

Senate Engrossed

insurance; prescription drugs; step therapy

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

CHAPTER 431
SENATE BILL 1270

AN ACT

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

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

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

4 CHAPTER 30
5 STEP THERAPY

6 ARTICLE 1. GENERAL PROVISIONS

7 20-3601. Definitions

8 IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

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

18 3. "EXIGENT CIRCUMSTANCE" MEANS THE ACTION OF A HEALTH CARE
19 INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT ON A STEP
20 THERAPY PROTOCOL EXCEPTION REQUEST WITHIN THE APPLICATION OF THE TIME
21 PERIODS FOR MAKING A NONEXPEDITED DECISION, AS DETERMINED AND DOCUMENTED
22 BY THE PRESCRIBING PROVIDER, COULD SERIOUSLY JEOPARDIZE THE INSURED'S,
23 ENROLLEE'S OR SUBSCRIBER'S LIFE, HEALTH OR ABILITY TO REGAIN MAXIMUM
24 FUNCTION OR CAUSE A SIGNIFICANT NEGATIVE CHANGE IN THE PATIENT'S MEDICAL
25 CONDITION.

26 4. "HEALTH CARE INSURER" HAS THE SAME MEANING PRESCRIBED IN SECTION
27 20-2501.

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

31 6. "MEDICALLY NECESSARY" MEANS, WITH RESPECT TO A PRESCRIPTION
32 DRUG, APPROPRIATE UNDER THE APPLICABLE STANDARD OF CARE:

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

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

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

37 7. "METHODOLOGIST" MEANS A PERSON THAT MANAGES RESEARCH DESIGN FOR
38 THE PURPOSE OF ACCURATE AND UNBIASED DATA COLLECTION AND THAT HAS
39 EXPERIENCE TESTING QUESTIONS THAT ARE GERMANE TO THE SUBJECT OF THE
40 RESEARCH.

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

44 9. "PHARMACY BENEFIT MANAGER" HAS THE SAME MEANING PRESCRIBED IN
45 SECTION 20-3321.

1 10. "SERIOUS ADVERSE REACTION":
2 (a) MEANS AN ADVERSE EVENT OR SUSPECTED ADVERSE REACTION IF, IN THE
3 VIEW OF EITHER THE INVESTIGATOR OR SPONSOR, THE EVENT OR REACTION RESULTS
4 IN ANY OF THE FOLLOWING OUTCOMES:
5 (i) DEATH.
6 (ii) A LIFE-THREATENING ADVERSE EVENT.
7 (iii) INPATIENT HOSPITALIZATION OR PROLONGING EXISTING
8 HOSPITALIZATION.
9 (iv) A PERSISTENT OR SIGNIFICANT INCAPACITY OR SUBSTANTIAL
10 DISRUPTION OF THE ABILITY TO CONDUCT NORMAL LIFE FUNCTIONS.
11 (v) A CONGENITAL ANOMALY OR BIRTH DEFECT.
12 (b) INCLUDES AN EVENT OR REACTION THAT MIGHT NOT RESULT IN DEATH,
13 BE LIFE THREATENING OR REQUIRE HOSPITALIZATION BUT, BASED ON APPROPRIATE
14 MEDICAL JUDGMENT, COULD JEOPARDIZE THE PATIENT'S HEALTH OR MEDICAL
15 SITUATION BY REQUIRING MEDICAL OR SURGICAL INTERVENTION TO PREVENT AT
16 LEAST ONE OF THE OUTCOMES LISTED IN SUBDIVISION (a) OF THIS PARAGRAPH.
17 11. "STEP THERAPY EXCEPTION" MEANS A STEP THERAPY PROTOCOL THAT IS
18 OVERRIDDEN IN FAVOR OF IMMEDIATE COVERAGE OF A HEALTH CARE PROVIDER'S
19 SELECTED PRESCRIPTION DRUG.
20 12. "STEP THERAPY PROTOCOL" MEANS A PROTOCOL OR PROGRAM THAT
21 ESTABLISHES THE SPECIFIC SEQUENCE IN WHICH PRESCRIPTION DRUGS THAT ARE FOR
22 A SPECIFIED MEDICAL CONDITION AND THAT ARE MEDICALLY NECESSARY FOR A
23 PARTICULAR PATIENT ARE COVERED BY A HEALTH CARE INSURER UNDER A HEALTH
24 CARE PLAN.
25 13. "UTILIZATION REVIEW" HAS THE SAME MEANING PRESCRIBED IN SECTION
26 20-2501.
27 14. "UTILIZATION REVIEW AGENT" HAS THE SAME MEANING PRESCRIBED IN
28 SECTION 20-2530.
29 20-3602. Applicability
30 THIS ARTICLE APPLIES TO:
31 1. ANY HEALTH CARE PLAN THAT IS SUBJECT TO STATE LAW REGULATING
32 INSURANCE, THAT PROVIDES PRESCRIPTION DRUG BENEFITS AND THAT INCLUDES
33 COVERAGE FOR A STEP THERAPY PROTOCOL REGARDLESS OF HOW THAT COVERAGE IS
34 DESCRIBED.
35 2. A CONTRACTOR, AGENT OR SIMILAR ENTITY THAT IMPLEMENTS COVERAGE
36 FOR A STEP THERAPY PROTOCOL ON BEHALF OF A HEALTH CARE PLAN, INCLUDING A
37 PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT.
38 20-3603. Clinical review criteria
39 A. CLINICAL REVIEW CRITERIA THAT ARE USED BY A HEALTH CARE INSURER,
40 PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT TO ESTABLISH A STEP
41 THERAPY PROTOCOL SHALL BE BASED ON CLINICAL PRACTICE GUIDELINES THAT:
42 1. RECOMMEND THAT THE PRESCRIPTION DRUGS BE TAKEN IN THE SPECIFIC
43 SEQUENCE REQUIRED BY THE STEP THERAPY PROTOCOL.
44 2. EXCEPT AS PROVIDED IN SUBSECTION B OF THIS SECTION, ARE
45 DEVELOPED AND ENDORSED BY A MULTIDISCIPLINARY PANEL OF EXPERTS THAT

