As Introduced

134th General Assembly
Regular Session
2021-2022

H. B. No. 336

Representatives Lipps, West

A BILL

To amend sections 3901.81, 3901.811, 3902.50, 3902.60, and 3902.70 and to enact sections 3902.72, 3902.73, 3902.74, 3902.75, 3902.76, 3902.77, 4729.66, 5167.124, 5167.125, 5167.126, 5167.127, and 5167.128 of the Revised Code to impose requirements relating to health plan issuers, Medicaid, pharmacies, and cancer drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3901.81, 3901.811, 3902.50, 3902.60, and 3902.70 be amended and sections 3902.72, 3902.73, 3902.74, 3902.75, 3902.76, 3902.77, 4729.66, 5167.124, 5167.125, 5167.126, 5167.127, and 5167.128 of the Revised Code be enacted to read as follows:

Sec. 3901.81. As used in this section and sections 3901.811 to 3901.815 of the Revised Code:

(A) "Auditing entity" means any person or government entity that performs a pharmacy audit, including a payer, a pharmacy benefit manager, or a third-party administrator licensed under Chapter 3959. of the Revised Code.

(B) "Business day" means any day of the week excluding

Saturday, Sunday, and a legal holiday, as defined in section 1.14 of the Revised Code.

(C) "Concurrent review" means a claims review within five business days of submission of claims for payment for the provision of dangerous drugs for which the payer or the auditing entity does not impose a penalty or demand to recoup money from the pharmacy in any amount.

(D) "Dangerous drug," "pharmacy," "practice of pharmacy," and "prescription" have the same meanings as in section 4729.01 of the Revised Code.

(E) "Fraud" means knowingly engaging in deception with the intent of personal enrichment or gain.

(F) "Payer" means any of the following that pays for or processes a claim for payment for the provision of dangerous drugs or pharmacy services:

(1) A health insuring corporation, as defined in section 1751.01 of the Revised Code;

(2) A person authorized to engage in the business of sickness and accident insurance under Title XXXIX of the Revised Code;

(3) A person or government entity providing coverage of dangerous drugs or pharmacy services to individuals on a self-insurance basis;

(4) A group health plan, as defined in 29 U.S.C. 1167;

(5) A service benefit plan, as referenced in 42 U.S.C. 1396a(a)(25);

(6) A medicaid managed care organization that has entered

into a contract with the department of medicaid pursuant to section 5167.10 of the Revised Code;

(7) Any other person or government entity that is, by law, contract, or agreement, responsible for paying for or processing a claim for payment for the provision of dangerous drugs or pharmacy services.

~~(F)~~ (G) "Pharmacy audit" means a review of one or more pharmacy records conducted by an auditing entity, one purpose of which is to identify discrepancies in claims for payment for the provision of dangerous drugs or pharmacy services. "Pharmacy audit" does not include concurrent review.

~~(G)~~ (H) "Pharmacy benefit manager" means a person that provides administrative services related to the processing of claims for payment for the provision of dangerous drugs or pharmacy services, including performing pharmacy audit compliance, negotiating pharmaceutical rebate agreements, developing and managing drug formularies and preferred drug lists, and administering programs for payers' prior authorization of claims for payment for the provision of dangerous drugs or pharmacy services.

~~(H)~~ (I) "Pharmacy record" means any record stored electronically or as a hard copy by a pharmacy that relates to the provision of dangerous drugs or pharmacy services or any other component of pharmacist care that is included in the practice of pharmacy.

Sec. 3901.811. (A) Except as provided in division (B) of this section, an auditing entity is subject to all of the following conditions when performing a pharmacy audit in this state:

(1) If it is necessary that the pharmacy audit be performed on the premises of a pharmacy, the auditing entity shall give the pharmacy that is the subject of the audit written notice of the date or dates on which the audit will be performed and the range of prescription numbers from which the auditing entity will select pharmacy records to audit. Notice of the date or dates on which the audit will be performed shall be given not less than ten business days before the date the audit is to commence. Notice of the range of prescription numbers from which the auditing entity will select pharmacy records to audit shall be received by the pharmacy not less than seven business days before the date the audit is to commence.

