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Bill Analysis

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Yosef Schiff and Erika Kramer, Attorneys

SUMMARY

Health plan issuers and affiliated pharmacies

- Prohibits a health plan issuer from taking certain actions that would favor the issuer's affiliated pharmacies or would result in a covered person being required to use an affiliated pharmacy or restricted from using an unaffiliated but in-network pharmacy.
- Prohibits a health plan issuer from preventing a pharmacy from joining the issuer's network if the pharmacy agrees to reasonable terms of the issuer's pharmacy provider contract and is otherwise in compliance with the law.
- Prohibits a health plan issuer from requiring a pharmacy, as a condition for joining its network, to meet accreditation standards or certification requirements that are inconsistent with or in addition to those of the Board of Pharmacy.

Incentive payment and adjustment systems

- Enacts requirements that a health plan issuer must meet in order to use an incentive payments and adjustment system, including the processes for determining payments and adjustments, standards for incentive payments and adjustments, and standards relating to a pharmacy's evaluation.

Notice of lower-cost alternatives

- Requires each contract between a health plan issuer and a pharmacy to 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.

Time limits to obtain certain cancer drugs

- Requires a health plan issuer to ensure that a covered person can obtain a covered orally administered prescription drug used to treat cancer within 72 hours following

submission of a clean claim or prior authorization request to the issuer, including, if necessary, by covering such a drug obtained out-of-network.

Medicaid managed care organizations

- Also applies the above requirements to Medicaid managed care organizations, and, as applicable, their pharmacy benefit managers.

Civil action

- Permits any covered person, pharmacy, or dispensing physician affected by a violation of any of the above provisions by a health plan issuer or a Medicaid managed care organization, or any of their intermediaries, to bring a civil action against the issuer or the intermediary for compensatory damages and injunctive or other equitable relief.

Pharmacy audits

- Prohibits an auditing entity from penalizing a pharmacy based solely on the fact that all materials requested by the auditing entity are not available during an onsite audit.
- Requires that a pharmacy have the opportunity to provide supplemental materials to an auditing entity after the completion of an onsite audit.
- Prohibits an auditing entity from rejecting a document solely because the document is not an original and requires the entity to accept documents sent via electronic or telephonic means.
- Limits an audit to the lesser of 250 prescriptions or the number of prescriptions dispensed by a pharmacy in the 24-month period before the audit.
- Specifies that a pharmacy is not required to pay any disputed recoupments resulting from an audit until after the audit's final disposition, including any relevant appeals or dispute processes.
- Prohibits an auditing entity from being compensated based on its level or amounts of recoupments.
- Regarding the existing prohibition against an auditing entity seeking recoupment from a pharmacy due to clerical errors absent financial harm, restricts an exception relating to incorrect directions to *materially* incorrect directions.
- Defines "fraud" as "knowingly engaging in deception with the intent of personal enrichment or gain" for the purposes of the fraud-based exemptions to the pharmacy audit law provisions that (1) require auditing entities to provide pharmacies notice of on-site audits, (2) prohibit auditing entities from seeking reimbursement based on clerical errors, and (3) require auditing entities to provide a preliminary audit report and an opportunity to provide additional information.
- Permits a pharmacy to seek injunctive relief against a payer or its contracted pharmacy benefit manager for violations of its pharmacy audit provisions by an auditing entity.

Mail-order drugs

- Prohibits a pharmacy from mailing a dangerous drug to a patient when an in-person consultation is required, unless the patient waives the consultation and elects to receive the dangerous drug via mail order.

DETAILED ANALYSIS

Health plan issuers and affiliated pharmacies

The bill prohibits a health plan issuer that issues a health benefit plan covering pharmacy services, including prescription drug coverage, from doing any of the following:

- Ordering or directing a covered person to fill a prescription at or obtain services from an affiliated pharmacy (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);
- Restricting a covered person's ability to select a pharmacy if the selected pharmacy is in the health plan issuer's pharmacy provider network;
- Imposing a cost-sharing requirement on the covered person that differs depending on which in-network pharmacy the covered person uses;
- Imposing 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;
- Preventing a pharmacy from participating in the health plan issuer's network if the pharmacy does both of the following:
  - Agrees to the reasonable and relevant terms and conditions of the health plan issuer's pharmacy provider contract;
  - Provides pharmacy services in accordance with all applicable state and federal laws.
- Requiring 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 Board of Pharmacy;
- Transferring or sharing records relating to prescription information containing patient-identifiable or prescriber-identifiable data to an affiliated pharmacy for any commercial purpose. This provision is not to 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.
- Knowingly making a misrepresentation to a covered person, pharmacist, pharmacy, or dispensing physician (a physician who dispenses a prescription drug, drug containing

certain controlled substances, drug intended for administration by injection other than through a natural orifice, or drug that is a biological product).[1]

