ARIZONA STATE SENATE

Fifty-Fifth Legislature, First Regular Session

AMENDED

FACT SHEET FOR S.B. 1270

insurance; prescription drugs; step therapy

Purpose

Outlines requirements for health care insurers (insurers) that implement a step therapy protocol for prescription drugs. Requires insurers to provide a process for step therapy exemption requests and sets deadlines for request responses.

Background

The Department of Insurance and Financial Institutions (DIFI) regulates policies, certificates, evidences of coverage and contracts of insurance that are issued or delivered by insurers. Examples of *insurers* include disability insurers, group disability insurers, blanket disability insurers, health care services organizations, hospital service corporations, medical service corporations and hospital and medical service corporations (A.R.S. § 20-1379).

Certain insurers with a prescription drug benefit that uses a drug formulary as a component of the health care plan must provide covered individuals with a notice regarding the applicable drug formulary. The notice must include: 1) an explanation of what a drug formulary is; 2) how the insurer determines which prescription drugs are included or excluded; and 3) how often the insurer reviews the contents of the drug formulary. These insurers must develop and maintain a process by which health care professionals may request authorization for medically necessary nonformulary prescription drugs, unless the pharmacy benefit plan does not require authorization. The insurer must approve an alternative prescription drug for an individual when: 1) the equivalent prescription drug on the formulary has been ineffective in the treatment of the individual's disease or condition; or 2) the equivalent prescription drug on the formulary has caused an adverse or harmful reaction in the individual (A.R.S. §§ 20-841.05 and 20-1057.02).

When calculating a covered individual's contribution to any out-of-pocket maximum, deductible, copayment, coinsurance or other cost sharing requirement, an insurer that provides pharmacy benefits or a pharmacy benefit manager (PBM) must include any cost sharing amount paid by the individual for a prescription drug that is without a generic equivalent or a prescription drug that is with a generic equivalent where the enrollee has obtained access to the prescription drug through: 1) prior authorization; 2) a step therapy protocol; or 3) the insurer's exceptions and appeals process (A.R.S. § 20-1126).

There may be a fiscal impact to the state General Fund associated with this legislation due to a potential increase in state employee health insurance costs if current prescription drug claims affected by the state's step therapy protocol are eliminated due to prescribed exceptions.

Provisions

Clinical Review Criteria

1. Requires an insurer, PBM or utilization review agent (URA), when establishing a step therapy protocol, to use clinical review criteria based on clinical practice guidelines that:
   a) recommend prescription drugs to be taken in a specific sequence required by the step therapy protocol;
   b) are developed and endorsed by a multidisciplinary panel of experts that manages conflicts of interest among members of the writing and review groups by:
      i. requiring the members to disclose any potential conflict of interest with an entity and recuse themselves from voting if they have a conflict of interest; and
      ii. using a methodologist to work with writing and review groups to provide objectivity in data analysis and ranking of evidence through preparing evidence tables and facilitating consensus;
   c) are based on high-quality studies, research and medical practice;
   d) are created by an explicit and transparent process that:
      i. minimizes biases and conflicts of interest;
      ii. explains the relationship between treatment options and outcomes;
      iii. rates the quality of the evidence supporting recommendations; and
      iv. considers relevant patient subgroups and preferences; and
   e) are regularly updated, at least annually, through a review of new evidence and research and newly developed treatments.

2. Allows, if no clinical guidelines are developed and endorsed by a multidisciplinary panel of experts, an insurer, PBM or URA to use peer review publications to fulfill that requirement.

3. Requires URAs, when considering clinical review criteria to establish a step therapy protocol, to also consider the needs of atypical patient populations and diagnoses.

4. Directs each insurer, PBM and URA to annually certify to DIFI that the clinical review criteria used in their step therapy protocol meet the prescribed requirements.

5. Requires an insurer, PBM or URA to submit their clinical review criteria for DIFI approval upon request.

6. Specifies that an insurer is not required to establish a new entity to develop clinical review criteria used for a step therapy protocol.

7. Authorizes DIFI to require an insurer to submit an annual certification or clinical review criteria for a PBM or URA that acts on the insurer's behalf and holds both parties jointly responsible for any omissions, errors or other deficiencies included in an annual submission or certification.

