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# STATE OF RHODE ISLAND

# IN GENERAL ASSEMBLY

## **JANUARY SESSION, A.D. 2015**

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## AN ACT

## RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES

<u>Introduced By:</u> Senators Coyne, Conley, Nesselbush, Morgan, and Goldin <u>Date Introduced:</u> May 07, 2015

Referred To: Senate Health & Human Services

It is enacted by the General Assembly as follows:

1	SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness
2	Insurance Policies" is hereby amended by adding thereto the following section:
3	<u>27-18-82. Step therapy protocol.</u> – (a) Legislative findings and declaration. The general
4	assembly makes the following findings:
5	(1) Health insurance plans are increasingly making use of step therapy policies under
6	which health plan members are required to try one or more prescription drugs before coverage is
7	provided for a drug recommended by the patient's health care provider.
8	(2) Such step therapy policies, where they are based on well-developed scientific
9	standards and administered in a flexible manner that takes into account the individual needs of
10	patients, can play an important role in controlling health care costs.
11	(3) In some cases, requiring a patient to follow a step therapy policy may have adverse
12	and even dangerous consequences for the patient who may either not realize a benefit from taking
13	a prescription drug or may suffer harm from taking the wrong drug.
14	(4) Without uniform policies across the state on step therapy, patients may not receive the
15	best and most appropriate treatment.
16	(5) It is imperative that step therapy policies throughout the state preserve physicians'
17	rights to make treatment decisions in the best interest of their patients.
18	(6) Based on these findings, the general assembly declares it a matter of public interest

that it require health plans to base step therapy requirements on appropriate clinical practice

1	guidelines developed by professional medical societies with expertise in the condition or
2	conditions under consideration; that patients be exempt from step therapy requirements when
3	impracticable or otherwise not in the best interest of the patients; and that patients and prescribers
4	have access to a transparent and independent process for requesting an exception of step therapy
5	requirements when appropriate.
6	(b) Definitions. As used in this section:
7	(1) "Clinical practice guidelines" means a systematically developed statement to assist
8	practitioner and patient decisions about appropriate health care for specific clinical circumstances.
9	(2) "Clinical review criteria" means the written screening procedures, decision abstracts,
10	clinical protocols and practice guidelines used by an insurer or health plan to determine the
11	medical necessity and appropriateness of health care services.
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 to be prescribed and paid for by a health plan.
15	(4) "Step therapy override determination" means a determination as to whether step
16	therapy should apply in a particular situation, or whether the step therapy protocol should be
17	overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug.
18	This determination is based on a review of the patient's and/or prescriber's request for an override,
19	along with supporting rationale and documentation.
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20	(5) "Utilization review organization" means an entity that conducts utilization review,
	other than a health carrier performing utilization review for its own health benefit plans.
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21 22 23 24	other than a health carrier performing utilization review for its own health benefit plans.  (c) Clinical review criteria, requirements and restrictions. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:
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21 22 23 24 25 26	other than a health carrier performing utilization review for its own health benefit plans.  (c) Clinical review criteria, requirements and restrictions. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:  (1) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and
220 221 222 223 224 225 226 227 228	other than a health carrier performing utilization review for its own health benefit plans.  (c) Clinical review criteria, requirements and restrictions. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:  (1) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and  (2) That recommend drugs be taken in the specific sequence required by the step therapy
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221 222 223 224 225 226 227 228 229	other than a health carrier performing utilization review for its own health benefit plans.  (c) Clinical review criteria, requirements and restrictions. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:  (1) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and  (2) That recommend drugs be taken in the specific sequence required by the step therapy protocol.  (d) Exceptions process transparency.  (1) Exceptions process. When coverage of medications for the treatment of any medical
221 222 223 224 225 226 227 228 229 330	other than a health carrier performing utilization review for its own health benefit plans.  (c) Clinical review criteria, requirements and restrictions. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:  (1) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and  (2) That recommend drugs be taken in the specific sequence required by the step therapy protocol.  (d) Exceptions process transparency.  (1) Exceptions process. When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a
221 222 223 224 225 226 227 228 229 330 331	other than a health carrier performing utilization review for its own health benefit plans.  (c) Clinical review criteria, requirements and restrictions. Clinical review criteria used to establish step therapy protocols shall be based on clinical practice guidelines:  (1) Independently developed by a professional medical society with expertise in the medical condition, or conditions, for which coverage decisions said criteria will be applied; and  (2) That recommend drugs be taken in the specific sequence required by the step therapy protocol.  (d) Exceptions process transparency.  (1) Exceptions process. When coverage of medications for the treatment of any medical condition are restricted for use by an insurer, health plan, or utilization review organization via a step therapy protocol, the patient and prescribing practitioner shall have access to a clear and

