REFERENCE TITLE: insurance; prescription drugs; step therapy

State of Arizona
Senate
Fifty-fifth Legislature
First Regular Session
2021

SB 1270

Introduced by
Senators Barto: Leach, Mesnard, Navarrete, Pace; Representative Cobb

AN ACT

AMENDING TITLE 20, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 30; RELATING TO PRESCRIPTION DRUGS.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 20, Arizona Revised Statutes, is amended by adding chapter 30, to read:

CHAPTER 30

STEP THERAPY

ARTICLE 1. GENERAL PROVISIONS

20-3601. Definitions

IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

1. "CLINICAL PRACTICE GUIDELINES" MEANS A SYSTEMATICALLY DEVELOPED STATEMENT TO ASSIST HEALTH CARE PROVIDERS AND PATIENTS IN MAKING DECISIONS ABOUT APPROPRIATE HEALTH CARE FOR SPECIFIC CLINICAL CIRCUMSTANCES AND CONDITIONS.

2. "CLINICAL REVIEW CRITERIA" MEANS THE WRITTEN SCREENING PROCEDURES, DECISION ABSTRACTS, CLINICAL PROTOCOLS AND PRACTICE GUIDELINES THAT ARE USED BY A HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION TO DETERMINE THE MEDICAL NECESSITY AND APPROPRIATENESS OF HEALTH CARE SERVICES.

3. "EXIGENT CIRCUMSTANCE" MEANS A SITUATION IN WHICH AN INSURED, ENROLLEE OR SUBSCRIBER IS EITHER:

(a) EXPERIENCING A HEALTH CONDITION THAT COULD SERIOUSLY JEOPARDIZE THE INSURED'S, ENROLLEE'S OR SUBSCRIBER'S LIFE, HEALTH OR ABILITY TO REGAIN MAXIMUM FUNCTION.

(b) UNDERGOING A CURRENT COURSE OF TREATMENT.

4. "HEALTH CARE INSURER" MEANS A DISABILITY INSURER, GROUP DISABILITY INSURER, BLANKET DISABILITY INSURER, HEALTH CARE SERVICES ORGANIZATION, HOSPITAL SERVICE CORPORATION, MEDICAL SERVICE CORPORATION OR HOSPITAL AND MEDICAL SERVICE CORPORATION.

5. "HEALTH CARE PLAN" MEANS A POLICY, CONTRACT OR EVIDENCE OF COVERAGE THAT A HEALTH CARE INSURER ISSUES TO AN INSURED, ENROLLEE OR SUBSCRIBER.

6. "MEDICALLY APPROPRIATE" MEANS APPROPRIATE UNDER THE APPLICABLE STANDARD OF CARE:

(a) TO IMPROVE OR PRESERVE HEALTH, LIFE OR FUNCTION.

(b) TO SLOW THE DETERIORATION OF HEALTH, LIFE OR FUNCTION.

(c) FOR THE EARLY SCREENING, PREVENTION, EVALUATION, DIAGNOSIS OR TREATMENT OF A DISEASE, CONDITION, ILLNESS OR INJURY.

7. "PHARMACEUTICAL SAMPLE" MEANS A UNIT OF A PRESCRIPTION DRUG THAT IS NOT INTENDED TO BE SOLD BUT IS INTENDED TO PROMOTE THE SALE OF THE PRESCRIPTION DRUG.

8. "PHARMACY BENEFITS MANAGER" MEANS A PERSON WHO ADMINISTERS PHARMACY BENEFITS FOR A HEALTH CARE INSURER.

9. "STEP THERAPY EXCEPTION" MEANS A STEP THERAPY PROTOCOL THAT IS OVERRIDDEN IN FAVOR OF IMMEDIATE COVERAGE OF A HEALTH CARE PROVIDER'S SELECTED PRESCRIPTION DRUG.

10. "STEP THERAPY PROTOCOL" MEANS A PROTOCOL OR PROGRAM THAT ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH PRESCRIPTION DRUGS THAT ARE FOR A SPECIFIED MEDICAL CONDITION AND THAT ARE MEDICALLY APPROPRIATE FOR A PARTICULAR PATIENT ARE COVERED BY A HEALTH CARE INSURER UNDER A HEALTH CARE PLAN.

