HOUSE BILL No. 1214

DIGEST OF INTRODUCED BILL

Citations Affected: IC 27-1-24.5; IC 35-52-27-9.3.

Synopsis: Pharmacy benefits managers. Specifies requirements that apply to a pharmacy benefits manager, including fiduciary duties owed a covered entity and contractual requirements for contracts with pharmacies. Provides that a pharmacy benefits manager who knowingly or intentionally violates these provisions commits a Class B misdemeanor.

Effective: July 1, 2015.

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January 13, 2015, read first time and referred to Committee on Insurance.

First Regular Session of the 119th General Assembly (2015)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2014 Regular Session and 2014 Second Regular Technical Session of the General Assembly.

HOUSE BILL No. 1214

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 27-1-24.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]:

Chapter 24.5. Pharmacy Benefits Managers

Sec. 1. (a) As used in this chapter, "covered entity" means any of the following:

(1) An insurer that issues an accident and sickness insurance policy (as defined in IC 27-8-5-27).

(2) A health maintenance organization.

(3) A health coverage program provided or administered by a state agency.

(4) A self-funded health coverage plan.

(b) The term does not include a limited service health maintenance organization.

Sec. 2. As used in this chapter, "covered individual" means an

individual who is entitled to coverage under a policy, contract, program, or plan provided or administered by a covered entity.

Sec. 3. As used in this chapter, "generic drug" means a chemically equivalent copy of a brand name drug with an expired patent.

Sec. 4. As used in this chapter, "labeler" means a person that:

(1) receives prescription drugs from a manufacturer or wholesaler;

(2) repackages the drugs for retail sale; and

(3) has a labeler code from the federal Food and Drug Administration (21 CFR 270.20 (1999)).

Sec. 5. As used in this chapter, "maximum allowable cost price" means a maximum reimbursement amount for a group of therapeutically equivalent and pharmaceutically equivalent multiple source drugs.

Sec. 6. As used in this chapter, "pharmaceutical equivalence" has the meaning set forth in the most recent edition of the federal Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

Sec. 7. As used in this chapter, "pharmacy benefits management" means:

(1) the procurement of a prescription drug at a negotiated rate for dispensation to a covered individual in Indiana;

(2) the administration or management of pharmacy benefits provided by a covered entity; or

(3) any of the following services in relation to administration of pharmacy benefits:

(A) Mail order pharmacy services.

(B) Claim 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) Patient compliance, therapeutic intervention, and generic substitution programs.

(F) Disease management programs.

Sec. 8. As used in this chapter, "pharmacy benefits manager" means a person who performs pharmacy benefits management on behalf of a covered entity.

Sec. 9. As used in this chapter, "therapeutic equivalence" has the meaning set forth in the federal Food and Drug

Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

Sec. 10. A pharmacy benefits manager owes a fiduciary duty to the covered entity and shall do all the following:

(1) Perform the pharmacy benefits manager's duties in accordance with the standards of conduct applicable to a fiduciary in an enterprise of similar character with similar aims.

(2) Notify the covered entity in writing of any activity, policy, or practice of the pharmacy benefits manager that presents a conflict of interest with the requirements of this chapter.

(3) Provide to the covered entity all financial and utilization information requested by the covered entity related to the pharmacy benefits manager's performance on behalf of the covered entity.

(4) With respect to the dispensing of a substitute prescription drug to a covered individual, the following:

(A) If the substitute prescription drug costs more than the prescribed drug, disclose to the covered entity the cost of both drugs and any benefit or payment accruing to the pharmacy benefits manager as a result of the substitution.

(B) Transfer to the covered entity any benefit or payment received by the pharmacy benefits manager as a result of:

(i) a substitution described in clause (A); or

(ii) a substitution of a lower priced, therapeutically equivalent generic drug for a higher priced prescribed drug.

