The Insulin Affordability Crisis: A Policy Proposal to Protect Minnesotans

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Abstract

The increasing prevalence of diabetes mellitus creates serious economic and health burdens for the state of Minnesota, which have been exacerbated by rising insulin prices. Factors contributing to cost increases include the controversial negotiations between pharmaceutical manufacturers and insurance companies, the lack of price transparency, and the scarcity of generic insulin options. This proposal recommends that Minnesota Legislature create a Prescription Drug Cost Review Board and Stakeholder Advisory Council to monitor drug prices and set statewide upper payment limits. This policy will protect Minnesotans from the undue burden of rising medication costs.

Problem

Global rates of diabetes mellitus are on the rise [1,2], and Minnesota has been severely afflicted by the health and economic burdens associated with this increasingly common condition [3]. As the prevalence of diabetes increases [4,5], America witnesses an alarming spike in insulin prices [6,7]. In Minnesota, the prohibitive cost of insulin caused the untimely death of 26—year—old Alec Smith, who developed diabetic ketoacidosis (DKA) after rationing his insulin. Due to his age, Smith had been removed from his parents health insurance and was unable to find affordable medication options [8]. This crisis demands policy intervention to reduce insulin costs and increase access to affordable prescriptions in Minnesota.

Magnitude of the Problem

In 2017, the Minnesota Department of Health (MDH) estimated that 386,480 Minnesotan adults had diabetes (7.9% of the state population), and an additional 18,000 are diagnosed each year (Figure 1) [3,9,10]. Rising diabetes rates have serious economic implications [11,12], and the Centers for Disease Control and Prevention (CDC) estimate the national average excess medical costs for a person with diabetes is $9,601 per year [5]. The annual cost to Minnesota for diabetes—related care is $4.7 billion and another $373 million per year for undiagnosed diabetics [9]. Recently, out—of—pocket costs were capped at $25 per month for individuals insured through Medica; however, many Minnesotans still pay hundreds per month in out—of—pocket expenses [13].

While exogenous insulin has improved since it was first discovered [14], prices have disproportionately increased over the past few decades, with a drastic upsurge in list prices [6,7,15]. Recent examples include Lantus (glargine), which increased by 171.3% per vial between 2010 and 2018, and HumaLog (lispro), which increased by 124.1% per vial from 2011 to 2017 [16]. While health insurance covers some of these costs, and the number of vials individuals require per month varies considerably, people with high—premium health plans and senior citizens on Medicare without prescription drug coverage still face financial strains. The estimated 350,000 Minnesotans without insurance must bear the full burden of list prices [16,17]. These financial barriers have serious ramifications, as insufficient insulin can lead to heart attack, stroke, DKA, and death [18], as was the unfortunate case for Alec Smith.

Political, Social, and Economic Factors

Insurance companies enlist third—party negotiators, called pharmacy benefit managers (PBMs), to arrange discounts with drug manufacturers [16,19].

Pharmaceutical companies set two prices for insulin: list price and net price. List price is the total reported cost, and net price is the amount insurance providers pay pharmaceutical companies after a discount [19]. The gap between these two prices, called the spread, determines the profit for pharmaceuticals and PBMs [16]. Drug manufacturers have increased the list price of insulin dramatically since 2007, yet the net price has grown at a much slower rate, even decreasing recently [20], leading to larger profit margins and a significant financial burden for diabetics (Figure 2) [20,21]. Several Attorneys General across the United States, including Minnesota, filed lawsuits against drug manufacturers for allegedly raising the list prices of prescription drugs to increase profits [16].

Patents and other regulations have resulted in few generic or biosimilar options [22]. Although insulin was originally introduced in the 1920s [14], it has remained on patent for almost a century due to small incremental formulary changes [22]. This loophole has allowed pharmaceuticals to maintain control over insulin even after the original patents expired, inhibiting the price reductions typically seen when generic options become available [23]. Socioeconomic factors contribute to diabetes outcomes as well, since education, income, housing and food security significantly alter diabetes—related mortality risk [24,25]. These disparities will only be heightened if the rampant rise in insulin prices continue.