11. "UTILIZATION REVIEW":

(a) MEANS A SYSTEM FOR REVIEWING THE APPROPRIATE AND EFFICIENT ALLOCATION OF INPATIENT HOSPITAL RESOURCES, INPATIENT MEDICAL SERVICES AND OUTPATIENT SURGERY SERVICES THAT ARE BEING GIVEN OR ARE PROPOSED TO BE GIVEN TO A PATIENT AND OF ANY MEDICAL, SURGICAL AND HEALTH CARE SERVICES OR CLAIMS FOR SERVICES THAT MAY BE COVERED BY A HEALTH CARE INSURER DEPENDING ON DETERMINABLE CONTINGENCIES, INCLUDING WITHOUT LIMITATION OUTPATIENT SERVICES, IN-OFFICE CONSULTATIONS WITH MEDICAL SPECIALISTS, SPECIALIZED DIAGNOSTIC TESTING, MENTAL HEALTH SERVICES, EMERGENCY CARE AND INPATIENT AND OUTPATIENT HOSPITAL SERVICES.

(b) DOES NOT INCLUDE ELECTIVE REQUESTS FOR THE CLARIFICATION OF COVERAGE.

12. "UTILIZATION REVIEW ORGANIZATION" MEANS AN ENTITY THAT CONDUCTS UTILIZATION REVIEW, OTHER THAN A PHARMACY BENEFITS MANAGER OR HEALTH CARE INSURER PERFORMING UTILIZATION REVIEW PURSUANT TO ITS OWN HEALTH CARE PLANS.

20-3602. Applicability

THIS ARTICLE APPLIES TO ANY HEALTH CARE PLAN THAT PROVIDES PRESCRIPTION DRUG BENEFITS AND THAT INCLUDES COVERAGE FOR A STEP THERAPY PROTOCOL REGARDLESS OF HOW THAT COVERAGE IS DESCRIBED.

20-3603. Clinical review criteria

A. CLINICAL REVIEW CRITERIA THAT ARE USED BY A HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION TO ESTABLISH A STEP THERAPY PROTOCOL SHALL BE BASED ON CLINICAL PRACTICE GUIDELINES THAT:

1. RECOMMEND THAT THE PRESCRIPTION DRUGS BE TAKEN IN THE SPECIFIC SEQUENCE REQUIRED BY THE STEP THERAPY PROTOCOL.

2. EXCEPT AS PROVIDED IN SUBSECTION B OF THIS SECTION, 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 DOING ALL OF THE FOLLOWING:

(a) REQUIRING THE MEMBERS TO DISCLOSE ANY POTENTIAL CONFLICT OF INTEREST WITH AN ENTITY, INCLUDING A HEALTH CARE INSURER OR PHARMACEUTICAL MANUFACTURER, AND RECUSE THEMSELVES FROM VOTING IF THEY HAVE A CONFLICT OF INTEREST.

(b) 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) OFFERING OPPORTUNITIES FOR PUBLIC REVIEW AND COMMENTS.

3. ARE BASED ON HIGH QUALITY STUDIES, RESEARCH AND MEDICAL PRACTICE.

4. ARE CREATED BY AN EXPLICIT AND TRANSPARENT PROCESS THAT DOES ALL OF THE FOLLOWING:

(a) MINIMIZES BIASES AND CONFLICTS OF INTEREST.

(b) EXPLAINS THE RELATIONSHIP BETWEEN TREATMENT OPTIONS AND OUTCOMES.

(c) RATES THE QUALITY OF THE EVIDENCE SUPPORTING RECOMMENDATIONS.

(d) CONSIDERS RELEVANT PATIENT SUBGROUPS AND PREFERENCES.

5. ARE CONTINUALLY UPDATED THROUGH A REVIEW OF NEW EVIDENCE AND RESEARCH AND NEWLY DEVELOPED TREATMENTS.

B. IF NO CLINICAL PRACTICE GUIDELINES EXIST THAT MEET THE REQUIREMENTS PRESCRIBED IN SUBSECTION A, PARAGRAPH 2 OF THIS SECTION, PEER REVIEWED PUBLICATIONS MAY BE USED.

C. WHEN CONSIDERING CLINICAL REVIEW CRITERIA TO ESTABLISH A STEP THERAPY PROTOCOL, A UTILIZATION REVIEW AGENT SHALL ALSO CONSIDER THE NEEDS OF ATYPICAL PATIENT POPULATIONS AND DIAGNOSES.

D. EACH HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER AND UTILIZATION REVIEW ORGANIZATION SHALL ANNUALLY CERTIFY TO THE DEPARTMENT THAT THE CLINICAL REVIEW CRITERIA USED IN THE INSURER'S, MANAGER'S OR ORGANIZATION'S STEP THERAPY PROTOCOL FOR PRESCRIPTION DRUGS MEET THE REQUIREMENTS PRESCRIBED BY THIS ARTICLE. ON THE DEPARTMENT'S REQUEST, THE HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION SHALL SUBMIT THE INSURER'S, MANAGER'S OR ORGANIZATION'S CLINICAL REVIEW CRITERIA FOR APPROVAL.