(2) The auditing entity shall not include in the pharmacy audit a review of a claim for payment for the provision of dangerous drugs or pharmacy services if the date of the pharmacy's initial submission of the claim for payment occurred more than twenty-four months before the date the audit commences.

(3) Absent an indication that there was an error in the dispensing of a drug, the auditing entity or payer shall not seek to recoup from the pharmacy that is the subject of the audit any amount that the pharmacy audit identifies as being the result of clerical or recordkeeping errors in the absence of financial harm. For purposes of this provision, an error in the dispensing of a drug is any of the following: selecting an incorrect drug, issuing <u>materially</u> incorrect directions, or dispensing a drug to the incorrect patient.

(4) The auditing entity shall not use the accounting practice of extrapolation when calculating a monetary penalty to be imposed or amount to be recouped as the result of the

pharmacy audit.

(5)(a) An auditing entity shall not penalize a pharmacy based solely on the fact that all materials requested by the auditing entity are not available during an onsite audit;

(b) A pharmacy shall have the opportunity to provide supplemental materials to an auditing entity after the completion of an onsite audit. Such materials shall be subject to the same documentation standards as materials reviewed during the onsite audit. An auditing entity shall not reject a document merely on the basis that the document is not an original and shall accept documents sent via electronic or telephonic means.

(6) An audit shall be limited to the lesser of the following:

(a) Two hundred fifty prescriptions;

(b) The number of prescriptions dispensed by a pharmacy in the twenty-four month period prior to the audit.

(B)(1) The condition in division (A)(1) of this section does not apply if, prior to the audit, the auditing entity has evidence, from its review of claims data, statements, or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.

(2) The condition in division (A)(3) of this section does not apply if the auditing entity has evidence, from its review of claims data, statements, or physical evidence or its use of other investigative methods, indicating that fraud or other intentional or willful misrepresentation exists.

(3) Division (A)(4) of this section does not apply when

the accounting practice of extrapolation is required by state or federal law.

(C) An auditing entity shall not be compensated based on the level or amounts of recoupments.

(D) A pharmacy shall not be required to pay any disputed recoupments resulting from an audit until after the final disposition of the audit, including the conclusion of any relevant appeals or dispute processes.

(E) A pharmacy may seek injunctive relief against a payer or its contracted pharmacy benefit manager for a violation of this section by an auditing entity.

Sec. 3902.50. As used in sections 3902.50 to ~~3902.54~~ 3902.77 of the Revised Code:

(A) "Ambulance" has the same meaning as in section 4765.01 of the Revised Code.

(B) "Clinical laboratory services" has the same meaning as in section 4731.65 of the Revised Code.

(C) "Cost sharing" means the cost to a covered person under a health benefit plan according to any copayment, coinsurance, deductible, or other out-of-pocket expense requirement.

(D) "Covered person," "health benefit plan," "health care services," and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.

(E) "Emergency facility" has the same meaning as in section 3701.74 of the Revised Code.

(F) "Emergency services" means all of the following as

described in 42 U.S.C. 1395dd:

(1) Medical screening examinations undertaken to determine whether an emergency medical condition exists;

(2) Treatment necessary to stabilize an emergency medical condition;

(3) Appropriate transfers undertaken prior to an emergency medical condition being stabilized.

(G) Except as in division (I) of this section and in sections 3902.51 to 3902.54 of the Revised Code, "health care provider" or "provider" has the same meaning as in section 3922.01 of the Revised Code.

(H) "Pharmacy" has the same meaning as in section 4729.01 of the Revised Code and also includes a dispensing physician.