Previous Policies

In 2019, the Alec Smith Emergency Insulin Act, which included a prescription drug cost review board, had overwhelming bipartisan support in both the Minnesota House and Senate; however, the bill was dropped during final negotiations [26–28]. An updated version of this bill is currently being discussed in the state Legislature [29,30]. Minnesota recently passed price transparency legislation as well [19,31,32], which require PBMs to disclose any price spreading, discounts, payments to pharmacies, and additional network fees. It also empowers the Commissioner of the Minnesota Department of Commerce (MDC) to regulate and remove PBMs licenses in Minnesota [31,32]. While these changes will increase price transparency, they do not take active steps to reduce prescription costs for Minnesotans.

Pressure for Action

In the past decade, insulin prices have increased considerably more than other injectable medications [15,16,33]. If action is not taken, tragic stories like Alec Smith's may become all too common and health disparities in Minnesota may increase [8]. Although the Attorney General has taken legal action against individual pharmaceutical companies, the state Legislature must pass statewide regulatory policies so Minnesota can remain a frontrunner in health and prevent similar catastrophes from happening in the future.

Policy Solution

Establish a Prescription Drug Cost Review Board and Stakeholder Advisory Council to analyze prescription medication costs in Minnesota and, when necessary, institute statewide upper payment limits.

High insulin prices have created an unjustifiable economic burden for Minnesotans with diabetes [8,34,35]. Establishing a Prescription Drug Cost Review Board (the Board, hereafter) and Stakeholder Advisory Council (the Council, hereafter) in Minnesota will reduce prices for essential drugs, like insulin, by monitoring the cost of prescription medications and, when necessary, setting statewide upper payment limits [36,37]. The Board will include five members appointed by the Governor, one member appointed by the Attorney General, and four members from state Legislature. The Council will be comprised of 24 members from consumer, industry, and provider coalitions [37]. Council members will follow typical appointment to a convening entity, through application to the Governor's office and Executive branch approval. The Board will have authority to convene meetings, propose legislation, and ensure price limitations remain constitutional. The Board and the Council will have voting privileges on final cost reviews and will be required to disclose conflicts of interest. Meetings will be open to the public, both in—person and online.

Drug manufacturers will be financially penalized if they do not notify the Board and Council 60—days prior to the following: 1). the wholesale acquisition costs for new brand—name medications entering the market are $30,000 or more per year or treatment course, 2). if existing brand—name medications are increased by more than 10% or $10,000 per year or treatment course, or 3). generic drugs are increased by more than 25% or $300 per year or treatment course, which is congruent with other state legislation [36,37].

The Board and Council will review notifications and determine if the price increase creates undue financial burden for Minnesotans. If so, an in—depth cost review will be conducted, taking no more than 60 days. The cost review process will utilize information from manufacturers, PBMs and health plans to outline the

impact these price changes have on cost sharing, alternative drug pricing, health plan costs, patient access, social service finances, and profit margins. If the price increase creates a significant cost barrier, as defined above, the Board and Council will propose a statewide upper payment limit for the medication, establishing the maximum amount a payer operating in Minnesota will pay for that prescription. The MDH, MDC, Minnesota Department of Human Services, and Minnesota Management and Budget will jointly notify affected stakeholders of these upper payment limits, and stakeholders will be allotted 30 days to respond. Finally, the Board will monitor drug availability to ensure Minnesotans retain access to the medication [36,37].

Effectiveness

This proposal merges legislation recently passed in Maryland and previously introduced in Minnesota [27,38–40] and complements the new price transparency laws. Furthermore, it can assist MDC when deciding to revoke licenses when consistently harmful price increases occur. Minnesota's Medicaid program caps enrollees' out—of—pocket costs for prescription drugs at $12 a month [41]; however, this policy aims to extend financial protection to all Minnesotans, regardless of their insurance status, by setting market—aware upper payment limits.

This proposal aims to limit the amount paid by consumers for particular medications and establishes strong bargaining power for both the state and companies operating in Minnesota when negotiating with drug manufacturers and PBMs for networks and costs. Maryland is among the first states to implement similar legislation [38–40], which provides a unique opportunity for other states to begin proposing similar policies; however, it is too early to determine the level of impact Maryland's legislation has had on drug pricing.