(5) If the pharmacy benefits manager derives any payment or benefit based on volume of sales for the dispensing of certain:

(A) prescription drugs; or

(B) classes or brands of prescription drugs;

in Indiana, transfer to the covered entity the payment or benefit.

(6) Disclose to the covered entity all financial terms and arrangements between the pharmacy benefits manager and a prescription drug manufacturer or labeler for any remuneration, including:

(A) formulary management and drug switching programs;

(B) educational support;

(C) claim processing and pharmacy network fees that are charged by retail pharmacies; and

(D) data sales fees.

Sec. 11. (a) A pharmacy benefits manager providing information described in section 10(3) or 10(6) of this chapter may designate the information as confidential.

(b) Information designated as confidential under subsection (a) may not be disclosed to any person by the covered entity without the consent of the pharmacy benefits manager, except that disclosure may be made in a court filing:

(1) under IC 27-4-1;

(2) when ordered by an Indiana court for good cause shown; or

(3) when made in a court filing under seal until otherwise ordered by the court.

(c) This section does not limit the authority of the department to investigate compliance with this chapter.

Sec. 12. A pharmacy benefits manager shall, with respect to a pharmacy with which the pharmacy benefits manager has entered into a contract, do all the following:

(1) Provide to the pharmacy:

(A) the market based sources used to determine the maximum allowable cost price lists of the pharmacy benefits manager at the beginning of each calendar year; and

(B) updated price information at least every seven (7) calendar days through an agreed upon updating process.

(2) Disclose to the pharmacy:

(A) the market based sources described in subdivision (1); and

(B) the identity of the pharmacy network or pharmacy to which each maximum allowable cost price list applies in an accessible and usable format.

(3) Ensure that maximum allowable cost prices are not set below market based sources available for purchase by pharmacies.

(4) Provide an agreed upon administrative appeals procedure to allow a pharmacy to appeal a listed maximum allowable cost price, including the following requirements:

(A) The pharmacy benefits manager must respond to the pharmacy not more than seven (7) calendar days after the pharmacy contests a maximum allowable cost price.

(B) If an update to a maximum allowable cost price is determined by the pharmacy benefits manager to be warranted:

(i) the effective date of the update must be retroactive based on the date of the appealing pharmacy's invoice;

(ii) the adjustment must be effective for all pharmacies in the pharmacy network of the appealing pharmacy; and

(iii) each pharmacy described in item (ii) must be permitted to rebill retroactively to the effective date.

(C) If the pharmacy benefits manager denies an appeal, the pharmacy benefits manager must provide to the appealing pharmacy the federal Food and Drug Administration's National Drug Code Directory number of the prescription drug from a wholesaler in Indiana.

(5) Not place a prescription drug on a maximum allowable cost price list unless:

(A) there are at least three (3) therapeutically equivalent, multiple source, generic drugs that are nationally available to be substituted for the prescription drug with a significant cost difference;

(B) the prescription drug:

(i) is listed as therapeutically equivalent and pharmaceutically equivalent, or is listed as "A" rated, in the most recent edition of the federal Food and Drug Administration's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations; or

(ii) has a similar rating by another nationally recognized reference; and

(C) the prescription drug is available from wholesalers for purchase by all pharmacies in Indiana and is not obsolete or temporarily unavailable.

(6) Disclose to a covered entity all the following:

(A) Whether the pharmacy benefits manager uses the same maximum allowable cost price list with respect to:

(i) billing the covered entity; and

(ii) reimbursing all pharmacies with which the pharmacy benefits manager has entered into a contract.

(B) If the pharmacy benefits manager uses multiple maximum allowable cost price lists, any differences between the amount paid to a pharmacy and the amount charged to the covered entity.

Sec. 12. A pharmacy benefits manager who knowingly or intentionally violates this chapter commits a Class B misdemeanor.

SECTION 2. IC 35-52-27-9.3 IS ADDED TO THE INDIANA

CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2015]: **Sec. 9.3. IC 27-1-24.5-12 defines a crime concerning pharmacy benefits managers.**