(I) "Unanticipated out-of-network care" means health care services, including clinical laboratory services, that are covered under a health benefit plan and that are provided by an out-of-network provider when either of the following conditions applies:

(1) The covered person did not have the ability to request such services from an in-network provider.

(2) The services provided were emergency services.

Sec. 3902.60. As used in sections 3902.60 and 3902.61 of the Revised Code:

(A) "Associated conditions" means the symptoms or side effects of stage four advanced metastatic cancer, or the treatment thereof, which would, in the judgment of the health care practitioner in question, jeopardize the health of a

covered individual if left untreated.

(B) ~~"Covered person," "health benefit plan," and "health plan issuer" have the same meanings as in section 3922.01 of the Revised Code.~~

~~(C)~~ "Stage four advanced metastatic cancer" means a cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes, or other areas or parts of the body.

Sec. 3902.70. As used in this section and section 3902.71 of the Revised Code:

(A) "340B covered entity" and "third-party administrator" have the same meanings as in section 5167.01 of the Revised Code.

(B) ~~"Health plan issuer" has the same meaning as in section 3922.01 of the Revised Code.~~

~~(C)~~ "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01 of the Revised Code.

Sec. 3902.72. As used in sections 3902.72 to 3902.77 of the Revised Code:

(A) "Affiliated pharmacy" means a pharmacy in which a health plan issuer, either directly or indirectly through one or more intermediaries, has an investment or ownership interest or with which it shares common ownership.

(B) "Dispensing physician" means a physician who dispenses a "dangerous drug" as that term is defined in section 4729.01 of the Revised Code.

(C) Notwithstanding section 3902.50 of the Revised Code,

"health plan issuer" has the same meaning as in section 3922.01 of the Revised Code, but also includes an auditing entity, as defined in section 3901.81 of the Revised Code.

(D) "Prior authorization" means any practice implemented by a health plan issuer in which coverage of a prescription drug is dependent upon a covered person or a physician obtaining approval from the health plan issuer prior to the drug being covered. "Prior authorization" includes prospective or utilization review procedures conducted prior to providing a drug.

Sec. 3902.73. (A) A health plan issuer that offers, issues, or administers a health benefit plan that covers pharmacy services, including prescription drug coverage, shall not do any of the following:

(1) Order or direct a covered person to fill a prescription at or obtain services from an affiliated pharmacy;

(2) Restrict a covered person's ability to select a pharmacy if the selected pharmacy is in the health plan issuer's pharmacy provider network;

(3) Impose a cost-sharing requirement on the covered person that differs depending on which in-network pharmacy the covered person uses;

(4) Impose any other condition on a covered person or pharmacy that restricts a covered person's ability to use an in-network pharmacy of the covered person's choosing;

(5) Prevent a pharmacy from participating in the health plan issuer's network if the pharmacy does both of the following:

(a) Agrees to the reasonable and relevant terms and conditions of the health plan issuer's pharmacy provider contract;

(b) Provides pharmacy services in accordance with all applicable state and federal laws.

(6) Require a pharmacy, as a condition of participation in the health plan issuer's network, to meet accreditation standards or certification requirements that are inconsistent with or in addition to those of the state board of pharmacy.

(7) Transfer or share records relating to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose. Division (A)(7) of this section shall not be construed to prohibit the exchange of prescription information between a health plan issuer and an affiliated pharmacy for the limited purposes of pharmacy reimbursement, formulary compliance, pharmacy care, or utilization review.

(8) Knowingly make a misrepresentation to a covered person, pharmacist, pharmacy, or dispensing physician.

(B) This section does not apply to either of the following:

(1) A health benefit plan offered by a health insuring corporation under which a majority of covered services are provided by physicians employed by the health plan issuer or by a single contracted medical group;

(2) Pharmacy services provided to an individual receiving inpatient or emergency services at a health care facility that provides medical services on an inpatient or resident basis.