1	documenting and making it easily accessible on the insurer's or health plan's website.
2	(2) Exceptions. An exception request shall be expeditiously granted if:
3	(i) The required drug is contraindicated or will likely cause an adverse reaction or
4	physical or mental harm to the patient;
5	(ii) The required drug is expected to be ineffective based on the known relevant physical
6	or mental characteristics of the insured/patient and the known characteristics of the drug regimen;
7	(iii) The enrollee has tried the step therapy required drug while under their current or a
8	previous health plan, or another drug in the same pharmacologic class or with the same
9	mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
10	diminished effect, or an adverse event; or
11	(iv) The patient is stable on a drug recommended by their health care provider for the
12	medical condition under consideration, based on, but not limited to, a trial with medication
13	samples or a prescription filled at a pharmacy.
14	(3) Effect of exception. Upon the granting of an exception request, the insurer, health
15	plan, utilization review organization, or other entity shall authorize dispensation of and coverage
16	for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
17	covered drug under such policy or contract.
18	(4) Limitations. This section shall not be construed to prevent:
19	(i) An insurer, health plan, or utilization review organization from requiring an enrollee
20	try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
21	drug;
22	(ii) A health care provider from prescribing a drug he or she determines is medically
23	appropriate.
24	(e) Regulations. Notwithstanding any general or special law to the contrary, the division
25	of insurance shall promulgate any regulations necessary to enforce this section.
26	SECTION 2. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service
27	Corporations" is hereby amended by adding thereto the following section:
28	27-19-73. Step therapy drug protocol (a) Legislative findings and declaration. The
29	general assembly makes the following findings:
30	(1) Health insurance plans are increasingly making use of step therapy policies under
31	which health plan members are required to try one or more prescription drugs before coverage is
32	provided for a drug recommended by the patient's health care provider.
33	(2) Such step therapy policies, where they are based on well-developed scientific
34	standards and administered in a flexible manner that takes into account the individual needs of

1	patients, can play an important role in controlling health care costs.
2	(3) In some cases, requiring a patient to follow a step therapy policy may have adverse
3	and even dangerous consequences for the patient who may either not realize a benefit from taking
4	a prescription drug or may suffer harm from taking the wrong drug.
5	(4) Without uniform policies across the state on step therapy, patients may not receive the
6	best and most appropriate treatment.
7	(5) It is imperative that step therapy policies throughout the state preserve physicians
8	rights to make treatment decisions in the best interest of their patients.
9	(6) Based on these findings, the general assembly declares it a matter of public interest
10	that it require health plans to base step therapy requirements on appropriate clinical practice
11	guidelines developed by professional medical societies with expertise in the condition or
12	conditions under consideration; that patients be exempt from step therapy requirements when
13	impracticable or otherwise not in the best interest of the patients; and that patients and prescribers
14	have access to a transparent and independent process for requesting an exception of step therapy
15	requirements when appropriate.
16	(b) Definitions. As used in this section:
17	(1) "Clinical practice guidelines" means a systematically developed statement to assist
18	practitioner and patient decisions about appropriate health care for specific clinical circumstances.
19	(2) "Clinical review criteria" means the written screening procedures, decision abstracts,
20	clinical protocols and practice guidelines used by an insurer or health plan to determine the
21	medical necessity and appropriateness of health care services.
22	(3) "Step therapy protocol" means a protocol or program that establishes the specific
23	sequence in which prescription drugs for a specified medical condition and medically appropriate
24	for a particular patient are to be prescribed and paid for by a health plan.
25	(4) "Step therapy override determination" means a determination as to whether step
26	therapy should apply in a particular situation, or whether the step therapy protocol should be
27	overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug.
28	This determination is based on a review of the patient's and/or prescriber's request for an override,
29	along with supporting rationale and documentation.
30	(5) "Utilization review organization" means an entity that conducts utilization review,
31	other than a health carrier performing utilization review for its own health benefit plans.
32	(c) Clinical review criteria. Requirements and restrictions. Clinical review criteria used to
33	establish step therapy protocols shall be based on clinical practice guidelines:
34	(1) Independently developed by a professional medical society with expertise in the