The above prohibitions do not apply to either of the following:

- 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;
- 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.[2]

Incentive payment and adjustment systems

The bill enacts requirements regarding the use of incentive payment and adjustment systems. "Incentive payments and adjustments" are 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. An "incentive payment and adjustment system" is 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.[3]

Under the bill, a health plan issuer, and any incentive payment and adjustment system the issuer uses to determine pharmacy reimbursement payments for prescription drugs, must meet all of the following requirements:

- The process for determining the incentive payments and adjustments, including performance criteria, must be described in an express contract between the issuer and the pharmacy entered into not less than six months before the start of the period in which the pharmacy's performance is to be measured;
- The incentive payments and adjustments must be based on the individual pharmacy's actual performance metrics under the performance criteria;
- The pharmacy's evaluation must be based on actual data received from the pharmacy and not extrapolated from a sample of data;
- The pharmacy's evaluation must be based on objective performance standards, not on its performance relative to other pharmacies;

[1] R.C. 3902.72(A) and (B) and 3902.73(A) and R.C. 4729.01, not in the bill.

[2] R.C. 3902.73(B).

[3] R.C. 3902.74(A).

- The pharmacy's performance must 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;
- The incentive payments and adjustments must not favor the health plan issuer's affiliated pharmacies or discriminate against nonaffiliated pharmacies;
- For each claim for which a pharmacy receives decreased reimbursement, the health plan issuer must 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 must be provided at the time the incentive payments and adjustments are applied or as soon as practicable thereafter.
- Any potential decrease in reimbursement to a pharmacy is, at a minimum, matched by an equal potential increase in reimbursement.[4]

Notice of lower-cost alternatives

Under the bill, each contract between a health plan issuer and a pharmacy must 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.[5]

Time limits to obtain certain cancer drugs

The bill implements requirements regarding how quickly a covered person must receive covered orally administered prescription drugs used to treat cancer following the submission of a clean claim or prior authorization request.

A "clean claim" is 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 U.S. Food and Drug Administration.[6]

"Prior authorization" is 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.[7]

Under the bill, a health plan issuer must ensure that a covered person can obtain a covered orally administered prescription drug used to treat cancer within 72 hours following submission of a clean claim or prior authorization request to the issuer, notwithstanding the

[4] R.C. 3902.74(B).

[5] R.C. 3902.75.

[6] R.C. 3902.76.

[7] R.C. 3902.72(D).

continuing-law requirement that an issuer respond to a prior authorization request within ten calendar days for nonurgent care services. If the issuer is unable to do so by requiring the covered person to use an in-network pharmacy or dispensing physician, the issuer must cover the drug if purchased from an out-of-network pharmacy or dispensing physician to the same extent as it would if the drug were dispensed in-network.[8]

The health plan issuer must, within 24 hours of submission of a clean claim or prior authorization request for the drug, confirm receipt of the claim and notify the prescribing provider in writing of both of the following:

- Whether the drug is covered;
- 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 72 hours following the initial submission of the claim.[9]

Lastly, if it is likely that the drug will not be available to a covered person within 72 hours of the initial submission, the bill requires the issuer to notify the covered person that the covered person can use another pharmacy or dispensing physician to obtain the drug, including an out-of-network pharmacy or dispensing physician. The notification must be written in a clear, concise, and intelligible manner.[10]

Medicaid managed care organizations

The bill applies all of the above requirements to Medicaid managed care organizations, and, as applicable, to their pharmacy benefit managers. In doing so, some terminology is modified to match the Medicaid law, such as using "enrollee" instead of "covered person."[11]

Civil action

The bill permits any covered person, pharmacy, or dispensing physician affected by a violation of any of the above provisions by a health plan issuer or a Medicaid managed care organization, or any of their intermediaries, including a Medicaid managed care organization's pharmacy benefit manager, to bring a civil action against the issuer or the intermediary for compensatory damages and injunctive or other equitable relief.[12]

Pharmacy audits

Continuing law places certain requirements on auditing entities, which are persons or government entities that perform pharmacy audits. A pharmacy audit is a review of pharmacy

[8] R.C. 3902.76(B) and R.C. 1739.05, 1751.72, 3923.041, and 5160.34, not in the bill.