Financial and Administrative Feasibility

Since members of the Council are not elected officials and will not receive legislative salaries, they will receive $5,000 annually for their membership. The Board and Council will be established with General Funds from the supplemental budget during the first two years of operation, which is expected to total $240,000. Funding after the first two years will be sustained through the Health Care Access Fund (HCAF) [41].

Using funding from the HCAF may face bipartisan resistance since both the Provider Tax and Wholesale Drug Distributor Tax were just reduced from 2% to 1.8%, beginning in 2020 [42,43]. These tax reductions tighten the budget of the HCAF, which supports a number of important recurrent expenditures [41]. Additional expenses in this budget may be a difficult political lift. However, given the magnitude of the HCAF, which is hundreds of millions, these proposed costs are relatively small.

Political Feasibility

Minnesota has split control in the legislature, with a democratic Governor, democrat—controlled House, and republican—controlled Senate [44]. This political dynamic requires all parties to approach policy with authenticity and compromise. As the 2020 legislative session continues, the feasibility of this proposal may be strained as the second year of the legislative biennium focuses on capital investment, or bonding, projects. Furthermore, as other priorities arise, such as the coronavirus pandemic, drug transparency legislation may fall lower on the agenda.

This proposal may face opposition from drug manufacturers due to the payment limits. However, to offset these challenges, the Council may include pharmaceutical representation, if selected. This mirrors the legislation in Maryland [38–40], as representation during the decision—making process of upper payment limits may appease opposed stakeholders.

Ethical Feasibility

Opponents of similar legislation might suggest that drug manufacturers will avoid states that impose upper payment limits, which would negatively impact people requiring those life—saving medications. While the Board and Council will monitor this, it is unlikely to occur as drug manufacturers would have to implement significant changes in supply chain operations to prevent the sale of their products in Minnesota [36]. Additionally, drug manufacturers already sell prescription drugs at different price points, but this policy may catalyze them to adjust prices in other states or slightly increase multiple other medication costs in Minnesota to offset these policies, which is cause for concern. However, the Board and Council will work to remain within the law of the Commerce Clause, which prohibits state laws from significantly burdening interstate business [37].

Policy Recommendation

One possible policy to effectively address the skyrocketing prescription drug prices in Minnesota is to establish a Prescription Drug Cost Review Board and Stakeholder Advisory Council.

Justification

The state of Minnesota can use both the expertise of the Council and the influence of the Board to wield the state's purchasing power by setting upper payment limits for prescription drugs, while remaining aware of market competition. When drug manufacturer price increases exceed the limits outlined in this proposal, the mandated reports and review process will help Minnesota Legislature to mitigate the financial burden associated with prescription medications. This will prevent avoidable health consequences, such as the untimely death of Alec Smith, protect people who require life—saving medications, like insulin, and make those prescriptions affordable to all Minnesotans.

