State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 815

02/07/2019 Authored by Acomb, Hamilton, Zerwas, Halverson, Loeffler and others
The bill was read for the first time and referred to the Committee on Health and Human Services Policy

A bill for an act

relating to human services; applying step therapy override procedures to state public health care programs; amending Minnesota Statutes 2018, sections 62Q.184, subdivisions 1, 3; 256B.0625, subdivision 13f.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. Minnesota Statutes 2018, section 62Q.184, subdivision 1, is amended to read:

Subdivision 1. **Definitions.** (a) For the purposes of this section, the terms in this subdivision have the meanings given them.

(b) "Clinical practice guideline" means a systematically developed statement to assist health care providers and enrollees in making decisions about appropriate health care services for specific clinical circumstances and conditions developed independently of a health plan company, pharmaceutical manufacturer, or any entity with a conflict of interest. A clinical practice guideline also includes a preferred drug list developed in accordance with section 256B.0625.

(c) "Clinical review criteria" means the written screening procedures, decision abstracts, clinical protocols, and clinical practice guidelines used by a health plan company to determine the medical necessity and appropriateness of health care services.

(d) "Health plan company" has the meaning given in section 62Q.01, subdivision 4, but ~~does not include a managed care organization or~~ also includes a county-based purchasing plan participating in a public program under chapter 256B or 256L~~, or~~ and an integrated health partnership under section 256B.0755.

(e) "Step therapy protocol" means a protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered and physician-administered drugs, are medically appropriate for a particular enrollee and are covered under a health plan.

(f) "Step therapy override" means that the step therapy protocol is overridden in favor of coverage of the selected prescription drug of the prescribing health care provider because at least one of the conditions of subdivision 3, paragraph (a), exists.

Sec. 2. Minnesota Statutes 2018, section 62Q.184, subdivision 3, is amended to read:

Subd. 3. **Step therapy override process; transparency.** (a) When coverage of a prescription drug for the treatment of a medical condition is restricted for use by a health plan company through the use of a step therapy protocol, enrollees and prescribing health care providers shall have access to a clear, readily accessible, and convenient process to request a step therapy override. The process shall be made easily accessible on the health plan company's website. A health plan company may use its existing medical exceptions process to satisfy this requirement. A health plan company shall grant an override to the step therapy protocol if at least one of the following conditions exist:

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

(i) cause an adverse reaction to the enrollee;

(ii) decrease the ability of the enrollee to achieve or maintain reasonable functional ability in performing daily activities; or

(iii) cause physical or mental harm to the enrollee;

(2) the enrollee has had a trial of the required prescription drug covered by their current or previous health plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and was adherent during such trial for a period of time sufficient to allow for a positive treatment outcome, and the prescription drug was discontinued by the enrollee's health care provider due to lack of effectiveness, or an adverse event. This clause does not prohibit a health plan company from requiring an enrollee to try another drug in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by the evidence-based and peer-reviewed clinical practice

guideline, Food and Drug Administration label, or pharmaceutical manufacturer's prescribing information; or

(3) the enrollee is currently receiving a positive therapeutic outcome on a prescription drug for the medical condition under consideration if, while on their current health plan or the immediately preceding health plan, the enrollee received coverage for the prescription drug and the enrollee's prescribing health care provider gives documentation to the health plan company that the change in prescription drug required by the step therapy protocol is expected to be ineffective or cause harm to the enrollee based on the known characteristics of the specific enrollee and the known characteristics of the required prescription drug.

(b) Upon granting a step therapy override, a health plan company shall authorize coverage for the prescription drug if the prescription drug is a covered prescription drug under the enrollee's health plan.

(c) The enrollee, or the prescribing health care provider if designated by the enrollee, may appeal the denial of a step therapy override by a health plan company using the complaint procedure under sections 62Q.68 to 62Q.73 or 256.045.

(d) In a denial of an override request and any subsequent appeal, a health plan company's decision must specifically state why the step therapy override request did not meet the condition under paragraph (a) cited by the prescribing health care provider in requesting the step therapy override and information regarding the procedure to request external review of the denial pursuant to section 62Q.73. A denial of a request for a step therapy override that is upheld on appeal is a final adverse determination for purposes of section 62Q.73 and is eligible for a request for external review by an enrollee pursuant to section 62Q.73.

