



Patient Affordability Legislation: How This Frontier in the Pharmaceuticals Industry May Shape Your Business

A Case Study on the Alec Smith Insulin Affordability Act



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| Introduction

At least 12 U.S. states have now passed laws that cap the insulin costs for diabetic patients. More than 30 are currently considering such legislation. While this development is fantastic news for furthering patient access to life-saving therapies, it may pose challenges for pharmaceutical manufacturers seeking operational solutions for reimbursement, compliance, and data handling.

This white paper outlines how one such law, Minnesota's Alec Smith Insulin Affordability Act, has impacted the pharmaceutical industry and provides guidance about strategies businesses can employ to rapidly add support.



Alec Smith Insulin Affordability Act

Diabetics die without insulin. It is a sad fact. Unfortunately, many diabetics struggle to afford their insulin. Such was the case with 26-year-old Alec Smith who was a Type I diabetic and was unable to afford the \$1,300 monthly cost of his insulin after aging out of his parents' insurance plan. Smith attempted to ration the medicine and died.

The new Minnesota law, the Alec Smith Insulin Affordability Act, goes into effect on July 1, 2020, and is aimed at preventing similar deaths moving forward.

Here is a breakdown of the law, its challenges, and the innovative solution created by Paysign.

| What is the Law?

The New Insulin Safety Net Program

The new law outlines steps manufacturers must take to establish procedures that will make emergency insulin available to people who qualify. In order to be eligible to receive an urgent need supply of insulin, patients must meet the following requirements:

Be a Minnesota resident

Must **not** be enrolled in medical assistance or MinnesotaCare

Must **not** be enrolled in prescription drug coverage that limits the total amount of cost-sharing that the enrollee is required to pay for a 30-day supply of insulin, including co-payments, deductibles, or coinsurance, to \$75 or less, regardless of the type or amount of insulin prescribed

Must **not** have received an urgent-need supply of insulin through this program within the previous 12 months

Must be in in urgent need of insulin

Under the law, **urgent need of insulin is defined as having less than a seven-day supply and in need of insulin to avoid potential negative health consequences.** Manufacturers are required to create an application process including an application where individuals will attest to meeting eligibility requirements. The form is required to be accessible through the manufacturer's website. This form will also be made available to pharmacies and health care providers who prescribe or dispense insulin, such as hospital emergency departments, urgent care clinics, and community health clinics.

Once the form is completed, a patient can submit the application along with a valid insulin prescription and a valid Minnesota identification card, driver's license, or permit. **The patient will be given a 30-day supply of insulin,** and the pharmacy must notify the prescriber that the prescription was filled within seventy-two hours.

The pharmacy can submit to the manufacturer for a claim of payment in an amount that covers acquisition costs unless the manufacturer agrees to send replacement inventory. **Pharmacies are able to collect a \$35 co-payment to cover the processing costs.** If patients have an ongoing need of assistance, pharmacies will have information about applying for medical assistance or MinnesotaCare, qualified health plans offered through MNsure, prescription drug discount and patient assistance programs.



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| Extended Program Reach

Manufacturers are required to provide a patient assistance program for qualified individuals to sign-up for if they so choose. Requirements for participating in such programs are outlined below:

Individual must be a Minnesota resident with a valid form of identification


The individual must have a family income that is equal to or less than 400 percent of the federal poverty guidelines

Must not be enrolled in medical assistance or MinnesotaCare or be eligible to receive health care through a federally funded program

Anyone interested in participating in a manufacturer's patient assistance program may apply directly to the manufacturer or a health care provider.



While manufacturers are required to reimburse pharmacies for acquisition costs or to replace the product, the latter is not required within any specific time frame. Reimbursement rates are not as cut and dry as one might think, as rates can vary from manufacturer to manufacturer. Manufacturers are also required to report to the state how many patients have participated, and the value of the insulin disbursed.



Paysign is in the process of creating such a solution that will focus not just on aiding manufacturers with reimbursement processes but creating patient affordability initiatives.

| The Pharmacist's Perspective

According to Sarah Derr, pharmacist, and Executive Director of the Minnesota Pharmacist Association, one of the biggest challenges facing pharmacists in connection with the law is ensuring that potential patients are aware of the program and do not end up rationing their insulin.

"It's more common than one might think, and there have been deaths because of rationing," she said. "And the law provides pharmacists with a means to provide help when we couldn't always before."

Another challenge is access to information, which Derr said can make the process more time consuming.

"Access to a real-time system that would increase communication between participating parties would be ideal," she said.

Paysign is in the process of creating such a solution that will focus not just on aiding manufacturers with reimbursement processes but creating patient affordability initiatives that ensure individuals in need will be able to have continued access to insulin by the removal of financial obstacles.

Derr said she believes that the law is going to change and save lives.

"I think this is something that should become a national standard."



The goal of Paysign's program is to offer two avenues through pharmacy and manufacturing that will put free insulin into the hands of the patient.

| A Solution For All

Paysign is in the business of solutions. We see a problem and it is our goal to create and implement streamlined programs and solutions that will resolve it quickly and efficiently.

And so, when it became clear that the new law might create some frustration and confusion for all involved parties, we decided to step in and help.

The goal of Paysign's program is to offer two avenues through pharmacy and manufacturing that will put free insulin into the hands of the patient. This will be achieved through a portal platform designed to allow pharmacies to enroll patients in emergency need programs with options based upon manufacturer guidelines.

Pharmacies will select a specific voucher offer, either a copay card that will pay the pharmacy through the standard NCPDP process or another card that will prompt a product replacement shipment to be sent directly to the pharmacy.

Brett Squire, Senior Director, Client Services and Informatics at Paysign said, *"This gives pharmacies and manufacturers a suite of tools to address this new law. By allowing a manufacturer to design a program that complies with the law, mitigates risk for abuse, and uses customs rates for reimbursement, we are putting the best options possible in front of our clients and the citizens of Minnesota."*



This operational solution will allow pharmacists to incorporate this program into their workflow and provide easy access to manufacturers who must comply with reimbursement without access to patient information. Strict HIPPA and anti-kickback laws will be followed to the letter.

Data aggregation will create a profile and tell a story about the patient, arming the manufacturer with knowledge about each individual's case. Squire elaborated *"This data will take full advantage of the pharmacy claim system, helping us ensure our clients can demonstrate compliance to the State of Minnesota."*

The portal will also provide a link to educational materials and allow doctors and healthcare providers to steer patients towards assistance programs.

For more information about Paysign's Patient Affordability solutions, visit paysign.com.

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