ARIZONA STATE SENATE

Fifty-Fifth Legislature, First Regular Session

FACT SHEET FOR S.B. 1270

insurance; prescription drugs; step therapy

Purpose

Outlines requirements for health care insurers that implement a step therapy protocol for prescription drugs. Requires health care 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 health care insurers. Examples of *health care 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 health care 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 health care 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 health care 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, a health care insurer that provides pharmacy benefits or a pharmacy benefits 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 health care 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 a health care insurer, PBM or utilization review organization, 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;
      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; and
      iii. offering opportunities for public review and comments;
   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 continually updated 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, a health care insurer, PBM or utilization review organization to use peer review publications to fulfill that requirement.

3. Requires a utilization review agent, 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 health care insurer, PBM and utilization review organization to annually certify to DIFI that the clinical review criteria used in their step therapy protocol meet the prescribed requirements.

5. Requires a health care insurer, PBM or utilization review organization to submit their clinical review criteria for DIFI approval upon request.

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

Step Therapy Exceptions

7. 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.

8. Allows a health care insurer, PBM or utilization review organization to use their existing medical exceptions process, if the process is consistent with prescribed step therapy protocol and exception request requirements.

9. Requires each health care insurer, health benefit plan, PBM and utilization review organization to make the process for a step therapy exception request easily accessible on their website.

10. Requires a health care insurer, PBM or utilization review organization to grant a step therapy exception, if sufficient submitted evidence demonstrates that the:
    a) required prescription drug is contraindicated or will likely cause an adverse 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 or with the same mechanism of action, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect or an adverse event;
    d) required prescription drug is not in the best interest of the patient based on medical necessity; or
    e) patient remained stable 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.

11. 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.

12. Directs a health care insurer, PBM or utilization review organization, upon granting a step therapy exception, to authorize coverage for the prescription drug prescribed by the patient's health care provider.

13. Requires a health care insurer, PBM or utilization review organization to respond to a step therapy exception determination request after receiving all required documentation within 72 hours, or within 24 hours if an exigent circumstance exists.

14. Deems a step therapy exception granted if a health care insurer, PBM or utilization review organization does not respond within the required time period.

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

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

Miscellaneous

17. Applies the step therapy requirements to any health care plan issued or renewed on or after December 31, 2022, that provides prescription drug benefits and that includes coverage for a step therapy protocol.

18. Exempts DIFI from rulemaking requirements relating to step therapy protocol guidelines for one year.

19. Defines relevant terms.

20. Becomes effective on the general effective date.

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