January 24, 2020

SENATE BILL No. 241

DIGEST OF SB 241 (Updated January 22, 2020 2:49 pm - DI 104)

Citations Affected: IC 27-1; noncode.

Synopsis: Pharmacy benefit managers regulation. Requires a pharmacy benefit manager to obtain a license issued by the department of insurance and sets forth requirements of the pharmacy benefit manager. Provides for the commissioner of the department of insurance to adopt rules to specify licensure, financial standards, and reporting requirements that apply to a pharmacy benefit manager. Sets forth requirements of a pharmacy benefit manager's reimbursement for a contracted pharmacy when using a maximum allowable cost for a drug product. Makes violations of the chapter concerning pharmacy benefit managers an unfair or deceptive act or practice in the business of insurance. Repeals the chapter of existing language on pharmacy benefit managers and moves the language concerning maximum allowable cost lists to the new chapter. Allows a pharmacy benefit manager to obtain the license not later than December 31, 2020, in order to do business in Indiana and provide services for any health provider contract beginning January 1, 2021.

Effective: July 1, 2020.

Brown L, Charbonneau, Merritt,
Stoops, Tomes, Mishler, Ruckelshaus, Grooms

January 9, 2020, read first time and referred to Committee on Health and Provider Services.
January 23, 2020, amended, reported favorably — Do Pass.

January 24, 2020

Second Regular Session of the 121st General Assembly (2020)

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 2019 Regular Session of the General Assembly.

SENATE BILL No. 241

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, 2020]:

Chapter 24.5. Pharmacy Benefit Managers

Sec. 1. As used in this chapter, "biological product" has the meaning set forth in 42 U.S.C. 262(i)(1).

Sec. 2. As used in this chapter, "claim processing service" means an administrative service performed in connection with the processing and adjudicating of a claim related to pharmacist services, including the following:

(1) Receiving payments for pharmacist services.

(2) Making payments to pharmacists or pharmacies for pharmacist services.

Sec. 3. As used in this chapter, "covered individual" means an individual who is entitled to coverage under a health plan.

Sec. 4. As used in this chapter, "generic drug" means a drug product that is identified by the drug's chemical name and that is:

(1) accepted by the federal Food and Drug Administration;

(2) available from at least three (3) sources; and

(3) therapeutically equivalent to an originating brand name drug.

Sec. 5. As used in this chapter, "health plan" means the following:

(1) A state employee health plan (as defined in IC 5-10-8-6.7).

(2) A policy of accident and sickness insurance (as defined in IC 27-8-5-1). However, the term does not include the coverages described in IC 27-8-5-2.5(a).

(3) An individual contract (as defined in IC 27-13-1-21) or a group contract (as defined in IC 27-13-1-16) that provides coverage for basic health care services (as defined in IC 27-13-1-4).

Sec. 6. As used in this chapter, "independent pharmacies" means pharmacies that are not a pharmacy benefit manager affiliate.

Sec. 7. As used in this chapter, "maximum allowable cost" means the maximum amount that a pharmacy benefit manager will reimburse a pharmacy for the cost of a generic prescription drug. The term does not include a dispensing fee or professional fee.

Sec. 8. As used in this chapter, "maximum allowable cost list" means a list of drugs that is used:

(1) by a pharmacy benefit manager; and

(2) to set the maximum amount that may be reimbursed to a pharmacy or pharmacist for a drug.

Sec. 9. As used in this chapter, "pharmacist" means an individual licensed as a pharmacist under IC 25-26.

Sec. 10. As used in this chapter, "pharmacist services" means products, goods, and services provided as part of the practice of pharmacy.

Sec. 11. As used in this chapter, "pharmacy" means the physical location:

(1) that is licensed under IC 25-26; and

(2) at which drugs, chemicals, medicines, prescriptions, and poisons are compounded, dispensed, or sold at retail.

Sec. 12. (a) As used in this chapter, "pharmacy benefit manager" means an entity that, on behalf of a health benefits plan, state agency, insurer, managed care organization, or other third party payor:

(1) contracts directly or indirectly with pharmacies to provide prescription drugs to individuals;

(2) administers a prescription drug benefit;

(3) processes or pays pharmacy claims;

(4) creates or updates prescription drug formularies;

(5) makes or assists in making prior authorization determinations on prescription drugs;

(6) administers rebates on prescription drugs; or

(7) establishes a pharmacy network.

(b) The term does not include the following:

(1) A person licensed under IC 16.

(2) A health provider who is:

(A) described in IC 25-0.5-1; and

(B) licensed or registered under IC 25.

(3) A consultant who only provides advice concerning the selection or performance of a pharmacy benefit manager.

