# WEST VIRGINIA LEGISLATURE

## 2017 REGULAR SESSION

## ENROLLED

# House Bill 2300

BY DELEGATES KELLY, ELLINGTON, SUMMERS, CRISS,

WAGNER, WARD, ATKINSON AND ROHRBACH

[Passed March 21, 2017; in effect ninety days from passage.]

AN ACT to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section, designated §33-15-4o; 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 §33-15-4o; 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.

(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.

## ARTICLE 16. GROUP ACCIDENT AND SICKNESS INSURANCE.

### §33-16-3aa. 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 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.

## 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 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 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.

## 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 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.

## ARTICLE 25A. HEALTH MAINTENANCE ORGANIZATION ACT.

### §33-25A-8o. 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 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.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

.....
*Chairman, House Committee*

.....
*Chairman, Senate Committee*

Originating in the House.

In effect ninety days from passage.

.....
*Clerk of the House of Delegates*

.....
*Clerk of the Senate*

.....
*Speaker of the House of Delegates*

.....
*President of the Senate*

_____

The within ..... this the.....

day of ....., 2017.

.....
*Governor*