

Senate File 436

S-3301

1 Amend Senate File 436 as follows:

2 1. By striking everything after the enacting clause and
3 inserting:

4 <Section 1. NEW SECTION. 514F.7 Use of step therapy
5 protocols.

6 1. *Definitions.* For the purposes of this section:

7 a. "*Authorized representative*" means the same as defined in
8 section 514J.102.

9 b. "*Clinical practice guidelines*" means a systematically
10 developed statement to assist health care professionals and
11 covered persons in making decisions about appropriate health
12 care for specific clinical circumstances and conditions.

13 c. "*Clinical review criteria*" means the same as defined in
14 section 514J.102.

15 d. "*Covered person*" means the same as defined in section
16 514J.102.

17 e. "*Health benefit plan*" means the same as defined in
18 section 514J.102.

19 f. "*Health care professional*" means the same as defined in
20 section 514J.102.

21 g. "*Health care services*" means the same as defined in
22 section 514J.102.

23 h. "*Health carrier*" means an entity subject to the
24 insurance laws and regulations of this state, or subject
25 to the jurisdiction of the commissioner, including an
26 insurance company offering sickness and accident plans, a
27 health maintenance organization, a nonprofit health service
28 corporation, a plan established pursuant to chapter 509A
29 for public employees, or any other entity providing a plan
30 of health insurance, health care benefits, or health care
31 services. "*Health carrier*" includes an organized delivery
32 system. "*Health carrier*" does not include a managed care
33 organization as defined in 441 IAC 73.1 when the managed care
34 organization is acting pursuant to a contract with the Iowa
35 department of human services to provide services to Medicaid

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(amending this SF 436 to CONFORM to HF 233)

1 recipients.

2 *i. "Pharmaceutical sample"* means a unit of a prescription
3 drug that is not intended to be sold and is intended to promote
4 the sale of the drug.

5 *j. "Step therapy override exception"* means a step therapy
6 protocol should be overridden in favor of coverage of the
7 prescription drug selected by a health care professional
8 within the applicable time frames and in compliance with the
9 requirements specified in section 505.26, subsection 7, for a
10 request for prior authorization of prescription drug benefits.
11 This determination is based on a review of the covered person's
12 or health care professional's request for an override, along
13 with supporting rationale and documentation.

14 *k. "Step therapy protocol"* means a protocol or program that
15 establishes a specific sequence in which prescription drugs for
16 a specified medical condition and medically appropriate for
17 a particular covered person are covered under a pharmacy or
18 medical benefit by a health carrier, a health benefit plan, or
19 a utilization review organization, including self-administered
20 drugs and drugs administered by a health care professional.

21 *l. "Utilization review"* means a program or process by which
22 an evaluation is made of the necessity, appropriateness, and
23 efficiency of the use of health care services, procedures, or
24 facilities given or proposed to be given to an individual.
25 Such evaluation does not apply to requests by an individual or
26 provider for a clarification, guarantee, or statement of an
27 individual's health insurance coverage or benefits provided
28 under a health benefit plan, nor to claims adjudication.
29 Unless it is specifically stated, verification of benefits,
30 preauthorization, or a prospective or concurrent utilization
31 review program or process shall not be construed as a guarantee
32 or statement of insurance coverage or benefits for any
33 individual under a health benefit plan.

34 *m. "Utilization review organization"* means an entity that
35 performs utilization review, other than a health carrier

1 performing utilization review for its own health benefit plans.

2 2. *Establishment of step therapy protocols.* A health
3 carrier, health benefit plan, or utilization review
4 organization shall consider available recognized evidence-based
5 and peer-reviewed clinical practice guidelines when
6 establishing a step therapy protocol. Upon written request
7 of a covered person, a health carrier, health benefit plan,
8 or utilization review organization shall provide any clinical
9 review criteria applicable to a specific prescription drug
10 covered by the health carrier, health benefit plan, or
11 utilization review organization.