1	medical condition, or conditions, for which coverage decisions said criteria will be applied; and
2	(2) That recommend drugs be taken in the specific sequence required by the step therapy
3	<u>protocol.</u>
4	(d) Exceptions process transparency.
5	(1) Exceptions process. When coverage of medications for the treatment of any medical
6	condition are restricted for use by an insurer, health plan, or utilization review organization via a
7	step therapy protocol, the patient and prescribing practitioner shall have access to a clear and
8	convenient process to request a step therapy exception determination. An insurer, health plan, or
9	utilization review organization may use its existing medical exceptions process to satisfy this
10	requirement. The process shall be disclosed to the patient and health care providers, including
11	documenting and making it easily accessible on the insurer's or health plan's website.
12	(2) Exceptions. An exception request shall be expeditiously granted if:
13	(i) The required drug is contraindicated or will likely cause an adverse reaction or
14	physical or mental harm to the patient;
15	(ii) The required drug is expected to be ineffective based on the known relevant physical
16	or mental characteristics of the insured/patient and the known characteristics of the drug regimen;
17	(iii) The enrollee has tried the step therapy required drug while under their current or a
18	previous health plan, or another drug in the same pharmacologic class or with the same
19	mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
20	diminished effect, or an adverse event; or
21	(iv) The patient is stable on a drug recommended by their health care provider for the
22	medical condition under consideration, based on, but not limited to, a trial with medication
23	samples or a prescription filled at a pharmacy.
24	(3) Effect of exception. Upon the granting of an exception request, the insurer, health
25	plan, utilization review organization, or other entity shall authorize dispensation of and coverage
26	for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
27	covered drug under such policy or contract.
28	(4) Limitations. This section shall not be construed to prevent:
29	(i) An insurer, health plan, or utilization review organization from requiring an enrollee
30	try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
31	<u>drug:</u>
32	(ii) A health care provider from prescribing a drug he or she determines is medically
33	appropriate.
34	(e) Regulations. Notwithstanding any general or special law to the contrary, the division

1	of insurance shall promulgate any regulations necessary to enforce this section.
2	SECTION 3. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service
3	Corporations" is hereby amended by adding thereto the following section:
4	27-20-69. Step therapy protocol (a) Legislative findings and declaration. The general
5	assembly makes the following findings:
6	(1) Health insurance plans are increasingly making use of step therapy policies under
7	which health plan members are required to try one or more prescription drugs before coverage is
8	provided for a drug recommended by the patient's health care provider.
9	(2) Such step therapy policies, where they are based on well-developed scientific
10	standards and administered in a flexible manner that takes into account the individual needs of
11	patients, can play an important role in controlling health care costs.
12	(3) In some cases, requiring a patient to follow a step therapy policy may have adverse
13	and even dangerous consequences for the patient who may either not realize a benefit from taking
14	a prescription drug or may suffer harm from taking the wrong drug.
15	(4) Without uniform policies across the state on step therapy, patients may not receive the
16	best and most appropriate treatment.
17	(5) It is imperative that step therapy policies throughout the state preserve physicians'
18	rights to make treatment decisions in the best interest of their patients.
19	(6) Based on these findings, the general assembly declares it a matter of public interest
20	that it require health plans to base step therapy requirements on appropriate clinical practice
21	guidelines developed by professional medical societies with expertise in the condition or
22	conditions under consideration; that patients be exempt from step therapy requirements when
23	impracticable or otherwise not in the best interest of the patients; and that patients and prescribers
24	have access to a transparent and independent process for requesting an exception of step therapy
25	requirements when appropriate.
26	(b) Definitions. As used in this section:
27	(1) "Clinical practice guidelines" means a systematically developed statement to assist
28	practitioner and patient decisions about appropriate health care for specific clinical circumstances.
29	(2) "Clinical review criteria" means the written screening procedures, decision abstracts,
30	clinical protocols and practice guidelines used by an insurer or health plan to determine the
31	medical necessity and appropriateness of health care services.
32	(3) "Step therapy protocol" means a protocol or program that establishes the specific
33	sequence in which prescription drugs for a specified medical condition and medically appropriate
34	for a particular patient are to be prescribed and paid for by a health plan

