

MINNESOTA BOARD OF PHARMACY

Report to the Legislature on the Minnesota Insulin Safety Net Program. (In compliance with Minnesota Statutes Section 151.74, Subd. 13)

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COST OF REPORT

Minnesota Statutes §3.197 states that a "report to the legislature must contain, at the beginning of the report, the cost of preparing the report, including any costs incurred by another agency or another level of government". The estimated cost of preparing this report was \$400.00. That is the approximate value, in terms of salary and benefits, of the time that Board staff spent preparing the report.				
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Introduction

The Board of Pharmacy (Board) is submitting this report to the Legislature in compliance with Minn. Stats. §151.74, subdivision 13, which states:

- Subd. 13. **Reports.** (a) By February 15 of each year, beginning February 15, 2021, each manufacturer shall report to the Board of Pharmacy the following:
- (1) the number of Minnesota residents who accessed and received insulin on an urgent-need basis under this section in the preceding calendar year;
- (2) the number of Minnesota residents participating in the manufacturer's patient assistance program in the preceding calendar year, including the number of Minnesota residents who the manufacturer determined were ineligible for their patient assistance program; and
- (3) the value of the insulin provided by the manufacturer under clauses (1) and (2).

For purposes of this paragraph, "value" means the wholesale acquisition cost of the insulin provided.

(b) By March 15 of each year, beginning March 15, 2021, the Board of Pharmacy shall submit the information reported in paragraph (a) to the chairs and ranking minority members of the legislative committees with jurisdiction over health and human services policy and finance. The board shall also include in the report any administrative penalties assessed under subdivision 10, including the name of the manufacturer and amount of the penalty assessed.

Reporting By Manufacturers

The four manufacturers participating in the Minnesota Insulin Safety Net Program are Eli Lilly and Company, Sanofi, Novo Nordisk, and Viatris. All four manufacturers submitted the required data for calendar year 2022 by the February 15, 2022 deadline. The data and other information reported are provided below.

The data submitted indicates that, collectively, the four manufacturers provided insulin under the Minnesota Insulin Safety Net Program to as many as **347 residents**. Since some residents may have received insulin under both the Urgent and Continuing Needs Programs, fewer total residents may have benefited. The total value of the insulin received by residents was **\$264,106.08**. (Based on the wholesale acquisition cost of the insulin – not the cost that the residents would have paid if they had purchased the insulin on their own). Note, the 2022 Insulin Safety Net Report for calendar year 2021 submitted by Novo Nordisk provided the total number of Minnesota residents *participating in their national PAP*, *irrespective if they requested or received coverage as a result of the Act.* Consequently, the reported number of residents having utilized the program and the value of the insulin received were artificially inflated in the 2022 report.

Novo Nordisk's 2023 Insulin Safety Net Report for calendar year 2022 include the number of commercially insured Minnesota patients who were provided free insulin and who are not eligible for coverage under Novo Nordisk's national PAP offering.

Eli Lilly

		Value (WAC) of insulin provided	Number of MN residents who applied but were ineligible for PAP
URGENT NEED PROGRAM	Number of MN residents who received insulin ⁺ : 101	\$65,078.92	N/A
PAP PROGRAM	Number of MN residents participating in PAP ^{+*} : 17	\$62,441.20	3

⁺ The report reflects participation in Lilly's Minnesota patient assistance programs only. Lilly offers a number of other insulin affordability solutions for patients. Minnesota residents may have accessed Lilly insulin through Lilly's other assistance programs, and these patients (and the value of the associated insulin) are not included in this report. Note a patient may have applied to the continuing care program to receive more than one product or used the urgent needs program for more than one product. In those cases, the patient is counted only one time in the respective program.

Novo Nordisk

Novo Nordisk provided the following data:

Urgent Need Recipients	50
Value of Insulin Provided to Urgent Need Recipients	\$31,820.65
Continuing Need Applicants	
Total number of participants	5
Total number of ineligible applicants	15
Value of Insulin Provided to Continuing Need Recipients	\$33,280.94
Total Value of Insulin Provided	\$65,101.59

^{+*} The "Number of MN residents" in the Lilly MN PAP Program reflects the number of unique patients who received product in 2022. This includes individuals who enrolled in 2021, but who continued to receive product in 2022 (when their enrollment expired), as well as new patients who enrolled in the program and received product in 2022.

Sanofi

Sanofi provided the following submission notes:

- 1. WAC = Wholesale Acquisition Cost
- 2. The below figures are reflective of the Minnesota mandated programs that Sanofi offers only and do not include data for any other Sanofi run programs
- 3. *The "manufacturer's patient assistance program" in Clause 2 below is only referring to the Minnesota mandated program that Sanofi offers
- 4. **The "Total number of participants" in Clause 2 below means the total number of Minnesota residents that received at least 1 shipment of product in calendar year 2022

Sanofi provided the following data:

Urgent Need Recipients	143
Value of Insulin Provided to Urgent Need Recipients	\$64,819
Continuing Need Applicants* (Clause 2)	
Total number of applicants	31
Total number of ineligible applicants	1
Value of Insulin Provided to Continuing Need Recipients	\$6,665.37
Total Value of Insulin Provided	\$71,484.37

Viatris

Viatris provided the following submission notes:

Until November 2022, Viatris has been previously exempt from the requirements codified at Minn. Stat. 151.74 (2020) (the "Act") because we had annual gross revenue from the sale of insulin in Minnesota of less than \$2 million. Based on sales data, we believe that we surpassed the sales threshold in November 2022, and we implemented our insulin affordability and urgent need programs on November 22, 2022. We do not have any data to report for the brief period in 2022 during which we became subject to the Minnesota requirements. We send this communication to inform you that we have nothing to report for calendar year 2022. Below is the format of the request for your reference:

Viatris provided the following data:

Urgent Need Recipients	0
Value of Insulin Provided to Urgent Need	\$0
Recipients	
Number of MN residents participating in	0
patient assistance programs (PAP)*	
Total number of applicants	0
Total number of ineligible applicants	0
Value of Insulin Provided to PAP patients	\$0
Number of MN residents participating in MN	0
Continuing Need Program*	
Total number of applicants	0
Total number of ineligible applicants	0
Value of Insulin Provided to Continuing Need	\$0
Recipients	
Total Value of Insulin Provided in MN	\$0

Assessment of Civil Penalties

The four insulin manufacturers complied with the provisions of Minn. Stats. §151.74. Consequently, the Board did not assess any civil penalties under subdivision 10.