WEST VIRGINIA LEGISLATURE

2017 REGULAR SESSION

Introduced

House Bill 2300

By Delegates Kelly, Ellington, Summers, Criss, Wagner, Ward, Atkinson and Rohrbach

[Introduced February 9, 2017; Referred

to the Committee on Health and Human Resources]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section, designated §33-15-40; to amend said code by adding thereto a new section, designated §33-16-3aa; to amend said code by adding thereto a new section, designated §33-24-7p; to amend said code by adding thereto a new section, designated §33-25-8m; and to amend said code by adding thereto a new section, designated §33-25A-8o, all relating to regulating step therapy protocols in health benefit plans which provide prescription drug benefits; providing for an exception from the protocols; setting out criteria for the exception; providing for an effective date; and setting out exclusions.

Be it enacted by the Legislature of West Virginia:

That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new section, designated §33-15-40; that said code be amended by adding thereto a new section, designated §33-16-3aa; that said code be amended by adding thereto a new section, designated §33-24-7p; that said code be amended by adding thereto a new section, designated §33-25-8m; and that said code be amended by adding thereto a new section, designated §33-25A-8o, all to read as follows:

ARTICLE 15. ACCIDENT AND SICKNESS INSURANCE.

§33-15-4o. Step therapy.

- (a) As used in this article:
- (1) "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health plan issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.
- (2) "Health plan issuer" or "issuer" means an entity required to be licensed under this chapter that contracts, or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services under a health benefit plan, including accident and sickness insurers, nonprofit hospital service corporations, medical service corporations and dental service organizations, prepaid limited health service organizations, health maintenance

organizations, preferred provider organizations, provider sponsored network, and any pharmacy benefit manager that administers a fully-funded or self-funded plan.

- (3) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by a health plan issuer or health benefit plan.
- (4) "Step therapy override determination" means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug. This determination is based on a review of the patient's or prescriber's request for an override, along with supporting rationale and documentation.
- (5) "Utilization review organization" means an entity that conducts utilization review, other than a health plan issuer performing utilization review for its own health benefit plan.
- (b) A health benefit plan that includes prescription drug benefits, and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted in this state on or after January 1, 2018, shall comply with the provisions of this article.
 - (c) Step therapy protocol exceptions include:
- (1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by health plan issuer 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. The process shall be made easily accessible on the health plan issuer's or utilization review organization's website. The health plan issuer or utilization review organization must provide a prescription drug for treatment of the medical condition at least until the step therapy exception determination is made.
 - (2) A step therapy override determination request shall be expeditiously granted if:
- (A) The required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient.

36	(B) The required prescription drug is expected to be ineffective based on the known
37	relevant physical or mental characteristics of the patient and the known characteristics of the
38	prescription drug regimen.
39	(C) The patient has tried the required prescription drug while under their current or a
40	previous health insurance or health benefit plan, or another prescription drug in the same
41	pharmacologic class or with the same mechanism of action and such prescription drug was
42	discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event.
43	(D) The required prescription drug is not in the best interest of the patient, based upon
44	medical appropriateness.
45	(E) The patient is stable on a prescription drug selected by their health care provider for
46	the medical condition under consideration.
47	(3) Upon the granting of a step therapy override determination, the health plan issuer or
48	utilization review organization shall authorize coverage for the prescription drug prescribed by the
49	patient's treating healthcare provider, provided such prescription drug is a covered prescription
50	drug under such policy or contract.
51	(4) This section shall not be construed to prevent:
52	(A) A health plan issuer or utilization review organization from requiring a patient to try an
53	AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription
54	<u>drug.</u>
55	(B) A health care provider from prescribing a prescription drug that is determined to be
56	medically appropriate.
	ARTICLE 16. GROUP ACCIDENT AND SICKNESS INSURANCE.
	§33-16-3aa. Step therapy.
1	(a) 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

of the costs of health care services.

(2) "Health plan issuer" or "issuer" means an entity required to be licensed under this chapter that contracts, or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services under a health benefit plan, including accident and sickness insurers, nonprofit hospital service corporations, medical service corporations and dental service organizations, prepaid limited health service organizations, health maintenance organizations, preferred provider organizations, provider sponsored network, and any pharmacy benefit manager that administers a fully-funded or self-funded plan.

