ARIZONA STATE SENATE
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TO: MEMBERS OF THE SENATE
APPROPRIATIONS COMMITTEE

DATE: February 19, 2024

SUBJECT: Strike everything amendment to S.B. 1164, relating to pharmacy benefits; coverage

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Purpose

Prohibits a pharmacy benefit manager (PBM) from limiting or excluding coverage of a prescription drug for any covered individual who is on a specific prescription drug and outlined conditions are met. Prescribes formulary change notification requirements and establishes a prescription coverage exemption determination process.

Background

The Department of Insurance and Financial Institutions (DIFI) regulates and monitors insurance companies and professionals operating in Arizona to protect the public and help ensure that these entities follow Arizona and federal law (Ariz. Const. art. 15 § 5). Beginning January 1, 2025, PBMs must apply and pay a fee to DIFI for a valid certificate of authority to operate as a PBM who performs services for a health plan subject to state jurisdiction (A.R.S. § 20-3333).

A *PBM* is a person, business or entity that, either directly or through an intermediary, manages the prescription drug coverage provided by a contracted insurer or other third-party payor, including the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to prescription drug coverage, contracting with network pharmacies and controlling the cost of covered prescription drugs (A.R.S. § 20-3321).

PBMs are charged with: 1) updating price and drug information for each list that the PBM maintains; 2) making the sources used to determine maximum allowable cost pricing available to each network pharmacy at the beginning of a contract or upon renewal; 3) establishing a process for network pharmacies to appeal its reimbursement for any drug subject to maximum allowable cost pricing; and 4) allowing a contracted pharmacy services organization to file an appeal of a drug on behalf of the organization's contracted pharmacies (A.R.S. § 20-3331).

If the outlined prohibition and requirements increase costs to the state employee health plan, there may be a fiscal impact to the state General Fund.

Provisions

PBM Prescription Drug Coverage

1. Prohibits a PBM, if the PBM enters into an agreement with a health care insurer (insurer) to provide PBM services, from limiting or excluding coverage of a prescription drug for any covered individual who is on a specific prescription drug, if:
   a) the drug was previously approved by the PBM or insurer for coverage for the covered individual; and
   b) the covered individual continues to be an enrollee of the insurer that the PBM has contracted with to provide PBM services.

2. Requires a PBM to continue coverage of a covered individual's prescription drug through the last day of the covered individual's plan year, if:
   a) the drug was previously approved by the PBM or insurer for coverage for the covered individual; and
   b) the covered individual continues to be an enrollee of the insurer that the PBM has contracted with to provide PBM services.

3. Prohibits the PBM, for the purposes of the above prohibition and requirement, from:
   a) limiting or reducing the maximum coverage of prescription drug benefits;
   b) increasing cost sharing for a covered prescription drug;
   c) moving a prescription drug to a more restrictive formulary tier; or
   d) removing a prescription drug from a formulary unless either:
      i. the U.S. Food and Drug Administration (FDA) revokes approval for or removes a prescription drug from the prescription drug market; or
      ii. the prescription drug manufacturer notifies the FDA of a manufacturing discontinuation or potential discontinuation.

4. Requires a PBM or insurer, if the PBM or insurer makes any formulary change during a plan year, to provide written notice of the formulary change for any prescription drug to each impacted covered individual and their prescribing health care provider at least 60 days before the change.

5. Allows a PBM or insurer to change a covered individual from a previously covered prescription drug only if the covered individual's prescribing health care provider provides written authorization for the change to the PBM or insurer.

6. Requires a PBM or insurer to provide written notice of the removal from, or an increase in cost-sharing for, a prescription drug on the drug formulary to each impacted covered individual and their prescribing health care provider at least 60 days before the end of the plan year, if the covered individual's prescribing provider did not previously approve a change in the prescription drug.

7. Requires the notice to set forth the process by which the covered individual's health care professional may request a prescription drug coverage exemption for the continued use of the nonformulary prescription drug and requires the exemption process to comply with the outlined prescription coverage exemption determination process.

Prescription Coverage Exemption Determination Process

8. Specifies that a prescription coverage exemption determination process is available to covered individuals and the prescribing health care professional to ensure continuity of care after a covered individual's renewal, as outlined.

9. Requires an insurer, PBM or utilization review agent that is contracted to provide PBM services for the insurer to provide a covered individual and prescribing health care professional with access to a clear and convenient process to request a coverage exemption determination.

10. Allows an insurer, PBM or utilization review agent to use its existing medical exceptions process to satisfy the prescription coverage exemption determination requirement, if the existing process is consistent with the prescribed requirements.

11. Requires an insurer, PBM or utilization review agent to respond to a coverage exemption determination request within 72 hours, unless exigent circumstances exist in which case the response must occur within 24 hours, as prescribed by federal law.

12. Requires an insurer, PBM or utilization review agent to approve a prescription drug coverage exemption for a covered individual who has been previously approved to receive the nonformulary prescription drug by the individual's current insurer or PBM and the prescribing health care provider continues to prescribe the drug for the individual's medical condition.

13. Requires an approval of a coverage exemption to be in writing and delivered to the covered individual and their treating health care provider.

14. Stipulates that, if the corporation authorizes a coverage exemption, the coverage exemption authorization is in effect until the end of the covered individual's plan year.

15. Requires a licensed pharmacist or medical director to make a denial of coverage in writing for an insurer's or PBM's denial of coverage for a nonformulary prescription drug.

16. Requires the written denial to contain an explanation of the denial that includes the medical or pharmacological reasons why the authorization was denied and a signature by the licensed pharmacist or medical director who made the decision to deny coverage.

17. Requires a corporation to:
    a) send a copy of the written denial to the covered individual's treating health care provider who requested the authorization;
    b) maintain copies of all written denials; and
    c) make the copies available to DIFI for inspection during regular business hours.

18. Allows a covered individual or their authorized representative to appeal any determination to deny a coverage exemption.

19. Requires the written notification to include the process in which a covered individual may appeal the determination.

Miscellaneous

20. Grants the Director of DIFI, if an insurer, PBM or utilization review agent violates the prescription drug coverage and exemption determination process requirements, the authority to impose a civil penalty against the insurer, PBM or utilization review agent.

21. Specifies that the outlined prescription drug coverage and exemption determination process requirements do not:
    a) prevent a health care provider from prescribing another prescription drug covered by the carrier, insurer or PBM, if the carrier, insurer or PBM is contracted to provide PBM services and the health care provider deems the prescription drug medically necessary for the covered individual; or

b) prevent an insurer or PBM from:
   i. adding a prescription drug to its formulary;
   ii. removing a prescription drug from its formulary, if the drug manufacturer has removed the drug for sale in the United States; or
   iii. making any formulary changes for patients who are not on a previously approved prescription drug.

22. Specifies that a policy that is issued or renewed by a disability insurer does not include a policy that provides limited benefit coverage.

23. Defines terms.

24. Applies the newly established drug coverage and exemption determination process requirements to contracts entered into, amended, extended or renewed beginning January 1, 2025.

25. Becomes effective on the general effective date.