1	(4) "Step therapy override determination" means a determination as to whether step
2	therapy should apply in a particular situation, or whether the step therapy protocol should be
3	overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug.
4	This determination is based on a review of the patient's and/or prescriber's request for an override,
5	along with supporting rationale and documentation.
6	(5) "Utilization review organization" means an entity that conducts utilization review,
7	other than a health carrier performing utilization review for its own health benefit plans.
8	(c) Clinical review criteria. Requirements and restrictions. Clinical review criteria used to
9	establish step therapy protocols shall be based on clinical practice guidelines:
10	(1) Independently developed by a professional medical society with expertise in the
11	medical condition, or conditions, for which coverage decisions said criteria will be applied; and
12	(2) That recommend drugs be taken in the specific sequence required by the step therapy
13	protocol.
14	(d) Exceptions process transparency.
15	(1) Exceptions process. When coverage of medications for the treatment of any medical
16	condition are restricted for use by an insurer, health plan, or utilization review organization via a
17	step therapy protocol, the patient and prescribing practitioner shall have access to a clear and
18	convenient process to request a step therapy exception determination. An insurer, health plan, or
19	utilization review organization may use its existing medical exceptions process to satisfy this
20	requirement. The process shall be disclosed to the patient and health care providers, including
21	documenting and making it easily accessible on the insurer's or health plan's website.
22	(2) Exceptions. An exception request shall be expeditiously granted if:
23	(i) The required drug is contraindicated or will likely cause an adverse reaction or
24	physical or mental harm to the patient;
25	(ii) The required drug is expected to be ineffective based on the known relevant physical
26	or mental characteristics of the insured/patient and the known characteristics of the drug regimen;
27	(iii) The enrollee has tried the step therapy required drug while under their current or a
28	previous health plan, or another drug in the same pharmacologic class or with the same
29	mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
30	diminished effect, or an adverse event; or
31	(iv) The patient is stable on a drug recommended by their health care provider for the
32	medical condition under consideration, based on, but not limited to, a trial with medication
33	samples or a prescription filled at a pharmacy.
34	(3) Effect of exception. Upon the granting of an exception request, the insurer, health

1	plan, utilization review organization, or other entity shall authorize dispensation of and coverage
2	for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
3	covered drug under such policy or contract.
4	(4) Limitations. This section shall not be construed to prevent:
5	(i) An insurer, health plan, or utilization review organization from requiring an enrollee
6	try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
7	drug;
8	(ii) A health care provider from prescribing a drug he or she determines is medically
9	appropriate.
10	(e) Regulations. Notwithstanding any general or special law to the contrary, the division
11	of insurance shall promulgate any regulations necessary to enforce this section.
12	SECTION 4. Chapter 27-20.1 of the General Laws entitled "Nonprofit Dental Service
13	Corporations" is hereby amended by adding thereto the following section:
14	27-20.1-23. Step therapy protocol (a) Legislative findings and declaration. The
15	general assembly makes the following findings:
16	(1) Health insurance plans are increasingly making use of step therapy policies under
17	which health plan members are required to try one or more prescription drugs before coverage is
18	provided for a drug recommended by the patient's health care provider.
19	(2) Such step therapy policies, where they are based on well-developed scientific
20	standards and administered in a flexible manner that takes into account the individual needs of
21	patients, can play an important role in controlling health care costs.
22	(3) In some cases, requiring a patient to follow a step therapy policy may have adverse
23	and even dangerous consequences for the patient who may either not realize a benefit from taking
24	a prescription drug or may suffer harm from taking the wrong drug.
25	(4) Without uniform policies across the state on step therapy, patients may not receive the
26	best and most appropriate treatment.
27	(5) It is imperative that step therapy policies throughout the state preserve physicians'
28	rights to make treatment decisions in the best interest of their patients.
29	(6) Based on these findings, the general assembly declares it a matter of public interest
30	that it require health plans to base step therapy requirements on appropriate clinical practice
31	guidelines developed by professional medical societies with expertise in the condition or
32	conditions under consideration; that patients be exempt from step therapy requirements when
33	impracticable or otherwise not in the best interest of the patients; and that patients and prescribers
34	have access to a transparent and independent process for requesting an exception of step therapy