1 MANAGES CONFLICTS OF INTEREST AMONG THE MEMBERS OF THE WRITING AND REVIEW
2 GROUPS BY DOING BOTH OF THE FOLLOWING:

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

7 (b) USING A METHODOLOGIST TO WORK WITH WRITING GROUPS TO PROVIDE
8 OBJECTIVITY IN DATA ANALYSIS AND RANKING OF EVIDENCE THROUGH PREPARING
9 EVIDENCE TABLES AND FACILITATING CONSENSUS.

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

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

14 (a) MINIMIZES BIASES AND CONFLICTS OF INTEREST.

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

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

18 (d) CONSIDERS RELEVANT PATIENT SUBGROUPS AND PREFERENCES.

19 5. ARE REGULARLY UPDATED AT LEAST ONCE A YEAR THROUGH A REVIEW OF
20 NEW EVIDENCE AND RESEARCH AND NEWLY DEVELOPED TREATMENTS.

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

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

27 D. EACH HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER AND
28 UTILIZATION REVIEW AGENT SHALL ANNUALLY CERTIFY TO THE DEPARTMENT THAT THE
29 CLINICAL REVIEW CRITERIA USED IN THE INSURER'S, MANAGER'S OR AGENT'S STEP
30 THERAPY PROTOCOL FOR PRESCRIPTION DRUGS MEET THE REQUIREMENTS PRESCRIBED
31 BY THIS ARTICLE. ON THE DEPARTMENT'S REQUEST, THE HEALTH CARE INSURER,
32 PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT SHALL SUBMIT THE
33 INSURER'S, MANAGER'S OR AGENT'S CLINICAL REVIEW CRITERIA FOR APPROVAL.
34 THE DEPARTMENT MAY REQUIRE A HEALTH CARE INSURER TO SUBMIT AN ANNUAL
35 CERTIFICATION OR CLINICAL REVIEW CRITERIA SUBMISSION FOR A PHARMACY
36 BENEFIT MANAGER OR UTILIZATION REVIEW AGENT THAT ACTS ON BEHALF OF THE
37 HEALTH CARE INSURER, AND THE HEALTH CARE INSURER AND THE PHARMACY BENEFIT
38 MANAGER OR UTILIZATION REVIEW AGENT SHALL BE HELD JOINTLY RESPONSIBLE FOR
39 ANY ERRORS, OMISSIONS, MISSTATEMENTS OR MISREPRESENTATIONS IN THAT ANNUAL
40 CERTIFICATION OR SUBMISSION. A HEALTH CARE INSURER THAT SUBMITS AN ANNUAL
41 CERTIFICATION OR CLINICAL REVIEW CRITERIA SUBMISSION ON BEHALF OF THE
42 HEALTH CARE INSURER'S PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT
43 SHALL PROVIDE THE PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT AT
44 LEAST FIFTEEN DAYS' ADVANCE NOTICE OF THE CERTIFICATION OR SUBMISSION, AND
45 THE PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT MAY SUBMIT AN

1 INDEPENDENT CERTIFICATION OR SUBMISSION, IN LIEU OF HAVING THE HEALTH CARE
2 INSURER MAKE THE CERTIFICATION OR SUBMISSION ON THE PHARMACY BENEFIT
3 MANAGER'S OR UTILIZATION REVIEW AGENT'S BEHALF.

