

**WEST VIRGINIA LEGISLATURE** FILED

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**2016 REGULAR SESSION**

OFFICE WEST VIRGINIA  
SECRETARY OF STATE

**ENROLLED**

**Committee Substitute**

**for**

**House Bill 4040**

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

[Passed March 12, 2016; in effect ninety days from passage.]

HB 4040

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[Passed March 12, 2016; in effect ninety days from passage.]

1 AN ACT to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section,  
2 designated §33-15-4m; to amend said code by adding thereto a new section, designated  
3 §33-16-3y; to amend said code by adding thereto a new section, designated §33-24-7n;  
4 to amend said code by adding thereto a new section, designated §33-25-8k; and to amend  
5 said code by adding thereto a new section, designated §33-25A-8m, all relating to  
6 regulating step therapy protocols in health benefit plans which provide prescription drug  
7 benefits; providing for an exception from the protocols; setting out criteria for the  
8 exception; providing for an effective date; and setting out exclusions.

*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 section, designated §33-15-4m; that said code be amended by adding thereto a new section,  
3 designated §33-16-3y; that said code be amended by adding thereto a new section, designated  
4 §33-24-7n; that said code be amended by adding thereto a new section, designated §33-25-8k;  
5 and that said code be amended by adding thereto a new section, designated §33-25A-8m, all to  
6 read as follows:

## **CHAPTER 33. INSURANCE.**

### **ARTICLE 15. ACCIDENT AND SICKNESS INSURANCE.**

#### **§33-15-4m. Step Therapy.**

1 (a) *Definitions.* — 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 any pharmacy  
11 benefit manager that administers a fully-funded or self-funded plan.

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

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

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

22 (b) *Application of article.* — A health benefit plan that includes prescription drug benefits,  
23 and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or  
24 otherwise contracted in this state on or after January 1, 2017, shall comply with the provisions of  
25 this article.

26 (c) *Step therapy protocol exceptions.* —

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

34 (2) A step therapy override determination request shall be expeditiously granted if:

35 (A) The required prescription drug is contraindicated or will likely cause an adverse  
36 reaction by or physical or mental harm to the patient.

37 (B) The required prescription drug is expected to be ineffective based on the known  
38 relevant physical or mental characteristics of the patient and the known characteristics of the  
39 prescription drug regimen.

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

44 (D) The required prescription drug is not in the best interest of the patient, based upon  
45 medical appropriateness.

46 (E) The patient is stable on a prescription drug selected by their health care provider for  
47 the medical condition under consideration.

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

52 (4) This section shall not be construed to prevent:

53 (A) A health plan issuer or utilization review organization from requiring a patient to try an  
54 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription  
55 drug.

56 (B) A health care provider from prescribing a prescription drug that is determined to be  
57 medically appropriate.

## **ARTICLE 16. GROUP ACCIDENT AND SICKNESS INSURANCE.**

### **§33-16-3y. Step Therapy.**

1           (a) *Definitions.* — 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 any pharmacy  
11 benefit manager that administers a fully-funded or self-funded plan.

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

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

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

22           (b) *Application of article* — A health benefit plan that includes prescription drug benefits,  
23 and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or  
24 otherwise contracted in this state on or after January 1, 2017, shall comply with the provisions of  
25 this article.

26           (c) *Step therapy protocol exceptions.* —

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

34 (2) A step therapy override determination request shall be expeditiously granted if:

35 (A) The required prescription drug is contraindicated or will likely cause an adverse  
36 reaction by or physical or mental harm to the patient.

37 (B) The required prescription drug is expected to be ineffective based on the known  
38 relevant physical or mental characteristics of the patient and the known characteristics of the  
39 prescription drug regimen.

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

44 (D) The required prescription drug is not in the best interest of the patient, based upon  
45 medical appropriateness.

46 (E) The patient is stable on a prescription drug selected by their health care provider for  
47 the medical condition under consideration.

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

52 (4) This section shall not be construed to prevent:

53 (A) A health plan issuer or utilization review organization from requiring a patient to try an  
54 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription  
55 drug.

56 (B) A health care provider from prescribing a prescription drug that is determined to be  
57 medically appropriate.

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

**§33-24-7n. Step Therapy.**

- 1 (a) *Definitions.* — 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 any pharmacy  
11 benefit manager that administers a fully-funded or self-funded plan.
- 12 (3) “Step therapy protocol” means a protocol or program that establishes the specific  
13 sequence in which prescription drugs for a specified medical condition, and medically appropriate  
14 for a particular patient, are covered by a health plan issuer or health benefit plan.
- 15 (4) “Step therapy override determination” means a determination as to whether a step  
16 therapy protocol should apply in a particular situation, or whether the step therapy protocol should



17 be overridden in favor of immediate coverage of the health care provider's selected prescription  
18 drug. This determination is based on a review of the patient's or prescriber's request for an  
19 override, along with supporting rationale and documentation.