8. Obligates an insurer to provide 15 days' advance notice to a PBM or URA of the certification or submission and permits a PBM or URA to submit a certification or submission independently of an insurer.

Step Therapy Exceptions

9. Entitles a patient and prescribing practitioner to have access to a clear and convenient process to request a step therapy exception, if prescription drug coverage for any medical condition is restricted through a step therapy protocol.

10. Allows an insurer, PBM or URA to use their existing medical exceptions process, if the process is consistent with prescribed step therapy protocol and exception request requirements.

11. Requires each insurer, health benefit plan, PBM and URA to make the process for a step therapy exception request, including a list of required information and documentation and relevant contact information, easily accessible on the entity's website

12. Requires an insurer, PBM or URA to grant a step therapy exception, if sufficient justification and supporting clinical documentation demonstrates that the:
    a) required prescription drug is contraindicated or will likely cause a serious reaction or physical or mental harm to the patient;
    b) required prescription drug is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen;
    c) patient has tried the required prescription drug while under the patient's current or previous health care plan, or another prescription drug in the same pharmacologic class with a similar side effect and efficacy profile or with the same mechanism of action, the patient's adherence during the trial was for a period of time sufficient to allow for a positive treatment outcome and the prescription drug was discontinued due to lack of efficacy or effectiveness, an adverse event or contraindication;
    d) required prescription drug is not in the best interest of the patient based on medical necessity because the drug is expected to cause specified negative impacts; or
    e) patient experienced a positive therapeutic outcome on a prescribed drug selected by the patient's health care provider for the medical condition under consideration while on the patient's current or previous health care plan.

13. Prohibits a health care provider from using a pharmaceutical sample to qualify a step therapy exception for a patient who remains stable on the drug.

14. Directs an insurer, PBM or URA, upon granting a step therapy exception, to authorize coverage for the prescription drug prescribed by the patient's health care provider if the drug is covered by the patient's health care plan.

15. Requires an insurer, PBM or URA to grant or deny a step therapy exception request within 72 hours, or within 24 hours if an exigent circumstance exists, after receiving the request.

16. Directs insurers, PBMs and URAs to notify a prescribing health care provider within 72 hours of receiving an incomplete exception request, or 24 hours in the case of an exigent circumstance, that additional information is required in order to grant or deny the request.

17. Deems a step therapy exception granted if an insurer, PBM or URA does not respond within the prescribed time period.

18. Allows an insured, enrollee or subscriber to appeal an adverse step therapy exception determination.

19. Specifies that the prescribed step therapy exception request requirements do not prevent:
    a) an insurer, PBM or URA from requiring a patient to try a generic equivalent before providing coverage for the equivalent branded prescription drug; or
    b) a health care provider from prescribing a prescription drug that is determined to be medically necessary.

Miscellaneous

20. Applies the step therapy requirements to:
    a) any state-regulated health care insurance plan issued or renewed on or after December 31, 2022, that provides prescription drug benefits and that includes coverage for a step therapy protocol;
    b) any policy, contract or evidence of coverage issued or renewed after December 31, 2022; and
    c) any contractor, agent or other entity that implements step therapy protocol coverage on behalf of a health care plan, PBM or URA.

21. Defines relevant terms.

22. Becomes effective on the general effective date.

Amendments Adopted by Committee

1. Allows DIFI to require the annual submittal of certifications and review criteria submissions by an insurer for a PBM or URA acting on their behalf and holds both parties responsible for any errors or insufficiencies included in a submission.

2. Requires an insurer to provide notice to a PBM or URA before submitting a certification or review criteria submission and permits a PBM or URA to file independently.

3. Outlines the procedure, notification and determination requirements for incomplete exception requests.

4. Outlines conditions that render a prescription drug required by a step therapy protocol to be not in the best interest of the patient.

5. Requires each insurer, PBM and URA to include contact information and a list of required documentation that pertains to exception requests on their websites.

6. Eliminates proposed language granting DIFI a rulemaking exemption.

7. Modifies and further defines relevant terms.

Amendments Adopted by Committee of the Whole

1. Clarifies that a patient may have tried a prescription drug in the same pharmacologic class with a similar side effect and efficacy profile as a drug requested for a step therapy exception.

2. Specifies that a patient's adherence during a drug trial must have provided enough time to allow for a positive treatment outcome.

Senate Action

HHS	2/3/21	DPA	8-0-0

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