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State of Minnesota

HOUSE OF REPRESENTATIVES

NINETY-FIRST SESSION

H. F. No. 284

01/22/2019 Authored by Halverson, Mann, Howard, Cantrell, Huot and others
The bill was read for the first time and referred to the Committee on Commerce
03/11/2019 Adoption of Report: Amended and re-referred to the Committee on Health and Human Services Policy
03/13/2019 Adoption of Report: Re-referred to the Judiciary Finance and Civil Law Division

A bill for an act

relating to health care; authorizing the commissioner of health to review costs for insulin products sold in Minnesota; determining if the cost is excessive; establishing a maximum level of reimbursement for insulin products if necessary; appropriating money; proposing coding for new law in Minnesota Statutes, chapter 62J.

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

Section 1. **[62J.871] REPORTING AND REVIEW OF COST OF INSULIN PRODUCTS.**

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

(b) "Commissioner" means the commissioner of health.

(c) "Excess cost" means the cost of appropriate utilization of an insulin product that is not sustainable to public and private health care systems in this state over a ten-year time period.

(d) "Group purchaser" has the meaning given in section 62J.03, subdivision 6, and includes pharmacy benefit managers, but does not include state and federal public health care programs.

(e) "Wholesale acquisition cost" or "WAC" has the meaning given in United States Code, title 42, section 1395W-3a(c)(6)(B).

Subd. 2. **Manufacturer reporting requirement; excess costs review.** (a) Each manufacturer of an insulin product made available in Minnesota must report to the commissioner of health by September 1, 2019, the wholesale acquisition cost for each insulin

product offered for sale in Minnesota. A manufacturer may submit with this report any documents or research related to the price, including, but not limited to:

(1) life cycle management;

(2) net average price in Minnesota that includes the net of all price concessions, such as discounts and rebates, but excludes in-kind concessions;

(3) market competition and context;

(4) projected revenue; and

(5) if available, estimated value or cost-effectiveness of the insulin product.

(b) The commissioner shall review the cost of an insulin product reported to the commissioner under this subdivision and make a determination as to whether appropriate utilization of the insulin product, based on utilization that is consistent with the United States Food and Drug Administration (FDA) label, has led or will lead to excess costs for the health care systems in this state.

(c) The commissioner may consider the following factors in determining excess costs:

(1) the price at which the insulin product has been and will be sold in this state;

(2) the average monetary price concession, discount, or rebate the manufacturer provides to a group purchaser in this state as reported by the manufacturer and the group purchaser expressed as a percent of the WAC for the insulin product;

(3) the total amount of the concession, discount, or rebate the manufacturer provides to each pharmacy benefit manager operating in this state for the insulin product, expressed as a percent of the wholesale acquisition cost;

(4) the price at which therapeutic alternatives have been or will be sold in this state;

(5) the average monetary price concession, discount, or rebate the manufacturer provides or is expected to provide to a group purchaser in the state or is expected to provide to group purchasers in the state for therapeutic alternatives;

(6) the cost to group purchasers based on patient access consistent with federal Food and Drug Administration (FDA) labeled indications;

(7) the impact on patient access resulting from the cost of the insulin product relative to insurance benefit design;

(8) the current or expected dollar value of insulin-specific patient access programs that are supported by manufacturers;

(9) the relative financial impacts to health, medical, or other social services costs that can be quantified and compared to baseline effects of existing therapeutic alternatives; and

(10) any other factors as determined by the commissioner.

(d) If, after considering the factors described in paragraph (c), the commissioner is unable to determine whether an insulin product will produce or has produced excess costs using the factors described, the commissioner may consider the following factors:

(1) manufacturer research and development costs, as indicated on the manufacturer's federal tax filing for the most recent tax year in proportion to the manufacturer's sales in this state;

(2) the portion of direct-to-consumer marketing costs eligible for favorable federal tax treatment in the most recent tax year that is specific to the insulin product under review and is multiplied by the ratio of total manufacturer in-state sales to total manufacturer sales in the United States for the insulin product under review;

(3) gross and net manufacturer revenues for the most recent tax year; and

(4) any additional factors as determined by the commissioner to be relevant.