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

7 20-3604. Exceptions; process

8 A. NOTWITHSTANDING ANY OTHER LAW, IF COVERAGE OF A PRESCRIPTION
9 DRUG FOR THE TREATMENT OF ANY MEDICAL CONDITION IS RESTRICTED FOR USE BY A
10 HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT
11 THROUGH THE USE OF A STEP THERAPY PROTOCOL, THE PATIENT AND PRESCRIBING
12 PROVIDER SHALL HAVE ACCESS TO A CLEAR AND CONVENIENT PROCESS TO REQUEST A
13 STEP THERAPY EXCEPTION DETERMINATION. A HEALTH CARE INSURER, PHARMACY
14 BENEFIT MANAGER OR UTILIZATION REVIEW AGENT MAY USE ITS EXISTING MEDICAL
15 EXCEPTIONS PROCESS TO SATISFY THIS REQUIREMENT IF THAT PROCESS IS
16 CONSISTENT WITH THE REQUIREMENTS PRESCRIBED IN SECTION 20-3603 AND THIS
17 SECTION. THE PROCESS SHALL BE MADE EASILY ACCESSIBLE ON THE HEALTH CARE
18 INSURER'S, HEALTH BENEFIT PLAN'S, PHARMACY BENEFIT MANAGER'S OR
19 UTILIZATION REVIEW AGENT'S WEBSITE AND SHALL INCLUDE A LIST OF THE
20 INFORMATION AND DOCUMENTATION THE HEALTH CARE INSURER, PHARMACY BENEFIT
21 MANAGER OR UTILIZATION REVIEW AGENT REQUIRES AND WHERE AND TO WHOM THE
22 PATIENT AND PRESCRIBING PROVIDER MUST SEND THE STEP THERAPY EXCEPTION
23 REQUEST.

24 B. A STEP THERAPY EXCEPTION REQUEST SHALL BE GRANTED IF SUFFICIENT
25 JUSTIFICATION AND ANY NECESSARY SUPPORTING CLINICAL DOCUMENTATION ARE
26 SUBMITTED TO ESTABLISH THAT ANY OF THE FOLLOWING APPLIES:

27 1. THE PRESCRIPTION DRUG REQUIRED BY THE STEP THERAPY PROTOCOL IS
28 CONTRAINDICATED OR WILL LIKELY CAUSE A SERIOUS ADVERSE REACTION BY OR
29 PHYSICAL OR MENTAL HARM TO THE PATIENT.

30 2. THE PRESCRIPTION DRUG REQUIRED BY THE STEP THERAPY PROTOCOL IS
31 EXPECTED TO BE INEFFECTIVE BASED ON THE KNOWN CLINICAL CHARACTERISTICS OF
32 THE PATIENT AND THE KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG
33 REGIMEN.

34 3. THE PATIENT HAS TRIED THE PRESCRIPTION DRUG REQUIRED BY THE STEP
35 THERAPY PROTOCOL WHILE UNDER THE PATIENT'S CURRENT OR PREVIOUS HEALTH CARE
36 PLAN, OR ANOTHER PRESCRIPTION DRUG IN THE SAME PHARMACOLOGIC CLASS WITH A
37 SIMILAR EFFICACY AND SIDE EFFECT PROFILE OR WITH THE SAME MECHANISM OF
38 ACTION, THE PATIENT'S ADHERENCE DURING THE TRIAL WAS FOR A PERIOD OF TIME
39 SUFFICIENT TO ALLOW FOR A POSITIVE TREATMENT OUTCOME AND THE PRESCRIPTION
40 DRUG WAS DISCONTINUED DUE TO LACK OF EFFICACY OR EFFECTIVENESS, AN ADVERSE
41 EVENT OR CONTRAINDICATION.

42 4. THE PRESCRIPTION DRUG REQUIRED BY THE STEP THERAPY PROTOCOL IS
43 NOT IN THE BEST INTEREST OF THE PATIENT BASED ON MEDICAL NECESSITY BECAUSE
44 THE PATIENT'S USE OF THE PRESCRIPTION DRUG IS EXPECTED TO CAUSE ANY OF THE
45 FOLLOWING:

1 (a) A BARRIER TO THE PATIENT'S ADHERENCE TO OR COMPLIANCE WITH THE
2 PATIENT'S PLAN OF CARE.

3 (b) A NEGATIVE IMPACT ON THE PATIENT'S COMORBID CONDITIONS.

4 (c) A CLINICALLY PREDICTABLE NEGATIVE DRUG INTERACTION.

5 (d) A DECREASE IN THE PATIENT'S ABILITY TO ACHIEVE OR MAINTAIN A
6 REASONABLY FUNCTIONAL ABILITY IN PERFORMING DAILY ACTIVITIES FOR WHICH THE
7 PATIENT HAS EXPERIENCED A POSITIVE THERAPEUTIC OUTCOME.