12 3. *Step therapy override exceptions process transparency.*

13 a. When coverage of a prescription drug for the
14 treatment of any medical condition is restricted for use
15 by a health carrier, health benefit plan, or utilization
16 review organization through the use of a step therapy
17 protocol, the covered person and the prescribing health
18 care professional shall have access to a clear, readily
19 accessible, and convenient process to request a step therapy
20 override exception. A health carrier, health benefit plan, or
21 utilization review organization may use its existing medical
22 exceptions process to satisfy this requirement. The process
23 used shall be easily accessible on the internet site of the
24 health carrier, health benefit plan, or utilization review
25 organization.

26 b. A step therapy override exception shall be approved by
27 a health carrier, health benefit plan, or utilization review
28 organization if any of the following circumstances apply:

29 (1) The prescription drug required under the step therapy
30 protocol is contraindicated pursuant to the drug manufacturer's
31 prescribing information for the drug or, due to a documented
32 adverse event with a previous use or a documented medical
33 condition, including a comorbid condition, is likely to do any
34 of the following:

35 (a) Cause an adverse reaction to a covered person.

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1 (b) Decrease the ability of a covered person to achieve
2 or maintain reasonable functional ability in performing daily
3 activities.

4 (c) Cause physical or mental harm to a covered person.

5 (2) The prescription drug required under the step therapy
6 protocol is expected to be ineffective based on the known
7 clinical characteristics of the covered person, such as the
8 covered person's adherence to or compliance with the covered
9 person's individual plan of care, and any of the following:

10 (a) The known characteristics of the prescription drug
11 regimen as described in peer-reviewed literature or in the
12 manufacturer's prescribing information for the drug.

13 (b) The health care professional's medical judgment based
14 on clinical practice guidelines or peer-reviewed journals.

15 (c) The covered person's documented experience with the
16 prescription drug regimen.

17 (3) The covered person has had a trial of a therapeutically
18 equivalent dose of the prescription drug under the step
19 therapy protocol while under the covered person's current or
20 previous health benefit plan for a period of time to allow for
21 a positive treatment outcome or of another prescription drug
22 in the same pharmacologic class or with the same mechanism
23 of action, and such prescription drug was discontinued by
24 the covered person's health care professional due to lack of
25 effectiveness.

26 (4) The covered person is currently receiving a positive
27 therapeutic outcome on a prescription drug selected by the
28 covered person's health care professional for the medical
29 condition under consideration while under the covered person's
30 current or previous health benefit plan. This subparagraph
31 shall not be construed to encourage the use of a pharmaceutical
32 sample for the sole purpose of meeting the requirements for a
33 step therapy override exception.

34 c. Upon approval of a step therapy override exception, the
35 health carrier, health benefit plan, or utilization review

1 organization shall authorize coverage for the prescription
2 drug selected by the covered person's prescribing health care
3 professional if the prescription drug is a covered prescription
4 drug under the covered person's health benefit plan.

5 *d.* A health carrier, health benefit plan, or utilization
6 review organization shall make a determination to approve or
7 deny a request for a step therapy override exception within the
8 applicable time frames and in compliance with the requirements
9 specified in section 505.26, subsection 7, for a request for
10 prior authorization of prescription drug benefits.

11 *e.* If a request for a step therapy override exception is
12 denied, the health carrier, health benefit plan, or utilization
13 review organization shall provide the covered person or the
14 covered person's authorized representative and the patient's
15 prescribing health care professional with the reason for the
16 denial and information regarding the procedure to request
17 external review of the denial pursuant to chapter 514J. Any
18 denial of a request for a step therapy override exception
19 that is upheld on appeal shall be considered a final adverse
20 determination for purposes of chapter 514J and is eligible
21 for a request for external review by a covered person or the
22 covered person's authorized representative pursuant to chapter
23 514J.

24 *4. Limitations.* This section shall not be construed to do
25 either of the following:

26 *a.* Prevent a health carrier, health benefit plan, or
27 utilization review organization from requiring a covered
28 person to try a prescription drug with the same generic name
29 and demonstrated bioavailability or a biological product that
30 is an interchangeable biological product pursuant to section
31 155A.32 prior to providing coverage for the equivalent branded
32 prescription drug.

33 *b.* Prevent a health care professional from prescribing
34 a prescription drug that is determined to be medically
35 appropriate.

1 Sec. 2. APPLICABILITY. This Act is applicable to a health
2 benefit plan that is delivered, issued for delivery, continued,
3 or renewed in this state on or after January 1, 2018.>

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