[9] R.C. 3902.76(C).

[10] R.C. 3902.76(D).

[11] R.C. 5167.124 to 5167.127.

[12] R.C. 3902.77 and 5167.128.

records, one purpose of which is to identify discrepancies in claims for payment for the provision of drugs or services.[13] The bill adds requirements regarding documentation and audit limits and amends a continuing requirement regarding the recoupments an auditing entity or payer may seek from a pharmacy in the case of an error.

Documentation and audit limits

The bill prohibits an auditing entity from penalizing a pharmacy based solely on the fact that all materials requested by the auditing entity are not available during an onsite audit. It also requires that a pharmacy have the opportunity to provide supplemental materials to an auditing entity after the completion of an onsite audit. These materials are subject to the same documentation standards as materials reviewed during the onsite audit. The auditing entity may not reject a document merely because the document is not an original and must accept documents sent via electronic or telephonic means.

Under the bill, an audit must be limited to the lesser of the following:

- 250 prescriptions;
- The number of prescriptions dispensed by a pharmacy in the 24-month period before the audit.[14]

Under the bill, a pharmacy is not required to pay any disputed recoupments resulting from an audit until after the audit's final disposition, including any relevant appeals or dispute processes. It also prohibits an auditing entity from being compensated based on its level or amounts of recoupments.[15]

Recoupment due to errors

Continuing law prohibits an auditing entity or payer from seeking to recoup from a pharmacy any amount that an audit identifies as resulting from clerical or recordkeeping errors in the absence of financial harm. However, this prohibition only applies when there is no indication that there was an error in the dispensing of a drug. Under existing law "error in the dispensing of a drug" includes, among other things, issuing incorrect directions; the bill restricts the aspect of the term *materially* incorrect directions.[16]

Fraud

Continuing law requires an auditing entity to give notice to a pharmacy when an audit will be performed on the premises of the pharmacy. And as stated under "**Recoupment due to errors**" above, it also prohibits an auditing entity or payer from seeking to recoup from a

[13] R.C. 3901.81.

[14] R.C. 3901.811(A)(5) and (6).

[15] R.C. 3902.811(C) and (D).

[16] R.C. 3901.811(A)(3).

pharmacy any amount that an audit identifies as resulting from clerical or recordkeeping errors in the absence of financial harm.[17]

Continuing law also requires an auditing entity to give a pharmacy 30 days to provide any additional information that is necessary to complete the preliminary audit report, deliver a preliminary audit report to the pharmacy within 60 days, and give a pharmacy at least 30 days to appeal a finding.[18]

None of these provisions applies in the case of fraud or other intentional or willful misrepresentation. The bill defines "fraud" as knowingly engaging in deception with the intent of personal enrichment or gain.[19]

Injunctive relief for pharmacies

The bill permits a pharmacy to seek injunctive relief against a payer or its contracted pharmacy benefit manager for violations of the pharmacy audit law by an auditing entity.[20]

Mail-order drugs

The bill prohibits a pharmacy from mailing 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, unless the patient voluntarily waives in writing the in-person consultation and elects to receive the dangerous drug via mail order.[21]

Definitions

"**Covered person**" means an individual covered by a health benefit plan.[22]

"**Health benefit plan**" means a policy, contract, or certificate offered by a health plan issuer to provide, arrange for, or pay for any of the costs of health care services. "Health benefit plan" does include certain specified types of limited coverage.[23]

"**Health plan issuer**" means an entity subject to the Ohio insurance laws that contracts or offers to contract to provide, arrange for, or pay for any of the costs of health care services under a health benefit plan. The term includes sickness and accident insurers, health insuring corporations, fraternal benefit societies, self-funded multiple employer welfare arrangements, and nonfederal, government health plans. "Health plan issuer" includes a third party

[17] R.C. 3901.811(A)(1) and (3).

[18] R.C. 3901.813(A), not in the bill.

[19] R.C. 3901.81 and 3901.811(B); R.C. 3901.813(B), not in the bill.

[20] R.C. 3902.811(E).

[21] R.C. 4729.66 and R.C. 4729.01, not in the bill.

[22] R.C. 3902.50.

[23] R.C. 3902.50.

administrator to the extent that the benefits it administers are subject to Ohio insurance laws. For the purposes of the bill, "health plan issuer" includes an auditing entity.[24]

HISTORY

Action	Date
Introduced	06-07-21

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[24] R.C. 3902.50 and 3902.72(C).