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

22 (b) *Application of article.* — A health benefit plan that includes prescription drug benefits,  
23 and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or  
24 otherwise contracted in this state on or after January 1, 2017, shall comply with the provisions of  
25 this article.

26 (c) *Step therapy protocol exceptions.* —

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

34 (2) A step therapy override determination request shall be expeditiously granted if:

35 (A) The required prescription drug is contraindicated or will likely cause an adverse  
36 reaction by or physical or mental harm to the patient.

37 (B) The required prescription drug is expected to be ineffective based on the known  
38 relevant physical or mental characteristics of the patient and the known characteristics of the  
39 prescription drug regimen.

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

44 (D) The required prescription drug is not in the best interest of the patient, based upon  
45 medical appropriateness.

46 (E) The patient is stable on a prescription drug selected by their health care provider for  
47 the medical condition under consideration.

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

52 (4) This section shall not be construed to prevent:

53 (A) A health plan issuer or utilization review organization from requiring a patient to try an  
54 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription  
55 drug.

56 (B) A health care provider from prescribing a prescription drug that is determined to be  
57 medically appropriate.

## **ARTICLE 25. HEALTH CARE CORPORATIONS.**

### **§33-25-8k. Step Therapy.**

1 (a) *Definitions.* — 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 any pharmacy  
11 benefit manager that administers a fully-funded or self-funded plan.

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

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

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

22 (b) *Application of article.* — A health benefit plan that includes prescription drug benefits,  
23 and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or  
24 otherwise contracted in this state on or after January 1, 2017, shall comply with the provisions of  
25 this article.

26 (c) *Step therapy protocol exceptions.* —

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

34 (2) A step therapy override determination request shall be expeditiously granted if:

35 (A) The required prescription drug is contraindicated or will likely cause an adverse  
36 reaction by or physical or mental harm to the patient.

37 (B) The required prescription drug is expected to be ineffective based on the known  
38 relevant physical or mental characteristics of the patient and the known characteristics of the  
39 prescription drug regimen.

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

44 (D) The required prescription drug is not in the best interest of the patient, based upon  
45 medical appropriateness.

46 (E) The patient is stable on a prescription drug selected by their health care provider for  
47 the medical condition under consideration.

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

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53 (A) A health plan issuer or utilization review organization from requiring a patient to try an  
54 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription  
55 drug.

56 (B) A health care provider from prescribing a prescription drug that is determined to be  
57 medically appropriate.

## **ARTICLE 25A. HEALTH MAINTENANCE ORGANIZATION ACT.**

### **§33-25A-8m. Step Therapy.**

1 (a) *Definitions.* — 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  
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7 any of the costs of health care services under a health benefit plan, including accident and  
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17 be overridden in favor of immediate coverage of the health care provider's selected prescription  
18 drug. This determination is based on a review of the patient's or prescriber's request for an  
19 override, along with supporting rationale and documentation.

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

22 (b) *Application of article.* — A health benefit plan that includes prescription drug benefits,  
23 and which utilizes step therapy protocols, and which is issued for delivery, delivered, renewed, or  
24 otherwise contracted in this state on or after January 1, 2017, shall comply with the provisions of  
25 this article.

26 (c) *Step therapy protocol exceptions.* —

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

34 (2) A step therapy override determination request shall be expeditiously granted if:

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37 (B) The required prescription drug is expected to be ineffective based on the known  
38 relevant physical or mental characteristics of the patient and the known characteristics of the  
39 prescription drug regimen.

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

44 (D) The required prescription drug is not in the best interest of the patient, based upon  
45 medical appropriateness.

46 (E) The patient is stable on a prescription drug selected by their health care provider for  
47 the medical condition under consideration.

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

52 (4) This section shall not be construed to prevent:

53           (A) A health plan issuer or utilization review organization from requiring a patient to try an  
54 AB-Rated generic equivalent prior to providing coverage for the equivalent branded prescription  
55 drug.

56           (B) A health care provider from prescribing a prescription drug that is determined to be  
57 medically appropriate.

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

  
.....  
Chairman, House Committee

  
.....  
Chairman, Senate Committee

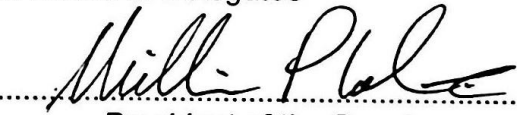
Originating in the House.

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

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The within is approved this the 29<sup>th</sup>  
day of March....., 2016.

  
.....  
Governor



PRESENTED TO THE GOVERNOR

MAR 24 2016

Time 3:44 pm