- (3) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by a health plan issuer or health benefit plan.
- (4) "Step therapy override determination" means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug. This determination is based on a review of the patient's or prescriber's request for an override, along with supporting rationale and documentation.
- (5) "Utilization review organization" means an entity that conducts utilization review, other than a health plan issuer performing utilization review for its own health benefit plan.
- (b) A health benefit plan that includes prescription drug benefits, and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted in this state on or after January 1, 2018, shall comply with the provisions of this article.
 - (c) Step therapy protocol exceptions include:
- (1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by health plan issuer 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. The process shall be made

easily accessible on the health plan issuer's or utilization review organization's website. The
health plan issuer or utilization review organization must provide a prescription drug for treatment
of the medical condition at least until the step therapy exception determination is made.
(2) A step therapy override determination request shall be expeditiously granted if:
(A) The required prescription drug is contraindicated or will likely cause an adverse
reaction by or physical or mental harm to the patient.
(B) The required prescription drug is expected to be ineffective based on the known
relevant physical or mental characteristics of the patient and the known characteristics of the
prescription drug regimen.
(C) The patient has tried the required prescription drug while under their current or a
previous health insurance or health benefit plan, or another prescription drug in the same
pharmacologic class or with the same mechanism of action and such prescription drug was
discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event.
(D) The required prescription drug is not in the best interest of the patient, based upon
medical appropriateness.
(E) The patient is stable on a prescription drug selected by their health care provider for
the medical condition under consideration.
(3) Upon the granting of a step therapy override determination, the health plan issuer or
utilization review organization shall authorize coverage for the prescription drug prescribed by the
patient's treating healthcare provider, provided such prescription drug is a covered prescription
drug under such policy or contract.
(4) This section shall not be construed to prevent:
(A) A health plan issuer or utilization review organization from requiring a patient to try an
AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription
<u>drug.</u>
(B) A health care provider from prescribing a prescription drug that is determined to be

medically appropriate.

ARTICLE 24. HOSPITAL SERVICE CORPORATIONS, MEDICAL SERVICE CORPORATIONS, DENTAL SERVICE CORPORATIONS AND HEALTH SERVICE CORPORATIONS.

§33-24-7p. Step therapy.

(a)	As	used	in	this	artic	e:

- (1) "Health benefit plan" means a policy, contract, certificate or agreement entered into, offered or issued by a health plan issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.
- (2) "Health plan issuer" or "issuer" means an entity required to be licensed under this chapter that contracts, or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services under a health benefit plan, including accident and sickness insurers, nonprofit hospital service corporations, medical service corporations and dental service organizations, prepaid limited health service organizations, health maintenance organizations, preferred provider organizations, provider sponsored network, and any pharmacy benefit manager that administers a fully-funded or self-funded plan.
- (3) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by a health plan issuer or health benefit plan.
- (4) "Step therapy override determination" means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug. This determination is based on a review of the patient's or prescriber's request for an override, along with supporting rationale and documentation.
- (5) "Utilization review organization" means an entity that conducts utilization review, other

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the medical condition under consideration.

than a health plan issuer performing utilization review for its own health benefit plan. (b) A health benefit plan that includes prescription drug benefits, and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted in this state on or after January 1, 2018, shall comply with the provisions of this article. (c) Step therapy protocol exceptions include: (1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by health plan issuer 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. The process shall be made easily accessible on the health plan issuer's or utilization review organization's website. The health plan issuer or utilization review organization must provide a prescription drug for treatment of the medical condition at least until the step therapy exception determination is made. (2) A step therapy override determination request shall be expeditiously granted if: (A) The required prescription drug is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the patient. (B) The required prescription drug is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen. (C) The patient has tried the required prescription drug while under their current or a previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event. (D) The required prescription drug is not in the best interest of the patient, based upon medical appropriateness. (E) The patient is stable on a prescription drug selected by their health care provider for

(3) Upon the granting of a step therapy override determination, the health plan issuer or
utilization review organization shall authorize coverage for the prescription drug prescribed by the
patient's treating healthcare provider, provided such prescription drug is a covered prescription
drug under such policy or contract.
(4) This section shall not be construed to prevent:
(A) A health plan issuer or utilization review organization from requiring a patient to try an
AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription
drug.
(B) A health care provider from prescribing a prescription drug that is determined to be
medically appropriate.
ARTICLE 25. HEALTH CARE CORPORATIONS.
§33-25-8m. Step therapy.
(a) As used in this article:
(1) "Health benefit plan" means a policy, contract, certificate or agreement entered into,
offered or issued by a health plan issuer to provide, deliver, arrange for, pay for, or reimburse any
of the costs of health care services.
(2) "Health plan issuer" or "issuer" means an entity required to be licensed under this
chapter that contracts, or offers to contract to provide, deliver, arrange for, pay for, or reimburse
any of the costs of health care services under a health benefit plan, including accident and
sickness insurers, nonprofit hospital service corporations, medical service corporations and
dental service organizations, prepaid limited health service organizations, health maintenance
organizations, preferred provider organizations, provider sponsored network, and any pharmacy
benefit manager that administers a fully-funded or self-funded plan.
(3) "Step therapy protocol" means a protocol or program that establishes the specific
sequence in which prescription drugs for a specified medical condition, and medically appropriate
for a particular patient, are covered by a health plan issuer or health benefit plan.

