

House Bill 519

By: Representatives Cooper of the 43rd, Broadrick of the 4th, Houston of the 170th, Hatchett of the 150th, and Taylor of the 173rd

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to
2 insurance generally, so as to require health benefit plans to utilize certain clinical review
3 criteria to establish step therapy protocols; to provide for a step therapy override
4 determination process; to provide for definitions; to provide for statutory construction; to
5 provide for rules and regulations; to provide for applicability; to provide for related matters;
6 to repeal conflicting laws; and for other purposes.

7 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

8 **SECTION 1.**

9 Chapter 24 of Title 33 of the Official Code of Georgia Annotated, relating to insurance
10 generally, is amended by adding a new Code section to read as follows:

11 "33-24-59.21.

12 (a) As used in this Code section, the term:

13 (1) 'Clinical practice guidelines' means a systematically developed statement to assist
14 practitioner and patient decisions about appropriate health care for specific clinical
15 circumstances and conditions.

16 (2) 'Clinical review criteria' means the written screening procedures, decision abstracts,
17 clinical protocols, and practice guidelines used by a health benefit plan or private review
18 agent to determine the medical necessity and appropriateness of health care services.

19 (3) 'Health benefit plan' means any hospital, health, or medical expense insurance policy;
20 hospital or medical service contract; employee welfare benefit plan; contract or
21 agreement with a health maintenance organization; subscriber contract or agreement;
22 contract or agreement with a preferred provider organization; accident and sickness
23 insurance benefit plan; or other insurance contract under any other name. The term shall
24 include any health insurance plan established under Article 1 of Chapter 18 of Title 45
25 and under Article 7 of Chapter 4 of Title 49, the 'Georgia Medical Assistance Act of
26 1977.'

27 (4) 'Practitioner' means a physician, dentist, podiatrist, or optometrist and shall include
28 any other person licensed under the laws of this state to use, mix, prepare, dispense,
29 prescribe, and administer drugs in connection with medical treatment for individuals to
30 the extent provided by the laws of this state.

31 (5) 'Private review agent' means an entity conducting a utilization review in a manner
32 similar to Chapter 46 of this title.

33 (6) 'Step therapy override determination' means a determination as to whether a step
34 therapy protocol should apply in a particular situation or whether the step therapy
35 protocol should be overridden in favor of immediate coverage of the prescribing
36 practitioner's selected prescription drug. This determination is based on a review of the
37 patient's or prescribing practitioner's request for an override along with supporting
38 rationale and documentation.

39 (7) 'Step therapy protocol' means a protocol or program that establishes the specific
40 sequence in which prescription drugs for a specified medical condition are medically
41 appropriate as determined by a prescribing practitioner for a particular patient, including
42 self administered and physician administered drugs, and are covered by an insurer or
43 health benefit plan.

44 (8) 'Utilization review' means a system conducted by an entity other than an insurer or
45 health plan performing a review for its own benefit for reviewing the appropriate and
46 efficient allocation of health care resources and services given or proposed to be given
47 to a patient or group of patients. The term can include, but is not limited to, peer to peer
48 review by a licensed practitioner in the same specialty as the practitioner whose services
49 are being reviewed.

50 (b) Clinical review criteria used to establish a step therapy protocol shall be based on
51 clinical practice guidelines that:

52 (1) Recommend that the prescription drugs be taken in the specific sequence required by
53 the step therapy protocol;

54 (2) Are developed and endorsed by an independent, multidisciplinary panel of experts
55 not affiliated with a health benefit plan or private review agent;

56 (3) Are based on high-quality studies, research, and medical practice;

57 (4) Are created by an explicit and transparent process that:

58 (A) Minimizes biases and conflicts of interest;

59 (B) Explains the relationship between treatment options and outcomes;

60 (C) Rates the quality of the evidence supporting recommendations; and

61 (D) Considers relevant patient subgroups and preferences; and

62 (5) Are continually updated through a review of new evidence and research.

63 (c) When coverage of a prescription drug for the treatment of any medical condition is
64 restricted for use by a health benefit plan or private review agent through the use of a step
65 therapy protocol, the patient and prescribing practitioner shall have access to a clear and
66 convenient process to request a step therapy override determination. A health benefit plan
67 or private review agent may use its existing medical exceptions process to satisfy this
68 requirement. The process shall be made easily accessible on the health benefit plan's or
69 private review agent's website.

70 (d) A step therapy override determination request shall be granted by a health benefit plan
71 or private review agent if:

72 (1) The required prescription drug is contraindicated or will likely cause an adverse
73 reaction or physical or mental harm to the patient;

74 (2) The required prescription drug is expected to be ineffective based on the known
75 relevant physical or mental characteristics of the patient and the known characteristics of
76 the prescription drug regimen;

77 (3) The patient has tried the required prescription drug while under his or her current or
78 previous health insurance or health benefit plan or another prescription drug in the same
79 pharmacologic class or with the same mechanism of action and such prescription drug
80 was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse
81 event;

82 (4) The required prescription drug is not in the best interest of the patient, based on
83 medical appropriateness; or

84 (5) The patient is stable on a prescription drug selected by his or her practitioner for the
85 medical condition under consideration.

86 (e) A health benefit plan or private review agent shall grant or deny a step therapy override
87 determination request or appeal of a step therapy override determination within:

88 (1) Twenty-four hours in an urgent health care situation; and

89 (2) Seventy-two hours in a nonurgent health care situation.

90 The Commissioner shall establish criteria for use in determining when a health care
91 situation is deemed urgent or nonurgent.

92 (f) Upon the granting of a step therapy override determination, the health benefit plan or
93 private review agent shall authorize coverage for the prescription drug prescribed by the
94 patient's practitioner, provided that such prescription drug is a covered prescription drug
95 under the patient's health benefit plan.

96 (g) This Code section shall not be construed to prevent:

97 (1) A health benefit plan or private review agent from requiring a patient to try an
98 AB-rated generic equivalent prior to providing coverage for the equivalent branded
99 prescription drug;

100 (2) A health benefit plan or private review agent from requiring a patient to try an
101 interchangeable biological product prior to providing coverage for the biological product;
102 or

103 (3) A practitioner from prescribing a prescription drug that is determined by such
104 practitioner to be medically appropriate.

105 (h) This Code section shall not be construed to impact a health benefit plan's ability to
106 substitute a generic drug for a brand name drug.

107 (i) The Commissioner shall adopt rules and regulations to implement the provisions of this
108 Code section.

109 (j) This Code section shall only apply to health benefit plans delivered, issued for delivery,
110 or renewed on or after July 1, 2017."

111 **SECTION 2.**

112 All laws and parts of laws in conflict with this Act are repealed.