1	requirements when appropriate.
2	(b) Definitions. As used in this section:
3	(1) "Clinical practice guidelines" means a systematically developed statement to assist
4	practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.
5	(2) "Clinical review criteria" means the written screening procedures, decision abstracts,
6	clinical protocols and practice guidelines used by an insurer or health plan to determine the
7	medical necessity and appropriateness of healthcare services.
8	(3) "Step therapy protocol" means a protocol or program that establishes the specific
9	sequence in which prescription drugs for a specified medical condition and medically appropriate
10	for a particular patient are to be prescribed and paid for by a health plan.
11	(4) "Step therapy override determination" means a determination as to whether step
12	therapy should apply in a particular situation, or whether the step therapy protocol should be
13	overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug.
14	This determination is based on a review of the patient's and/or prescriber's request for an override,
15	along with supporting rationale and documentation.
16	(5) "Utilization review organization" means an entity that conducts utilization review,
17	other than a health carrier performing utilization review for its own health benefit plans.
18	(c) Clinical review criteria. Requirements and restrictions. Clinical review criteria used to
19	establish step therapy protocols shall be based on clinical practice guidelines:
20	(1) Independently developed by a professional medical society with expertise in the
21	medical condition, or conditions, for which coverage decisions said criteria will be applied; and
22	(2) That recommend drugs be taken in the specific sequence required by the step therapy
23	protocol.
24	(d) Exceptions process transparency.
25	(1) Exceptions process. When coverage of medications for the treatment of any medical
26	condition are restricted for use by an insurer, health plan, or utilization review organization via a
27	step therapy protocol, the patient and prescribing practitioner shall have access to a clear and
28	convenient process to request a step therapy exception determination. An insurer, health plan, or
29	utilization review organization may use its existing medical exceptions process to satisfy this
30	requirement. The process shall be disclosed to the patient and health care providers, including
31	documenting and making it easily accessible on the insurer's or health plan's website.
32	(2) Exceptions. An exception request shall be expeditiously granted if:
33	(i) The required drug is contraindicated or will likely cause an adverse reaction or
34	physical or mental harm to the patient:

-	(ii) The required drug is expected to be mercetive based on the known referance physical
2	or mental characteristics of the insured/patient and the known characteristics of the drug regimen;
3	(iii) The enrollee has tried the step therapy required drug while under their current or a
4	previous health plan, or another drug in the same pharmacologic class or with the same
5	mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
6	diminished effect, or an adverse event; or
7	(iv) The patient is stable on a drug recommended by their health care provider for the
8	medical condition under consideration, based on, but not limited to, a trial with medication
9	samples or a prescription filled at a pharmacy.
10	(3) Effect of exception. Upon the granting of an exception request, the insurer, health
11	plan, utilization review organization, or other entity shall authorize dispensation of and coverage
12	for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
13	covered drug under such policy or contract.
14	(4) Limitations. This section shall not be construed to prevent:
15	(i) An insurer, health plan, or utilization review organization from requiring an enrollee
16	try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
17	drug;
18	(ii) A health care provider from prescribing a drug he or she determines is medically
19	appropriate.
20	(e) Regulations. Notwithstanding any general or special law to the contrary, the division
21	of insurance shall promulgate any regulations necessary to enforce this section.
22	SECTION 5. Chapter 27-41 of the General Laws entitled "Health Maintenance
23	Organizations" is hereby amended by adding thereto the following section:
24	27-41-86. Step therapy protocol (a) Legislative findings and declaration. The general
25	assembly makes the following findings:
26	(1) Health insurance plans are increasingly making use of step therapy policies under
27	which health plan members are required to try one or more prescription drugs before coverage is
28	provided for a drug recommended by the patient's health care provider.
29	(2) Such step therapy policies, where they are based on well-developed scientific
30	standards and administered in a flexible manner that takes into account the individual needs of
31	patients, can play an important role in controlling health care costs.
32	(3) In some cases, requiring a patient to follow a step therapy policy may have adverse
33	and even dangerous consequences for the patient who may either not realize a benefit from taking
34	a prescription drug or may suffer harm from taking the wrong drug