Sec. 3902.74. (A) As used in this section:

(1) "Incentive payments and adjustments" means price concessions, rebates, discounts, fees, reconciliation adjustments, bonuses, performance payments, incentives, and any other payment adjustment determined through the use of performance criteria, regardless of when such adjustments are applied.

(2) "Incentive payment and adjustment system" means a system established by a health plan issuer for determining the amount of payments to participating pharmacies that uses incentive payments and adjustments to determine such payment amounts.

(B) If a health plan issuer uses an incentive payment and adjustment system to determine pharmacy reimbursement payments for prescription drugs, the issuer and system shall meet all of the following requirements:

(1) The process for determining the incentive payments and adjustments, including performance criteria, shall be described in an express contract between the health plan issuer and the pharmacy entered into not less than six months prior to the start of the period in which the pharmacy's performance is to be measured.

(2) The incentive payments and adjustments shall be based on the individual pharmacy's actual performance metrics under the performance criteria.

(3) The pharmacy's evaluation shall be based on actual data received from the pharmacy and not extrapolated from a sample of data.

(4) The pharmacy's evaluation shall be based on objective

performance standards, not on its performance relative to other pharmacies.

(5) The pharmacy's performance shall be evaluated using only performance criteria over which a pharmacy has meaningful control and that appropriately correspond to the types of services offered by the pharmacy, including the dispensing of specialty drugs.

(6) The incentive payments and adjustments shall not favor the health plan issuer's affiliated pharmacies or discriminate against nonaffiliated pharmacies.

(7) For each claim for which a pharmacy receives decreased reimbursement, the health plan issuer shall provide the pharmacy a written explanation detailing how the pharmacy failed to meet the applicable performance criteria and describing the steps it must take to improve its performance. The written explanation shall be provided at the time the incentive payments and adjustments are applied or as soon as practicable thereafter.

(8) Any potential decrease in reimbursement to a pharmacy is, at a minimum, matched by an equal potential increase in reimbursement.

Sec. 3902.75. Each contract between a health plan issuer and a pharmacy shall include a system by which the pharmacy can inform a covered person when a drug is available at a lower cost if purchased outside of the health benefit plan.

Sec. 3902.76. (A) As used in this section, "clean claim" means a claim that can be processed without obtaining additional information from the prescribing provider or a third party, is not for a recipient who receives financial assistance for the drug, and is not for a prescribed drug that is associated with a

national drug shortage that has been reported to the United States food and drug administration.

(B) A health plan issuer shall ensure that a covered person can obtain a covered orally administered prescription drug used to treat cancer within seventy-two hours following submission of a clean claim or prior authorization request to the health plan issuer, notwithstanding the prior authorization time limits established in section 1751.72 or 3923.041 of the Revised Code. If the health plan issuer is unable to do so by requiring the covered person to use a pharmacy in the issuer's pharmacy provider network or a dispensing physician in the issuer's physician provider network, the issuer shall cover the drug if purchased from an out-of-network pharmacy or out-of-network dispensing physician to the same extent as it would if the drug were dispensed by an in-network pharmacy or dispensing physician.

(C) Within twenty-four hours of submission to a health plan issuer of a clean claim or prior authorization request for the drug, the health plan issuer shall confirm receipt of the claim and notify the prescribing provider in writing of both of the following:

(1) Whether the drug is covered;

(2) If the drug is covered, any delay in authorization or coverage that would likely result in the covered person not being able to receive the drug within seventy-two hours following the initial submission of the claim.

(D) If it is likely that the drug will not be available to a covered person within seventy-two hours of the initial submission, the health plan issuer shall notify the covered

person that the covered person can use another pharmacy or dispensing physician to obtain the drug, including a pharmacy or dispensing physician that is not part of the health plan issuer's pharmacy provider or physician provider network. The notification shall be written in a clear, concise, and intelligible manner.