Sec. 13. As used in this chapter, "pharmacy benefit manager affiliate" means a pharmacy or pharmacist that directly or indirectly, through one (1) or more intermediaries:

(1) owns or controls;

(2) is owned or controlled by; or

(3) is under common ownership or control with;

a pharmacy benefit manager.

Sec. 14. As used in this chapter, "pharmacy benefit manager network" means a group of pharmacies or pharmacists that is offered:

(1) through an agreement or health plan contract; and

(2) to provide pharmacist services for health plans.

Sec. 15. As used in this chapter, "pharmacy services administrative organization" means an organization that assists independent pharmacies and pharmacy benefit managers or health plans to achieve administrative efficiencies, including contracting and payment efficiencies.

Sec. 16. (a) As used in this chapter, "rebate" means a discount or other price concession that is:

(1) based on use of a prescription drug; and

(2) paid by a manufacturer or third party to a pharmacy benefit manager, pharmacy services administrative organization, or pharmacy after a claim has been processed and paid at a pharmacy.

(b) The term includes an incentive, a disbursement, and a reasonable estimate of a volume based discount.

Sec. 17. As used in this chapter, "third party" means a person other than a:

(1) pharmacy benefit manager; or

(2) covered individual.

Sec. 18. A person shall, before establishing or operating as a pharmacy benefit manager, apply to and obtain a license from the commissioner under this chapter.

Sec. 19. A pharmacy benefit manager shall do the following:

(1) Provide a pharmacy benefit manager network for a covered individual to obtain prescription drugs from a pharmacy within a reasonable distance from the covered individual's residence.

(2) Not include a mail order pharmacy in the determination of compliance with subdivision (1).

(3) Annually submit to the commissioner a pharmacy benefit manager network adequacy report describing covered individuals' access to pharmacies included in the pharmacy benefit manager network in Indiana, as required under section 20(b)(3)(B)(i) of this chapter.

(4) Provide equal access and incentives to all pharmacies within the pharmacy benefit network.

Sec. 20. (a) The commissioner shall do the following:

(1) Prescribe an application for use in applying for a license to operate as a pharmacy benefit manager.

(2) Adopt rules under IC 4-22-2 to establish the following:

(A) Pharmacy benefit manager licensing requirements.

(B) Licensing fees.

(C) A license application.

(D) Financial standards for pharmacy benefit managers.

(b) The commissioner may do the following:

(1) Charge a license application fee and renewal fees established under subsection (a)(2) in an amount not to exceed five hundred dollars ($500) to be deposited in the department of insurance fund established by IC 27-1-3-28.

(2) Examine or audit the books and records of a pharmacy benefit manager to determine if the pharmacy benefit manager is in compliance with this chapter.

(3) Adopt rules under IC 4-22-2 to:

(A) implement this chapter; and

(B) specify requirements for the following:

(i) Pharmacy benefit manager network adequacy.

(ii) Prohibited market conduct practices.

(iii) Data reporting in connection with violations of state law.

(iv) Rebates.

(v) Compensation.

(vi) Maximum allowable cost list compliance and enforcement requirements.

(vii) Prohibitions and limits on pharmacy benefit manager practices that require licensure under IC 25-22.5.

(viii) Pharmacy benefit manager affiliate information sharing.

(ix) Lists of health plans administered by a pharmacy benefit manager in Indiana.

(c) Information or data acquired during an examination or audit under subsection (b), including financial information and proprietary information, is confidential.

Sec. 21. A pharmacy benefit manager doing business in Indiana shall, at least every seven (7) days, update, and make available to pharmacies, the pharmacy benefit manager's maximum allowable cost list.

Sec. 22. (a) Beginning June 1, 2021, and annually thereafter, a pharmacy benefit manager shall submit a report containing data from the immediately preceding calendar year to the commissioner containing all of the following:

(1) The aggregate amount of all rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers for:

(A) all insurers; and

(B) each insurer;

with which the pharmacy benefit manager contracted during the immediately preceding calendar year.

(2) The aggregate amount of administrative fees that the pharmacy benefit manager received from all pharmaceutical manufacturers for:

(A) all insurers; and

(B) each insurer;

with which the pharmacy benefit manager contracted during the immediately preceding calendar year.

(3) The aggregate amount of retained rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers and did not pass through to insurers with which the pharmacy benefit manager contracted during the immediately preceding calendar year.

(4) The highest, lowest, and mean aggregate retained rebate

for:

(A) all insurers; and

(B) each insurer;

with which the pharmacy benefit manager contracted during the immediately preceding calendar year.

(b) Not later than sixty (60) days after the commissioner receives a report required by this section, the commissioner shall publish the report on the department's Internet web site.

