacy with a covered entity to administer and manage payment for pharmacy benefits for covered individuals.

(6) "Pharmacy benefit manager" means an entity that performs pharmacy benefit management. "Pharmacy benefit manager" includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of pharmacy benefit management for a covered entity.

41-6303. APPLICABILITY. All pharmacy benefit managers who provide pharmacy benefit management for covered entities, or affecting covered lives, in this state, and any contract for pharmacy benefit management entered into in this state or by a covered entity in this state, must comply with the provisions of this chapter. The provisions of this chapter shall not apply to medical assistance as defined in chapter 2, title 56, Idaho Code.

41-6304. REQUIRED PRACTICES FOR PHARMACY BENEFIT MANAGERS. (1) The business of pharmacy benefit management is one affected by the public interest, requiring that pharmacy benefit managers act in good faith, abstain from deception, and practice honesty and equity in all pharmacy benefit management matters.

(2) A pharmacy benefit manager shall notify the covered entity in writing of any activity, policy or practice of the pharmacy benefit manager that directly or indirectly presents any conflict of interest with the duties imposed by this section.

(3) A pharmacy benefit manager shall provide to a covered entity all financial and utilization information requested by the covered entity relating to providing benefits to covered individuals through that covered entity and all financial and utilization information relating to services to that covered entity. A pharmacy benefit manager providing information under this section may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a covered entity under the provisions of this section may not be disclosed by the

covered entity to any person without the consent of the pharmacy benefit manager or ordered by a court for good cause shown.

(4) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a covered individual, the following provisions shall apply when a pharmacy benefit manager derives any payment or benefit related to the price or cost of a drug dispensed through a pharmacy benefit management contract:

(a) The pharmacy benefit manager may substitute a lower-priced generic or therapeutically equivalent drug for a higher-priced prescribed drug;

(b) With regard to substitutions in which the substitute drug costs more than the prescribed drug, the substitution must be made for medical reasons that benefit the covered individual. If a substitution is being made under the provisions of this subsection, the pharmacy benefit manager shall obtain the approval of the prescribing health professional or that person's authorized representative after disclosing to the covered individual and the covered entity the cost of both drugs and any benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution; and

(c) The pharmacy benefit manager shall disclose in full to the covered entity any benefit or payment received in any form by the pharmacy benefit manager as a result of a prescription drug substitution under the provisions of this subsection.

(5) A pharmacy benefit manager who derives any payment or benefit for the dispensation of prescription drugs within this state based on volume of sales for certain prescription drugs or classes or brands of drugs within the state must disclose such payment or benefit in full to the covered entity.

(6) A pharmacy benefit manager shall disclose to the covered entity all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer or labeler including, without limitation, formulary management and drug-switch programs, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies and data sales fees.

(7) The agreement between a pharmacy benefit manager and a covered entity must include a provision allowing the covered entity to have audited the pharmacy benefit manager's books, accounts and records, including deidentified utilization information, as necessary to confirm that the benefit of a payment received by the pharmacy benefit manager is being disclosed as required by the contract and that other contractual provisions are being executed as agreed by the parties.

(8) A pharmacy benefit manager shall take no action that would restrict a covered individual's choice of pharmacy from which to receive prescription medication.

41-6305. REGISTRATION. As of January 1, 2017, all pharmacy benefit managers shall, pursuant to this title, register with the director of the Idaho department of insurance before providing services to covered entities and individuals. Registration shall be effective for two (2) years and may be renewed for an additional two (2) years. The director of the Idaho department of insurance may deny, suspend, revoke or refuse to renew a registration

in circumstances specified in this chapter or in rules promulgated pursuant to the provisions of this chapter.

41-6306. WAIVERS. Any waiver by a covered entity of the provisions of this chapter is contrary to public policy and is unenforceable and void.

41-6307. ENFORCEMENT. The practices covered by the provisions of this chapter are matters vitally affecting the public interest for the purpose of applying chapter 13, title 41, Idaho Code. A violation of this chapter is not reasonable in relation to the development and preservation of business and is an unfair or deceptive act in trade or commerce and an unfair method of competition for the purpose of applying chapter 13, title 41, Idaho Code.

41-6308. RULEMAKING AUTHORITY. The director of the Idaho department of insurance may promulgate, adopt and enforce rules, including fee rules, necessary to implement the provisions of this chapter.

SECTION 3. That Chapter 18, Title 41, Idaho Code, be, and the same is hereby amended by the addition thereto of a NEW SECTION, to be known and designated as Section 41-1852, Idaho Code, and to read as follows:

41-1852. MAXIMUM ALLOWABLE COST -- PHARMACY BENEFIT MANAGERS. (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 (2) manufacturers.

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

(e) "Pharmacy benefit manager" is as defined in section 41-6203, Idaho Code.

(f) "Therapeutically equivalent" means drugs that are approved by the United States food and drug administration for interstate distribution and the food and drug administration has determined that the drugs will provide essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

(2) A pharmacy benefit manager:

(a) May not place a drug on a list unless there are at least two (2) therapeutically equivalent, multiple source drugs or at least one (1) generic drug available from only one (1) 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 uti-

lized 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 (7) 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; and

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

(3) A pharmacy benefit manager shall 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 the provisions of this section must be completed within thirty (30) calendar days of the pharmacy making the claim for which appeal has been requested.

(4) A pharmacy benefit manager shall 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 (7) 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) 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.

(6) This section shall not apply to medical assistance as defined in chapter 2, title 56, Idaho Code.

SECTION 4. SEVERABILITY. The provisions of this act are hereby declared to be severable and if any provision of this act or the application of such provision to any person or circumstance is declared invalid for any reason, such declaration shall not affect the validity of the remaining portions of this act.