E. THIS SECTION DOES NOT REQUIRE A HEALTH CARE INSURER TO ESTABLISH A NEW ENTITY TO DEVELOP CLINICAL REVIEW CRITERIA USED FOR A STEP THERAPY PROTOCOL.

20-3604. Exceptions; process

A. NOTWITHSTANDING ANY OTHER LAW, IF COVERAGE OF A PRESCRIPTION DRUG FOR THE TREATMENT OF ANY MEDICAL CONDITION IS RESTRICTED FOR USE BY A HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION THROUGH THE USE OF A STEP THERAPY PROTOCOL, THE PATIENT AND PRESCRIBING PRACTITIONER SHALL HAVE ACCESS TO A CLEAR AND CONVENIENT PROCESS TO REQUEST A STEP THERAPY EXCEPTION DETERMINATION. A HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION MAY USE ITS EXISTING MEDICAL EXCEPTIONS PROCESS TO SATISFY THIS REQUIREMENT IF THAT PROCESS IS CONSISTENT WITH THE REQUIREMENTS PRESCRIBED IN SECTION 20-3603 AND THIS SECTION. THE PROCESS SHALL BE MADE EASILY ACCESSIBLE ON THE HEALTH CARE INSURER'S, HEALTH BENEFIT PLAN'S, PHARMACY BENEFITS MANAGER'S OR UTILIZATION REVIEW ORGANIZATION'S WEBSITE.

B. A STEP THERAPY EXCEPTION DETERMINATION REQUEST SHALL BE GRANTED IF SUFFICIENT EVIDENCE IS SUBMITTED TO ESTABLISH THAT ANY OF THE FOLLOWING APPLIES:

1. THE REQUIRED PRESCRIPTION DRUG IS CONTRAINDICATED OR WILL LIKELY CAUSE AN ADVERSE REACTION BY OR PHYSICAL OR MENTAL HARM TO THE PATIENT.

2. THE 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.

3. THE 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.

4. THE REQUIRED PRESCRIPTION DRUG IS NOT IN THE BEST INTEREST OF THE PATIENT BASED ON MEDICAL NECESSITY.

5. THE 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. A HEALTH CARE PROVIDER MAY NOT USE A PHARMACEUTICAL SAMPLE FOR THE PURPOSE OF QUALIFYING FOR AN EXCEPTION TO STEP THERAPY UNDER THIS PARAGRAPH.

C. ON GRANTING A STEP THERAPY EXCEPTION DETERMINATION, THE HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION SHALL AUTHORIZE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE PATIENT'S TREATING HEALTH CARE PROVIDER.

D. UNLESS AN EXIGENT CIRCUMSTANCE EXISTS, A HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION SHALL RESPOND TO A REQUEST FOR A STEP THERAPY EXCEPTION DETERMINATION WITHIN SEVENTY-TWO HOURS AFTER RECEIVING ALL DOCUMENTATION THE HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION REQUIRES AND DISCLOSES PURSUANT TO SUBSECTION A OF THIS SECTION. IF AN EXIGENT CIRCUMSTANCE EXISTS, THE HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION SHALL RESPOND TO THE REQUEST WITHIN TWENTY-FOUR HOURS AFTER RECEIVING ALL DOCUMENTATION THE HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION REQUIRES AND DISCLOSES PURSUANT TO SUBSECTION A OF THIS SECTION. IF THE HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION DOES NOT RESPOND WITHIN THE TIME PERIOD PRESCRIBED BY THIS SUBSECTION, THE STEP THERAPY EXCEPTION IS DEEMED GRANTED.

E. AN INSURED, ENROLLEE OR SUBSCRIBER MAY APPEAL AN ADVERSE STEP THERAPY EXCEPTION DETERMINATION.

F. THIS SECTION DOES NOT PREVENT EITHER OF THE FOLLOWING:

1. A HEALTH CARE INSURER, PHARMACY BENEFITS MANAGER OR UTILIZATION REVIEW ORGANIZATION FROM REQUIRING A PATIENT TO TRY A GENERIC EQUIVALENT BEFORE PROVIDING COVERAGE FOR THE EQUIVALENT BRANDED PRESCRIPTION DRUG.

2. A HEALTH CARE PROVIDER FROM PRESCRIBING A PRESCRIPTION DRUG THAT IS DETERMINED TO BE MEDICALLY APPROPRIATE.

Sec. 2. Department of insurance and financial institutions; rulemaking exemption

For the purposes of this act, the department of insurance and financial institutions is exempt from the rulemaking requirements of title 41, chapter 6, Arizona Revised Statutes, for one year after the effective date of this act.

Sec. 3. Applicability

This act applies to any policy, contract or evidence of coverage delivered, issued for delivery or renewed on or after December 31, 2022.