(c) A pharmacy benefit manager that provides information under this section may designate the information as a trade secret (as defined in IC 24-2-3-2). Information designated as a trade secret under this subsection must not be published under subsection (b), unless required under subsection (d).

(d) Disclosure of information designated as a trade secret under subsection (c) may be ordered by a court of Indiana for good cause shown or made in a court filing.

Sec. 23. (a) A pharmacy benefit manager shall do the following:

(1) Identify to contracted pharmacies the sources used by the pharmacy benefit manager to calculate the drug product reimbursement paid for covered drugs available under the pharmacy health benefit plan administered by the pharmacy benefit manager.

(2) Establish an appeal process for contracted pharmacies, pharmacy services administrative organizations, or group purchasing organizations to appeal and resolve disputes concerning the maximum allowable cost pricing.

(3) Establish an Internet web site to support the appeal process described in subdivision (2) that allows contracted pharmacies, pharmacy services administrative organizations, and group purchasing organizations to submit appeals on maximum allowable cost pricing.

(b) The appeal process required by subsection (a)(2) must include the following:

(1) The right to appeal a claim not to exceed sixty (60) days following the initial filing of the claim.

(2) The investigation and resolution of a filed appeal by the pharmacy benefit manager not later than ten (10) calendar days from the filing of the appeal.

(3) If an appeal is denied, a requirement that the pharmacy benefit manager do the following:

(A) Provide the reason for the denial.

(B) Identify:

(i) the national drug code of a drug product that is commercially available with no minimum purchase amounts; and

(ii) the source where the drug product may be purchased at a price that is at or below the stated maximum allowable cost and from a licensed wholesaler by any contract pharmacy.

(C) Identify alternative sources for a drug product as described in clause (B) if the contracting pharmacy provides reasonable evidence to the pharmacy benefit manager that the pharmacy is unable to source the drug product as described in clause (B).

(4) If an appeal is approved, a requirement that the pharmacy benefit manager do the following:

(A) Change the maximum allowable cost of the drug for the pharmacy that filed the appeal as of the initial date of service that the appealed drug was dispensed.

(B) Adjust the maximum allowable cost of the drug for the appealing pharmacy and for all other contracted pharmacies in the network of the pharmacy benefit manager that filled a prescription for patients covered under the same health benefit plan beginning on the initial date of service the appealed drug was dispensed.

(C) Individually notify all other contracted pharmacies in the network of the pharmacy benefit manager that a retroactive maximum allowable cost adjustment has been made as a result of an approved appeal that is effective on the initial date of service the appealed drug was dispensed.

(D) Adjust the drug product reimbursement for contracted pharmacies that resubmit claims to reflect the adjusted maximum allowable cost, if applicable.

(E) Allow the appealing pharmacy and all other contracted pharmacies in the network that filled the prescriptions for patients covered under the same health benefit plan to reverse and resubmit claims and receive payment based on the adjusted maximum allowable cost from the initial date of service the appealed drug was dispensed.

(F) Make retroactive price adjustments in the next payment cycle.

(5) The establishment of procedures for auditing submitted claims by a contract pharmacy in a manner established by administrative rules under IC 4-22-2 by the department. The

auditing procedures:

(A) may not use extrapolation or any similar methodology;

(B) may not allow for recovery by a pharmacy benefit manager of a submitted claim due to clerical or other error where the patient has received the drug for which the claim was submitted;

(C) must allow for recovery by a contract pharmacy for underpayments by the pharmacy benefit manager; and

(D) may only allow for the pharmacy benefit manager to recover overpayments on claims that are actually audited and discovered to include a recoverable error.

(c) The department must approve the manner in which a pharmacy benefit manager may respond to an appeal filed under this section. The department shall establish a process for a pharmacy benefit manager to obtain approval from the department under this section.

Sec. 24. (a) For every drug for which the pharmacy benefit manager establishes a maximum allowable cost to determine the drug product reimbursement, the pharmacy benefit manager shall make available to all contracted pharmacies in a manner established by the department by administrative rule described in subsection (b) the following:

(1) Information identifying the national drug pricing compendia or sources used to obtain the drug price data.

(2) The comprehensive list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.

(3) Weekly updates to the list of drugs subject to maximum allowable cost and the actual maximum allowable cost for each drug.

(b) The department shall adopt rules under IC 4-22-2 concerning the manner in which a pharmacy benefit manager shall communicate the following to contracted pharmacies:

(1) Drug price data should be used to establish drug reimbursements by pharmacy benefit managers as described in subsection (a)(1).

(2) The comprehensive list of drugs described in subsection (a)(2).