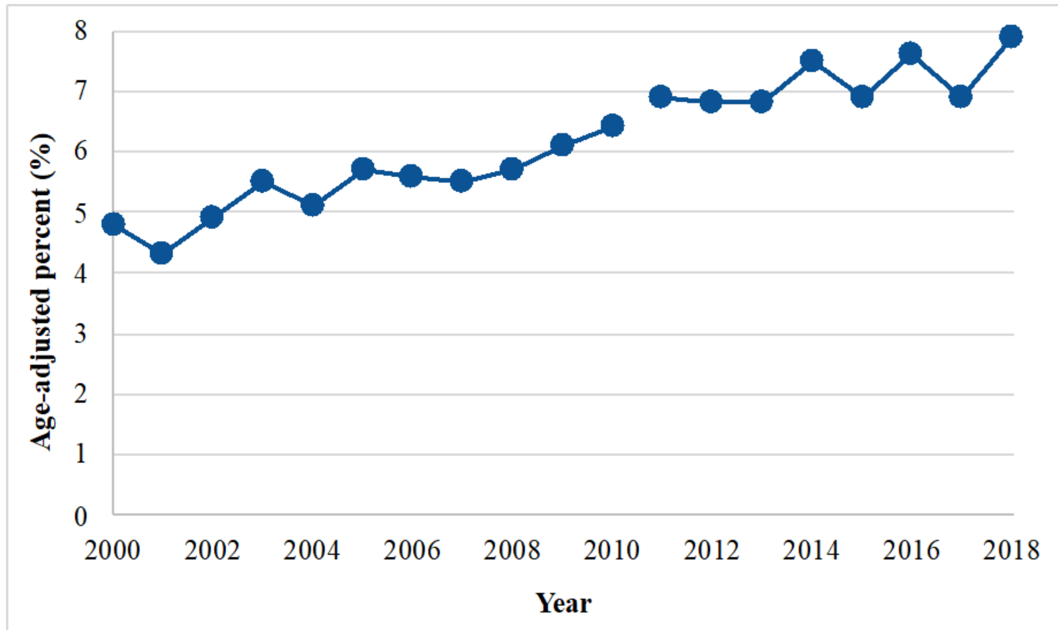

Figure 1: *Adults with diabetes in Minnesota by year, age—adjusted percent. A change in survey methods occurred between 2010 and 2011.* Created by the authors using data from the CDC National Diabetes Surveillance System, Minnesota Data [10].

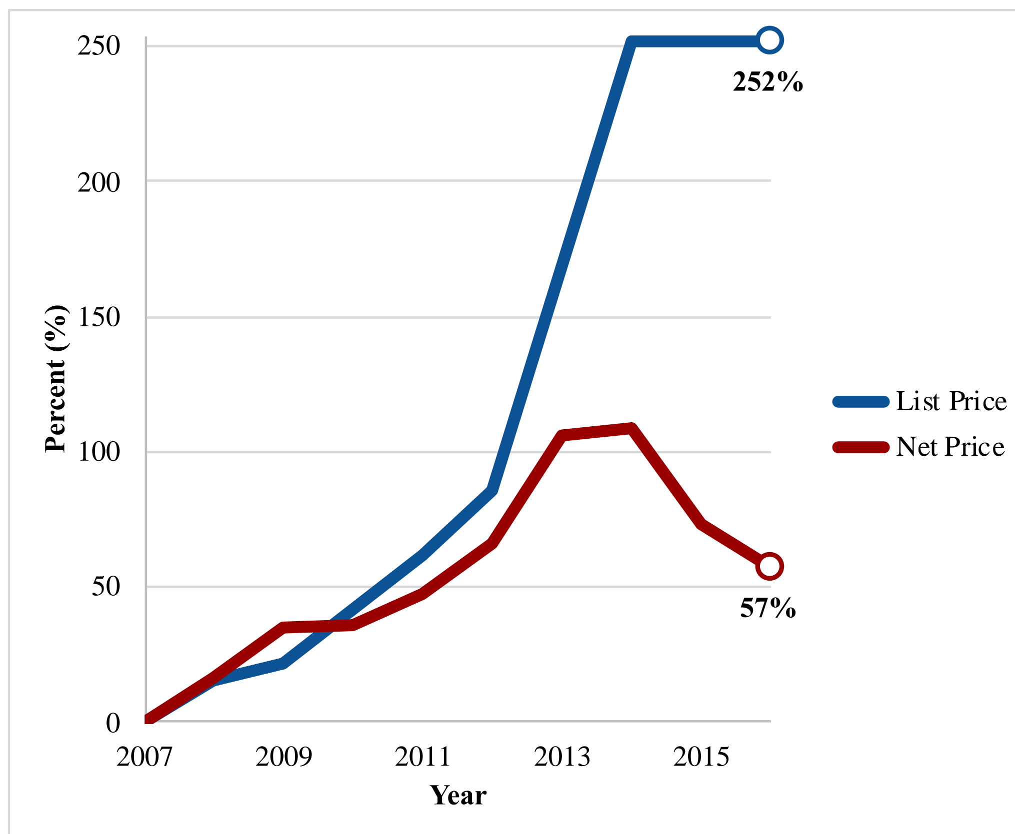

Figure 2: *Visual representation of changes in list price and net price for Lantus (glargine).* Created by the authors based on a graphic from The Wall Street Journal, data originally from Truven Health Analytics (list price) and Sanford C. Bernstein & Co. (net price) [20,21].

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