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SB 1270: insurance; prescription drugs; step therapy
Sponsor: Senator Barto, LD 15
Committee on Health & Human Services

Overview

Outlines clinical review criteria and exception request requirements for health care insurers (insurers) that implement step therapy protocol for prescription drugs.

History

An *insurer* includes a disability insurer, group disability insurer, blanket disability insurer, health care services organization, hospital service corporation, medical service corporation or hospital, medical, dental and optometric service corporation (A.R.S. § 20-1379).

A *pharmacy benefit manager* (PBM) is a person, business or other entity that, pursuant to a contract or under an employment relationship with an insurer or third-party payer, either directly or through an intermediary manages the prescription drug coverage provided by the insurer or other third-party payor, including: 1) the processing and payment of claims for prescription drugs; 2) the performance of drug utilization review; 3) the processing of drug prior authorization requests; 4) the adjudication of appeals or grievances related to prescription drug coverage; 5) contracting with network pharmacies; and 6) controlling the cost of covered prescription drugs (A.R.S. § 20-3321).

Utilization review agent is defined as persons and entities that perform utilization review and includes any health care insurer whose utilization review plan includes the direct or indirect denial of requested medical or health care services or the denial of claims (A.R.S. § 20-2530).

Provisions

Clinical Review Criteria

1. Requires clinical review criteria that are used by an insurer, PBM or utilization review agent to establish a step therapy protocol based on clinical practice guidelines that:
   a) Recommend that the prescription drugs be taken in the 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 the members of the writing and review groups by:
      i. Requiring the members to disclose any potential conflict of interest with an entity, including an insurer or pharmaceutical manufacturer, and recuse themselves from voting if they have a conflict of interest; and
      ii. Using a methodologist to work with writing 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 meets specified requirements; and
   e) Are regularly updated at least once a year through a review of new evidence, research and newly developed treatments. (Sec. 1)

☐ Prop 105 (45 votes)	☐ Prop 108 (40 votes)	☐ Emergency (40 votes)	☐ Fiscal Note

2. Allows peer reviewed publications to be used if no clinical practice guidelines exist that meet the specified requirements. (Sec. 1)

3. Instructs a utilization review agent to consider the needs of atypical patient populations and diagnoses when considering clinical review criteria. (Sec. 1)

4. Requires each insurer, PBM and utilization review agent to:
   a) Annually certify to the Arizona Department of Insurance and Financial Institutions (DIFI) that the clinical review criteria used in the step therapy protocol meets the outlined requirements; and
   b) Submit the clinical review criteria for approval, on DIFI's request. (Sec. 1)

5. Allows DIFI to require an insurer to submit an annual certification or clinical review criteria submission for a PBM or utilization review agent that acts on behalf of the insurer.

6. Specifies that the insurer and the PBM or utilization review agent must both be held responsible for any errors, omissions, misstatements or misrepresentations in the annual certification or submission. (Sec. 1)

7. Requires an insurer to provide a PBM or utilization review agent at least 15 days' notice of the certification or submission. (Sec. 1)

8. Allows a PBM or utilization review agent to submit an independent certification or submission. (Sec. 1)

9. States that an insurer is not required to establish a new entity to develop clinical review criteria. (Sec. 1)

Step Therapy Exceptions

10. Mandates a patient and prescribing provider to have access to a clear and convenient process to request a step therapy exception if coverage of a prescription drug is restricted for use by an insurer, PBM or utilization review agent through the use of a step therapy protocol.
    a) Allows an insurer, PBM or utilization review agent to use its existing medical exceptions process to satisfy this requirement, if that process is consistent with statutory requirements. (Sec. 1)

11. Requires the medical exception process to:
    a) Be easily accessible on the insurer's, health benefit plan's, PBM's or utilization review agent's website;
    b) Include a list of the information and documentation required; and
    c) Include where and to whom the patient and prescribing provider must send the step therapy exception request. (Sec. 1)

12. Requires a step therapy exception request to be granted if sufficient justification and any necessary supporting clinical documentation are submitted to establish that:
    a) The required prescription drug is contraindicated or will likely cause a serious adverse reaction by or physical or mental harm to the patient;
    b) The required prescription drug is expected to be ineffective based on known clinical characteristics of the patient and the prescription drug regimen;
    c) The patient has tried the required prescription drug while under a current or previous health care plan, or another prescription drug in the same pharmacologic class with a similar efficacy and side effect profile;
    d) The required prescription drug is not in the best interest of the patient based on medical necessity because the patient's use of the prescription drug is expected to cause specified conditions; and

   e) The patient has experienced a positive therapeutic outcome on a prescribed drug selected by the patient's health care provider (provider). (Sec. 1)

13. Prohibits a provider from using a pharmaceutical sample for the purpose of qualifying for an exception to step therapy. (Sec. 1)
14. Requires an insurer, PBM and utilization review agent to authorize coverage for the prescribed prescription drug if it is covered by the patient's health care plan. (Sec. 1)
15. Requires an insurer, PBM and utilization review agent to grant or deny an exception request within 72 hours, or within 24 hours if an exigent circumstance exists, after receiving the request. (Sec. 1)
16. Instructs an insurer, PBM and utilization review agent to notify a prescribing provider within 72 hours of receiving an incomplete exception request, or within 24 hours if an exigent circumstance exists, that additional or clinically relevant information is required in order to approve or deny the exception request. (Sec. 1)
17. States that an exception request is granted if the prescribing provider does not receive a determination or request for additional information from an insurer, PBM or utilization review agent within the prescribed time period. (Sec. 1)
18. Allows an insured, enrollee or subscriber to appeal an adverse step therapy exception determination. (Sec. 1)
19. Stipulates that the step therapy exception request requirements do not prevent:
    a) An insurer, PBM or utilization review agent from requiring a patient to try an ab-rated generic equivalent before providing coverage for the equivalent branded prescription drug; and
    b) A provider from prescribing a prescription drug that is determined to be medically necessary. (Sec. 1)

Miscellaneous

20. Defines related terms. (Sec. 1)
21. Applies this act to:
    a) Any health care plan that is subject to state law regulating insurance, that provides prescription drug benefits and that includes coverage for step therapy protocol regardless of how that coverage is described; and
    b) A contractor, agent or similar entity that implements coverage for a step therapy protocol on behalf of a health care plan, including a PBM or utilization review agent. (Sec. 1)
22. Applies this act to any policy, contract or evidence of coverage delivered, issued for delivery or renewed on or after December 31, 2022. (Sec. 1)