1	(4) Without uniform poncies across the state on step therapy, patients may not receive the
2	best and most appropriate treatment.
3	(5) It is imperative that step therapy policies throughout the state preserve physicians'
4	rights to make treatment decisions in the best interest of their patients.
5	(6) Based on these findings, the general assembly declares it a matter of public interest
6	that it require health plans to base step therapy requirements on appropriate clinical practice
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8	conditions under consideration; that patients be exempt from step therapy requirements when
9	impracticable or otherwise not in the best interest of the patients; and that patients and prescribers
10	have access to a transparent and independent process for requesting an exception of step therapy
11	requirements when appropriate.
12	(b) Definitions. As used in this section:
13	(1) "Clinical practice guidelines" means a systematically developed statement to assist
14	practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.
15	(2) "Clinical review criteria" means the written screening procedures, decision abstracts,
16	clinical protocols and practice guidelines used by an insurer or health plan to determine the
17	medical necessity and appropriateness of healthcare services.
18	(3) "Step therapy protocol" means a protocol or program that establishes the specific
19	sequence in which prescription drugs for a specified medical condition and medically appropriate
20	for a particular patient are to be prescribed and paid for by a health plan.
21	(4) "Step therapy override determination" means a determination as to whether step
22	therapy should apply in a particular situation, or whether the step therapy protocol should be
23	overridden in favor of immediate coverage of the patient's and/or prescriber's preferred drug.
24	This determination is based on a review of the patient's and/or prescriber's request for an override,
25	along with supporting rationale and documentation.
26	(5) "Utilization review organization" means an entity that conducts utilization review,
27	other than a health carrier performing utilization review for its own health benefit plans.
28	(c) Clinical review criteria. Requirements and restrictions. Clinical review criteria used to
29	establish step therapy protocols shall be based on clinical practice guidelines:
30	(1) Independently developed by a professional medical society with expertise in the
31	medical condition, or conditions, for which coverage decisions said criteria will be applied; and
32	(2) That recommend drugs be taken in the specific sequence required by the step therapy
33	protocol.
34	(d) Exceptions process transparency.

•	(1) Exceptions process. When coverage of medications for the treatment of any medical
2	condition are restricted for use by an insurer, health plan, or utilization review organization via a
3	step therapy protocol, the patient and prescribing practitioner shall have access to a clear and
4	convenient process to request a step therapy exception determination. An insurer, health plan, or
5	utilization review organization may use its existing medical exceptions process to satisfy this
6	requirement. The process shall be disclosed to the patient and health care providers, including
7	documenting and making it easily accessible on the insurer's or health plan's website.
8	(2) Exceptions. An exception request shall be expeditiously granted if:
9	(i) The required drug is contraindicated or will likely cause an adverse reaction or
10	physical or mental harm to the patient;
11	(ii) The required drug is expected to be ineffective based on the known relevant physical
12	or mental characteristics of the insured/patient and the known characteristics of the drug regimen;
13	(iii) The enrollee has tried the step therapy required drug while under their current or a
14	previous health plan, or another drug in the same pharmacologic class or with the same
15	mechanism of action and such drugs were discontinued due to lack of efficacy or effectiveness,
16	diminished effect, or an adverse event; or
17	(iv) The patient is stable on a drug recommended by their health care provider for the
18	medical condition under consideration, based on, but not limited to, a trial with medication
19	samples or a prescription filled at a pharmacy.
20	(3) Effect of exception. Upon the granting of an exception request, the insurer, health
21	plan, utilization review organization, or other entity shall authorize dispensation of and coverage
22	for the drug prescribed by the enrollee's treating health care provider, provided such drug is a
23	covered drug under such policy or contract.
24	(4) Limitations. This section shall not be construed to prevent:
25	(i) An insurer, health plan, or utilization review organization from requiring an enrollee
26	try an AB-rated generic equivalent prior to providing reimbursement for the equivalent branded
27	<u>drug;</u>
28	(ii) A health care provider from prescribing a drug he or she determines is medically
29	appropriate.
30	(e) Regulations. Notwithstanding any general or special law to the contrary, the division
31	of insurance shall promulgate any regulations necessary to enforce this section.
32	SECTION 6. This act shall take effect upon passage and shall apply to health insurance
33	policies and health benefit plans delivered, issued for delivery, or renewed on or after January 1,
34	2016.

LC002579

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## **EXPLANATION**

### BY THE LEGISLATIVE COUNCIL

OF

## AN ACT

## RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES

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This act would require that a step therapy protocol be included in all health care insurance policies and health insurance plans.

This act would take effect upon passage and would apply to health insurance policies and health benefit plans delivered, issued for delivery, or renewed on or after January 1, 2016.

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