Sec. 3902.77. Any covered person or pharmacy affected by a violation of sections 3902.73 to 3902.76 of the Revised Code by a health plan issuer or one or more of its intermediaries may bring a civil action against the health plan issuer or the intermediary for compensatory damages and injunctive or other equitable relief.

Sec. 4729.66. No pharmacy shall mail a dangerous drug to a patient when the patient's prescriber has indicated that the patient needs an in-person consultation at the time the original or refill prescription is dispensed; provided, however, that a patient may voluntarily waive in writing the in-person consultation and elect to receive the dangerous drug via mail order.

Sec. 5167.124. (A) As used in this section and section 5167.124 of the Revised Code:

(1) "Affiliated pharmacy" means a pharmacy in which a medicaid managed care organization, or a pharmacy benefit manager under contract with the medicaid director or a medicaid managed care organization to administer its prescribed drugs benefit, either directly or indirectly through one or more intermediaries, has an investment or ownership interest or with which it shares common ownership.

(2) "Dispensing physician" has the same meaning as in

section 3902.72 of the Revised Code.

(3) "Pharmacy" has the same meaning as in section 3902.50 of the Revised Code.

(B) A medicaid managed care organization, or a pharmacy benefit manager under contract with the medicaid director or a medicaid managed care organization to administer its prescribed drugs benefit, shall not do any of the following:

(1) Order or direct an enrollee to fill a prescription at or obtain services from an affiliated pharmacy;

(2) Restrict an enrollee's ability to use a pharmacy if the pharmacy is in the organization's pharmacy provider network;

(3) Impose a cost-sharing requirement on an enrollee that differs depending on which participating in-network pharmacy the enrollee uses;

(4) Impose any other condition on an enrollee or a pharmacy that restricts the enrollee's ability to use an in-network pharmacy of the enrollee's choosing;

(5) Prevent a pharmacy from becoming a participating pharmacy if the pharmacy does both of the following:

(a) Agrees to the reasonable and relevant terms and conditions of the medicaid managed care organization's pharmacy provider contract;

(b) Provides pharmacy services in accordance with state and federal law.

(6) Require a pharmacy, as a condition of participating in the organization's network, to meet accreditation standards or certification requirements that are inconsistent with or in

addition to those of the state board of pharmacy;

(7) Transfer or share records relating to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose. This division shall not be construed to prohibit the exchange of prescription information between a medicaid managed care organization and an affiliated pharmacy for the limited purposes of pharmacy reimbursement, formulary compliance, pharmacy care, or utilization review.

(8) Knowingly make a misrepresentation to an enrollee, pharmacist, pharmacy, or dispensing physician.

(C) This section does not apply to either of the following:

(1) A health benefit plan that is offered under the care management system and under which a majority of covered services are provided by physicians employed by the medicaid managed care organization or by a single contracted medical group;

(2) Pharmacy services provided to an individual receiving inpatient or emergency services at a health care facility that provides medical services on an inpatient or resident basis.

Sec. 5167.125. (A) As used in this section, "incentive payments and adjustments" and "incentive payment and adjustment system" have the same meanings as in section 3902.74 of the Revised Code.

(B) If a medicaid managed care organization uses an incentive payment and adjustment system to determine the payment owed to a pharmacy for dispensing a prescribed drug to an enrollee, the system shall meet all of the following requirements:

(1) The process for determining the incentive payments and adjustments, including any performance criteria, shall be described in an express contract between the medicaid managed care organization and the pharmacy entered into not less than six months prior to the start of the period when the pharmacy's performance will be measured.

(2) The incentive payments and adjustments shall be based on the individual pharmacy's actual performance metrics under the performance criteria.

(3) The pharmacy's evaluation shall be based on actual data received from the pharmacy and not extrapolated from a sample of data.

(4) The pharmacy's evaluation shall be based on objective performance standards, not on its performance relative to other pharmacies.

(5) The pharmacy's performance shall be evaluated using only performance criteria over which the pharmacy has meaningful control and that appropriately correspond to the types of services offered by the pharmacy, including the dispensing of specialty drugs.

