

WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

House Bill 4040

BY DELEGATES KELLY, ROHRBACH, COOPER, FRICH
SOBONYA, BORDER, FAIRCLOTH, ATKINSON, PERDUE,
PERRY AND WAXMAN

[Introduced January 18, 2016;
referred to the Committee on Health and Human
Resources.]

1 A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article,
 2 designated §33-16I-1, §33-16I-2, §33-16I-3 and §33-16I-4, all relating to regulating step
 3 therapy protocols in health benefit plans which provide prescription drug benefits.

Be it enacted by the Legislature of West Virginia:

1 That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new
 2 article, designated §33-16I-1, §33-16I-2, §33-16I-3 and §33-16I-4, all and to read as follows:

ARTICLE 16I: REGULATION OF STEP THERAPY PROTOCOLS.

§33-16I-1. Legislative findings.

1 The legislature hereby finds and declares that:

2 (1) Health benefit plans are increasingly making use of step therapy protocols under which
 3 patients are required to try one or more prescription drugs before coverage is provided for a drug
 4 selected by the patient's health care provider.

5 (2) The legislature further finds that, in some cases, requiring a patient to follow a step
 6 therapy protocol may have adverse and even dangerous consequences for the patient who may
 7 not realize a benefit from taking a prescription drug or may suffer harm from taking an
 8 inappropriate drug.

9 (3) The legislature further finds that, without uniform policies in the state for step therapy
 10 protocols, patients may not receive the best and most appropriate treatment.

11 (4) The legislature further finds that it is imperative that step therapy protocols in the state
 12 preserve the health care provider's right to make treatment decisions in the best interest of the
 13 patient.

14 (5) Therefore, the legislature declares it a matter of public interest that patients be exempt
 15 from step therapy protocols when inappropriate or otherwise not in the best interest of the patients
 16 and that patients have access to a fair and expeditious process for requesting an exception to a
 17 step therapy protocol when appropriate.

§33-16I-2. Definitions.

1 As used in this article:

2 (1) "Health benefit plan" means a policy, contract, certificate or agreement entered into,
3 offered or issued by a health plan issuer to provide, deliver, arrange for, pay for, or reimburse any
4 of the costs of health care services.

5 (2) "Health plan issuer" or "issuer" means an entity required to be licensed under this
6 chapter that contracts, or offers to contract to provide, deliver, arrange for, pay for, or reimburse
7 any of the costs of health care services under a health benefit plan, including accident and
8 sickness insurers, nonprofit hospital service corporations, medical service corporations and
9 dental service organizations, prepaid limited health service organizations, health maintenance
10 organizations, preferred provider organizations, provider sponsored network and government
11 payers, including but not limited to Medicaid, Medicare and the public employees insurance
12 agency, and any pharmacy benefit manager that administers a fully-funded or self-funded plan.

13 (3) "Step therapy protocol" means a protocol or program that establishes the specific
14 sequence in which prescription drugs for a specified medical condition, and medically appropriate
15 for a particular patient, are covered by a health plan issuer or health benefit plan.

16 (4) "Step therapy override determination" means a determination as to whether a step
17 therapy protocol should apply in a particular situation, or whether the step therapy protocol should
18 be overridden in favor of immediate coverage of the health care provider's selected prescription
19 drug. This determination is based on a review of the patient's or prescriber's request for an
20 override, along with supporting rationale and documentation.

21 (5) "Utilization review organization" means an entity that conducts utilization review, other
22 than a health plan issuer performing utilization review for its own health benefit plan.

§33-16I-3. Application of article.

1 Any health benefit plan that includes prescription drug benefits, and which utilizes step
2 therapy protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted
3 in this state on or after July 1, 2016, shall comply with the provisions of this article.

§33-16I-4. Step therapy protocol exceptions.

1 (a) When coverage of a prescription drug for the treatment of any medical condition is
2 restricted for use by health plan issuer or utilization review organization through the use of a step
3 therapy protocol, the patient and prescribing practitioner shall have access to a clear and
4 convenient process to request a step therapy exception determination. The process shall be
5 made easily accessible on the health plan issuer's or utilization review organization's website.
6 The health plan issuer or utilization review organization must provide a prescription drug for
7 treatment of the medical condition at least until the step therapy exception determination is made.

8 (b) A step therapy override determination request shall be expeditiously granted if:

9 (1) The required prescription drug is contraindicated or will likely cause an adverse
10 reaction by or physical or mental harm to the patient.

11 (2) The required prescription drug is expected to be ineffective based on the known
12 relevant physical or mental characteristics of the patient and the known characteristics of the
13 prescription drug regimen.

14 (3) The patient has tried the required prescription drug while under their current or a
15 previous health insurance or health benefit plan, or another prescription drug in the same
16 pharmacologic class or with the same mechanism of action and such prescription drug was
17 discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event.

18 (4) The required prescription drug is not in the best interest of the patient, based upon
19 medical appropriateness.

20 (5) The patient is stable on a prescription drug selected by their health care provider for
21 the medical condition under consideration.

22 (c) Upon the granting of a step therapy override determination, the health plan issuer or
23 utilization review organization shall authorize coverage for the prescription drug prescribed by the
24 patient's treating healthcare provider, provided such prescription drug is a covered prescription
25 drug under such policy or contract.

- 26 (d) This section shall not be construed to prevent:
27 (1) A health plan issuer or utilization review organization from requiring a patient to try an
28 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription
29 drug.
30 (2) A health care provider from prescribing a prescription drug that is determined to be
31 medically appropriate.

NOTE: The purpose of this bill is to regulate the use of step therapy protocols by providing a simple and expeditious process for exceptions to the protocols that the health care provider deems not in the best interests of the patient.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.