(e) A health plan company shall respond to a step therapy override request or an appeal within five days of receipt of a complete request. In cases where exigent circumstances exist, a health plan company shall respond within 72 hours of receipt of a complete request. If a health plan company does not send a response to the enrollee or prescribing health care provider if designated by the enrollee within the time allotted, the override request or appeal is granted and binding on the health plan company.

(f) Step therapy override requests must be accessible to and submitted by health care providers, and accepted by group purchasers electronically through secure electronic transmission, as described under section 62J.497, subdivision 5.

(g) Nothing in this section prohibits a health plan company from:

(1) requesting relevant documentation from an enrollee's medical record in support of a step therapy override request; or

(2) requiring an enrollee to try a generic equivalent drug pursuant to section 151.21, or a biosimilar, as defined under United States Code, chapter 42, section 262(i)(2), prior to providing coverage for the equivalent branded prescription drug.

(h) This section shall not be construed to allow the use of a pharmaceutical sample for the primary purpose of meeting the requirements for a step therapy override.

Sec. 3. Minnesota Statutes 2018, section 256B.0625, subdivision 13f, is amended to read:

Subd. 13f. **Prior authorization.** (a) The Formulary Committee shall review and recommend drugs which require prior authorization. The Formulary Committee shall establish general criteria to be used for the prior authorization of brand-name drugs for which generically equivalent drugs are available, but the committee is not required to review each brand-name drug for which a generically equivalent drug is available.

(b) Prior authorization may be required by the commissioner before certain formulary drugs are eligible for payment. The Formulary Committee may recommend drugs for prior authorization directly to the commissioner. The commissioner may also request that the Formulary Committee review a drug for prior authorization. Before the commissioner may require prior authorization for a drug:

(1) the commissioner must provide information to the Formulary Committee on the impact that placing the drug on prior authorization may have on the quality of patient care and on program costs, information regarding whether the drug is subject to clinical abuse or misuse, and relevant data from the state Medicaid program if such data is available;

(2) the Formulary Committee must review the drug, taking into account medical and clinical data and the information provided by the commissioner; and

(3) the Formulary Committee must hold a public forum and receive public comment for an additional 15 days.

The commissioner must provide a 15-day notice period before implementing the prior authorization.

(c) Except as provided in subdivision 13j, prior authorization shall not be required or utilized for any atypical antipsychotic drug prescribed for the treatment of mental illness if:

(1) there is no generically equivalent drug available; and

(2) the drug was initially prescribed for the recipient prior to July 1, 2003; or

(3) the drug is part of the recipient's current course of treatment.

This paragraph applies to any multistate preferred drug list or supplemental drug rebate program established or administered by the commissioner. Prior authorization shall automatically be granted for 60 days for brand name drugs prescribed for treatment of mental illness within 60 days of when a generically equivalent drug becomes available, provided that the brand name drug was part of the recipient's course of treatment at the time the generically equivalent drug became available.

(d) Prior authorization shall not be required or utilized for any antihemophilic factor drug prescribed for the treatment of hemophilia and blood disorders where there is no generically equivalent drug available if the prior authorization is used in conjunction with any supplemental drug rebate program or multistate preferred drug list established or administered by the commissioner.

(e) The commissioner may require prior authorization for brand name drugs whenever a generically equivalent product is available, even if the prescriber specifically indicates "dispense as written-brand necessary" on the prescription as required by section 151.21, subdivision 2.

(f) Notwithstanding this subdivision, the commissioner may automatically require prior authorization, for a period not to exceed 180 days, for any drug that is approved by the United States Food and Drug Administration on or after July 1, 2005. The 180-day period begins no later than the first day that a drug is available for shipment to pharmacies within the state. The Formulary Committee shall recommend to the commissioner general criteria to be used for the prior authorization of the drugs, but the committee is not required to review each individual drug. In order to continue prior authorizations for a drug after the 180-day period has expired, the commissioner must follow the provisions of this subdivision.

(g) Prior authorization under this subdivision shall comply with section 62Q.184.