(3) The weekly updates to the list of drugs described in subsection (a)(3).

Sec. 25. (a) For every drug for which a pharmacy benefit manager establishes a maximum allowable cost to determine

reimbursement for the drug product, the pharmacy benefit manager shall make available to the department, upon request of the department, information that is needed to resolve an appeal.

(b) If the pharmacy benefit manager fails to promptly make available to the department the information as required in subsection (a), the department shall consider the appeal granted in favor of the appealing pharmacy.

Sec. 26. (a) A pharmacy benefit manager shall:

(1) review any drug the pharmacy benefit manager subjects to a maximum allowable cost to set the drug product reimbursement; and

(2) make any adjustments to reimbursement for the maximum allowable cost for the drug;

at least every seven (7) calendar days. The pharmacy benefit manager shall immediately implement any adjustment to the reimbursement to the maximum allowable cost in calculating payments for all pharmacies that have contracted with the pharmacy benefit manager.

(b) The pharmacy benefit manager shall, for every drug for which the pharmacy benefit manager establishes a maximum allowable cost for reimbursement of a drug product, ensure that a drug subject to a maximum allowable cost meets the following:

(1) Is generally available for purchase by pharmacies and pharmacists from an appropriately licensed national or regional wholesaler.

(2) Is not any of the following:

(A) Obsolete.

(B) Temporarily unavailable.

(C) Included on a drug shortage list.

(D) Unable to be lawfully substituted.

(3) Is rated either as:

(A) an "A" or "B" rating in the most recent version of the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations; or

(B) a "NR", "NA", or a similar rating by a nationally recognized reference.

(4) Is reimbursed at a rate based solely on the drug if the drug does not have a therapeutically equivalent drug.

(c) A pharmacy benefit manager shall, for every drug for which the pharmacy benefit manager establishes a maximum allowable cost for reimbursement of a drug product, ensure that reimbursement for a drug that is subject to maximum allowable

cost is based solely on the drug and therapeutically equivalent drugs listed in the most recent version of the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

(d) A pharmacy benefit manager shall reimburse for a drug for which the pharmacy benefit manager establishes a maximum allowable cost as follows:

(1) For a "B" rated drug, reimbursement based solely on that drug.

(2) For a "NR" or "NA" drug with a similar rating by a nationally recognized reference, reimbursement is based solely on the drug and other drugs with that rating that are a therapeutically equivalent drug.

Sec. 27. (a) A violation of this chapter is an unfair or deceptive act or practice in the business of insurance under IC 27-4-1-4.

(b) The department may also adopt rules under IC 4-22-2 to set forth fines for a violation under this chapter.

SECTION 2. IC 27-1-24.8 IS REPEALED [EFFECTIVE JULY 1, 2020]. (Pharmacy Benefit Managers).

SECTION 3. [EFFECTIVE JULY 1, 2020] **(a) Notwithstanding IC 27-1-24.5, as added by this act, a pharmacy benefit manager must be licensed by the department of insurance not later than December 31, 2020, in order to do business in Indiana and provide services for any health provider contract (as defined in IC 27-1-37-3) that is in effect beginning or after January 1, 2021.**

(b) This SECTION expires December 31, 2021.

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred Senate Bill No. 241, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 4, line 30, delete "." and insert "**in an amount not to exceed five hundred dollars ($500) to be deposited in the department of insurance fund established by IC 27-1-3-28.**".

Page 5, line 11, after "(b)" insert "**, including financial information and proprietary information,**".

Page 5, delete lines 12 through 20.

Page 5, line 21, delete "22." and insert "**21.**".

Page 5, line 25, delete "23." and insert "**22.**".

Page 6, line 23, delete "24." and insert "**23.**".

Page 8, line 23, delete "25." and insert "**24.**".

Page 9, line 5, delete "26." and insert "**25.**".

Page 9, line 14, delete "27." and insert "**26.**".

Page 10, line 20, delete "28." and insert "**27.**".

Page 10, after line 25, begin a new paragraph and insert:

"SECTION 3. [EFFECTIVE JULY 1, 2020] **(a) Notwithstanding IC 27-1-24.5, as added by this act, a pharmacy benefit manager must be licensed by the department of insurance not later than December 31, 2020, in order to do business in Indiana and provide services for any health provider contract (as defined in IC 27-1-37-3) that is in effect beginning or after January 1, 2021.**

(b) This SECTION expires December 31, 2021."

Renumber all SECTIONS consecutively.

and when so amended that said bill do pass.

(Reference is to SB 241 as introduced.)

CHARBONNEAU, Chairperson

Committee Vote: Yeas 9, Nays 2.