(6) The incentive payments and adjustments shall not favor the medicaid managed care organization's affiliated pharmacies or discriminate against nonaffiliated pharmacies.

(7) For each claim for which a pharmacy receives a decreased payment, the medicaid managed care organization shall provide to the pharmacy a written explanation detailing how the pharmacy failed to meet the applicable performance criteria and describing the steps it must take to improve its performance. The written explanation shall be provided at the time the

incentive payments or adjustments are applied, or as soon as practicable thereafter.

(8) Any potential decrease in payment to a pharmacy from incentive payments and adjustments shall be matched, at minimum, by a potential increase in payment to the pharmacy.

Sec. 5167.126. Each contract between a medicaid managed care organization and a pharmacy shall include a system by which the pharmacy can inform an enrollee whenever a prescribed drug is available at a lower cost outside of coverage under the medicaid managed care organization's plan.

Sec. 5167.127. (A) As used in this section:

(1) "Clean claim" has the same meaning as in section 3902.76 of the Revised Code.

(2) "Dispensing physician" has the same meaning as in section 3902.72 of the Revised Code.

(B) A medicaid managed care organization shall ensure that an enrollee can obtain an orally administered prescribed drug used to treat cancer within seventy-two hours following submission of a clean claim or prior authorization request to the medicaid managed care organization, notwithstanding the prior authorization requirement time limits established in section 5160.34 of the Revised Code. If the medicaid managed care organization is unable to do so through a pharmacy in the organization's pharmacy network or a dispensing physician in the organization's provider network, it shall cover the drug if purchased from an out-of-network pharmacy to the same extent as if the drug were dispensed by an in-network pharmacy or dispensing physician.

(C) Within twenty-four hours of submission to a medicaid

managed care organization of a clean claim or prior authorization request for the drug, the medicaid managed care organization shall confirm receipt of the claim or request and notify the prescribing provider in writing of both of the following:

(1) Whether the drug is covered;

(2) If the drug is covered, any delay in authorization or coverage that would likely result in the enrollee not being able to receive the drug within seventy-two hours from the initial submission of the claim.

(D) If it is likely that the drug will not be available to an enrollee within seventy-two hours from the initial submission, the medicaid managed care organization shall notify the enrollee that the medicaid recipient enrollee can use another pharmacy or dispensing physician to obtain the drug, including a pharmacy or dispensing physician that is not part of the organization's pharmacy or physician provider network. The notification shall be written in a clear, concise, and intelligible manner.

Sec. 5167.128. Any enrollee or pharmacy affected by a violation of sections 5167.123 to 5167.126 of the Revised Code by a medicaid managed care organization or one or more of the organization's intermediaries, including a pharmacy benefit manager, may bring a civil action against the organization or the intermediary for compensatory damages and injunctive or other equitable relief.

Section 2. That existing sections 3901.81, 3901.811, 3902.50, 3902.60, and 3902.70 of the Revised Code are hereby repealed.

Section 3. Sections 3901.81, 3901.811, 3902.50, 3902.60, and 3902.70 of the Revised Code, as amended in this act, and sections 3902.72, 3902.73, 3902.74, 3902.75, 3902.76, and 3902.77 of the Revised Code, as enacted in this act, apply to health benefit plans, as defined in section 3922.01 of the Revised Code, delivered, issued for delivery, modified, or renewed on or after the effective date of those sections.

Section 4. Sections 3901.81, 3901.811, 3902.50, 3902.60, and 3902.70 of the Revised Code, as amended in this act, and sections 3902.72, 3902.73, 3902.74, 3902.75, 3902.76, and 3902.77 of the Revised Code, as enacted in this act, apply to contracts between health plan issuers, as defined in section 3922.01 of the Revised Code, and pharmacies entered into, modified, or renewed on or after the effective date of those sections.