(4) "Step therapy override determination" means a determination as to whether a step				
therapy protocol should apply in a particular situation, or whether the step therapy protocol should				
be overridden in favor of immediate coverage of the health care provider's selected prescription				
drug. This determination is based on a review of the patient's or prescriber's request for an				
override, along with supporting rationale and documentation.				
(5) "Utilization review organization" means an entity that conducts utilization review, other				
than a health plan issuer performing utilization review for its own health benefit plan.				
(b) A health benefit plan that includes prescription drug benefits, and which utilizes step				
therapy protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted				
in this state on or after January 1, 2018, shall comply with the provisions of this article.				
(c) Step therapy protocol exceptions include:				
(1) When coverage of a prescription drug for the treatment of any medical condition is				
restricted for use by health plan issuer 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. The process shall be made				
easily accessible on the health plan issuer's or utilization review organization's website. The				
health plan issuer or utilization review organization must provide a prescription drug for treatment				
of the medical condition at least until the step therapy exception determination is made.				
(2) A step therapy override determination request shall be expeditiously granted if:				
(A) The required prescription drug is contraindicated or will likely cause an adverse				
reaction by or physical or mental harm to the patient.				
(B) The required prescription drug is expected to be ineffective based on the known				
relevant physical or mental characteristics of the patient and the known characteristics of the				
prescription drug regimen.				
(C) The patient has tried the required prescription drug while under their current or a				

previous health insurance or health benefit plan, or another prescription drug in the same

41 pharmacologic class or with the same mechanism of action and such prescription drug was 42 discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event. 43 (D) The required prescription drug is not in the best interest of the patient, based upon 44 medical appropriateness. 45 (E) The patient is stable on a prescription drug selected by their health care provider for 46 the medical condition under consideration. 47 (3) Upon the granting of a step therapy override determination, the health plan issuer or 48 utilization review organization shall authorize coverage for the prescription drug prescribed by the 49 patient's treating healthcare provider, provided such prescription drug is a covered prescription 50 drug under such policy or contract. 51 (4) This section shall not be construed to prevent: 52 (A) A health plan issuer or utilization review organization from requiring a patient to try an 53 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription 54 drug. 55 (B) A health care provider from prescribing a prescription drug that is determined to be 56 medically appropriate. ARTICLE 25A. HEALTH MAINTENANCE ORGANIZATION ACT. §33-25A-8o. Step therapy. 1 (a) 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

dental service organizations, prepaid limited health service organizations, health maintenance organizations, preferred provider organizations, provider sponsored network, and any pharmacy benefit manager that administers a fully-funded or self-funded plan.

- (3) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, and medically appropriate for a particular patient, are covered by a health plan issuer or health benefit plan.
- (4) "Step therapy override determination" means a determination as to whether a step therapy protocol should apply in a particular situation, or whether the step therapy protocol should be overridden in favor of immediate coverage of the health care provider's selected prescription drug. This determination is based on a review of the patient's or prescriber's request for an override, along with supporting rationale and documentation.
- (5) "Utilization review organization" means an entity that conducts utilization review, other than a health plan issuer performing utilization review for its own health benefit plan.
- (b) A health benefit plan that includes prescription drug benefits, and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted in this state on or after January 1, 2018, shall comply with the provisions of this article.
 - (c) Step therapy protocol exceptions include:
- (1) When coverage of a prescription drug for the treatment of any medical condition is restricted for use by health plan issuer 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. The process shall be made easily accessible on the health plan issuer's or utilization review organization's website. The health plan issuer or utilization review organization must provide a prescription drug for treatment of the medical condition at least until the step therapy exception determination is made.
 - (2) A step therapy override determination request shall be expeditiously granted if:
 - (A) The required prescription drug is contraindicated or will likely cause an adverse

reaction by or physical or mental harm to the patient.

- (B) The required prescription drug is expected to be ineffective based on the known relevant physical or mental characteristics of the patient and the known characteristics of the prescription drug regimen.
- (C) The patient has tried the required prescription drug while under their current or a previous health insurance or health benefit plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action and such prescription drug was discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event.
- (D) The required prescription drug is not in the best interest of the patient, based upon medical appropriateness.
- (E) The patient is stable on a prescription drug selected by their health care provider for the medical condition under consideration.
- (3) Upon the granting of a step therapy override determination, the health plan issuer or utilization review organization shall authorize coverage for the prescription drug prescribed by the patient's treating healthcare provider, provided such prescription drug is a covered prescription drug under such policy or contract.
 - (4) This section shall not be construed to prevent:
- (A) A health plan issuer or utilization review organization from requiring a patient to try an AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription drug.
- (B) A health care provider from prescribing a prescription drug that is determined to be 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.