(e) Notwithstanding section 62U.04, subdivision 11, the commissioner may use the Minnesota all-payer claims database (APCD) to conduct the analysis required under this section.

(f) Prior to making a determination on the cost of an insulin product, the commissioner shall provide an opportunity for the public to provide comments, including an opportunity to submit written comments to the commissioner.

Subd. 3. **Advisory work group.** (a) The commissioner may convene a work group to provide advice to the commissioner on insulin cost issues and to represent stakeholders' views. If convened, the members of the work group must have demonstrated knowledge and expertise in one or more of the following areas: health care cost trends and drivers; practice of medicine; pharmaceutical business; patient perspectives; clinical and health care research; and the health care marketplace.

(b) A work group member must disclose to the commissioner any conflicts of interest, including the type, nature, and magnitude of the interests involved. For purposes of this subdivision, a conflict of interest means a financial or personal association that has the potential to bias or have the appearance of biasing a person's decisions in matters relating to the commissioner's duties under this section or before the work group.

Subd. 4. **Public data; proprietary information.** (a) Any submission made to the commissioner related to a insulin cost review shall be made available to the public with the exception of information determined by the commissioner to be proprietary or information that could qualify as a trade secret.

(b) The commissioner shall establish the standards for the information to be considered proprietary under paragraph (a), including standards for heightened consideration of proprietary information for submissions for a cost review of a drug that is not yet approved by the federal Food and Drug Administration.

(c) Prior to the commissioner establishing the standards under paragraph (b), the public shall be provided notice and the opportunity to submit comments.

Subd. 5. **Determinations; compliance; remedies.** (a) In the event the commissioner finds that the spending on an insulin product reviewed under this section creates excess costs for group purchasers and consumers, the commissioner shall establish a maximum level of reimbursement to be billed and paid among:

(1) group purchasers and pharmacies or administering entities;

(2) wholesale distributors and pharmacies or administering entities; and

(3) pharmacies or administering entities and uninsured consumers or consumers who are enrolled in a health plan but who have not yet met the health plan's deductible.

(b) The maximum level of reimbursement set by the commissioner under paragraph (a) must not create more than a 50 percent net profit margin for the manufacturer. For purposes of this subdivision, "net profit margin" means a financial ratio used to calculate the percentage of profit a manufacturer produces from its total revenue. The net profit margin is equal to net profit divided by total revenue.

(c) The commissioner shall determine how each participant in the supply chain of the insulin product shall be remunerated.

(d) An entity who obtains price concessions from a drug manufacturer that results in a lower net cost to the stakeholder than the maximum rate established by the commissioner shall not be considered to be out of compliance.

(e) The Office of the Attorney General shall provide guidance to stakeholders concerning activities that could be considered noncompliant that are in addition to billing and payment where drug costs exceed the rates established by the commissioner.

(f) The noncompliance of an entity to bill or pay a reimbursement rate in accordance with the rate established by the commissioner under this subdivision shall be referred to the Office of the Attorney General. If the Office of the Attorney General finds that an entity was noncompliant with the commissioner reimbursement requirements, the attorney general may pursue remedies consistent with chapter 8 or appropriate criminal charges if there is evidence of intentional profiteering.

Subd. 6. **Compliance with reporting.** If a drug manufacturer fails to report to the commissioner as required by this section, or submit any information requested by the commissioner under this section, the commissioner may refer the matter to the attorney general for review and possible action as permitted under chapter 8; or may establish a maximum level of reimbursement as authorized under subdivision 5 without the reported information from the manufacturer. If the commissioner establishes a maximum level of reimbursement due to noncompliance of the reporting requirements, the manufacturer does not have the right to appeal the commissioner's decision as permitted under subdivision 7.

Subd. 7. **Appeals.** (a) Persons affected by a decision of the commissioner may request an appeal of the commissioner's decision within 30 days of the date of the decision. The commissioner shall hear the appeal and render a decision within 60 days of the hearing.

(b) All appeal decisions are subject to judicial review in accordance with chapter 14.

Sec. 2. **APPROPRIATION.**

$..... in fiscal year 2020 is appropriated from the general fund to the commissioner of health for the implementation of section 1.