8 5. THE PATIENT HAS EXPERIENCED A POSITIVE THERAPEUTIC OUTCOME ON A
9 PRESCRIBED DRUG SELECTED BY THE PATIENT'S HEALTH CARE PROVIDER FOR THE
10 MEDICAL CONDITION UNDER CONSIDERATION WHILE ON THE PATIENT'S CURRENT OR
11 PREVIOUS HEALTH CARE PLAN. A HEALTH CARE PROVIDER MAY NOT USE A
12 PHARMACEUTICAL SAMPLE FOR THE PURPOSE OF QUALIFYING FOR AN EXCEPTION TO
13 STEP THERAPY UNDER THIS PARAGRAPH.

14 C. ON GRANTING A STEP THERAPY EXCEPTION DETERMINATION, THE HEALTH
15 CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT SHALL
16 AUTHORIZE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE PATIENT'S
17 TREATING HEALTH CARE PROVIDER IF THE PRESCRIPTION DRUG IS COVERED BY THE
18 PATIENT'S HEALTH CARE PLAN.

19 D. THE HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION
20 REVIEW AGENT SHALL GRANT OR DENY A STEP THERAPY EXCEPTION REQUEST WITHIN
21 SEVENTY-TWO HOURS AFTER RECEIVING THE REQUEST. IN A CASE IN WHICH AN
22 EXIGENT CIRCUMSTANCE EXISTS, THE HEALTH CARE INSURER, PHARMACY BENEFIT
23 MANAGER OR UTILIZATION REVIEW AGENT SHALL GRANT OR DENY THE STEP THERAPY
24 EXCEPTION REQUEST WITHIN TWENTY-FOUR HOURS AFTER RECEIVING THE REQUEST.
25 IF THE STEP THERAPY EXCEPTION REQUEST IS INCOMPLETE OR ADDITIONAL
26 CLINICALLY RELEVANT INFORMATION IS REQUIRED, THE HEALTH CARE INSURER,
27 PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT SHALL NOTIFY THE
28 PRESCRIBING PROVIDER WITHIN SEVENTY-TWO HOURS AFTER RECEIVING THE REQUEST,
29 OR WITHIN TWENTY-FOUR HOURS IF AN EXIGENT CIRCUMSTANCE EXISTS, THAT
30 ADDITIONAL OR CLINICALLY RELEVANT INFORMATION IS REQUIRED IN ORDER TO
31 APPROVE OR DENY THE STEP THERAPY EXCEPTION REQUEST PURSUANT TO THE
32 REQUIREMENTS OUTLINED IN SUBSECTION A OF THIS SECTION. THE HEALTH CARE
33 INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT SHALL GRANT
34 OR DENY THE STEP THERAPY EXCEPTION REQUEST WITHIN SEVENTY-TWO HOURS AFTER
35 RECEIVING THE REQUESTED ADDITIONAL OR CLINICALLY RELEVANT INFORMATION, OR
36 WITHIN TWENTY-FOUR HOURS IF AN EXIGENT CIRCUMSTANCE EXISTS. IF THE
37 PRESCRIBING PROVIDER DOES NOT RECEIVE A DETERMINATION OR REQUEST FOR
38 ADDITIONAL OR CLINICALLY RELEVANT INFORMATION FROM THE HEALTH CARE
39 INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION REVIEW AGENT WITHIN THE
40 TIME PERIOD PRESCRIBED BY THIS SUBSECTION, THE EXCEPTION IS DEEMED
41 GRANTED.

42 E. AN INSURED, ENROLLEE OR SUBSCRIBER MAY APPEAL AN ADVERSE STEP
43 THERAPY EXCEPTION DETERMINATION AS PRESCRIBED IN CHAPTER 15, ARTICLE 2 OF
44 THIS TITLE.

1 F. THIS SECTION DOES NOT PREVENT EITHER OF THE FOLLOWING:
2 1. A HEALTH CARE INSURER, PHARMACY BENEFIT MANAGER OR UTILIZATION
3 REVIEW AGENT FROM REQUIRING A PATIENT TO TRY AN AB-RATED GENERIC
4 EQUIVALENT BEFORE PROVIDING COVERAGE FOR THE EQUIVALENT BRANDED
5 PRESCRIPTION DRUG.
6 2. A HEALTH CARE PROVIDER FROM PRESCRIBING A PRESCRIPTION DRUG THAT
7 IS DETERMINED TO BE MEDICALLY NECESSARY.
8 Sec. 2. Applicability
9 This act applies to any policy, contract or evidence of coverage
10 delivered, issued for delivery or renewed on or after December 31, 2022.

APPROVED BY THE GOVERNOR JULY 9, 2021.

FILED IN THE OFFICE OF THE SECRETARY OF STATE JULY 9, 2021.