Interim Joint Committee on Health, Welfare, and Family Services
Diabetes and Prescription Drug Affordability
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My name is Gary Dougherty and I am the Director of State Government Affairs for the American Diabetes Association® (ADA), the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic.

I appreciate Chair Moser's invitation to provide a brief background on diabetes, its treatment, complications, and prevalence in the Commonwealth of Kentucky. I have also been asked to discuss the barriers to patient assistance programs and share some insight into some insulin affordability initiatives that may be worthy of consideration in Kentucky.

Diabetes 101 – The Difference Between Type 1 and Type 2

More than 37.3 million Americans have diabetes[1] and, here in Kentucky, nearly 475,000 people have diabetes, an additional 101,000 have diabetes and don't know it, and more than 1.1 million have prediabetes, with higher than normal blood glucose levels, but not yet high enough to be diagnosed with diabetes.[2]

To provide some context, everyone needs insulin, which is a hormone produced in the pancreas, in order to survive. But some people with diabetes don't produce it naturally, or don't produce enough, so they must buy and administer insulin to safeguard their health and their life. All people with type 1 diabetes and many with type 2 need insulin to live and to avoid devastating complications that include blindness, kidney failure, lower limb amputation, heart attack, stroke, and even death.

Very broadly, type 1 diabetes, which used to be called juvenile diabetes, occurs when the pancreas stops producing insulin. This accounts for about 5-10% of people with diabetes. They must administer insulin multiple times a day in order to survive.

In type 2 diabetes, which used to be called adult-onset diabetes and affects about 90-95% of those with diabetes, either the pancreas produces an inadequate supply of insulin or the body is resistant to its effect or both. Type 2 diabetes can be managed by diet, exercise, and medication. However, when the pancreas stops making a sufficient amount of insulin, type 2 patients may also need to administer insulin.

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Statistics[3] show that, for people with type 2 diabetes:

- 82% also have hypertension,
- 78% are clinically obese,
- 77% have high cholesterol,
- 24% have kidney disease, and
- 22% have cardiovascular disease.

This, of course, is not an exhaustive list of co-existing conditions since we know people also experience retinopathy, neuropathy, and complications I previously referenced.

Those who don't have diabetes, but do have elevated blood glucose levels, have prediabetes and are at risk for developing type 2 diabetes. There are interventions that can be taken to lower this risk, such as the National Diabetes Prevention Program (NDPP), that can help prevent or delay the development of diabetes. We know that participants in the NDPP who lost 5-7% of their body weight and added 150 minutes of exercise per week cut their risk of developing type 2 diabetes by up to 58%.[4]

However, for those with type 1 or type 2 diabetes who require insulin, the cost has spiraled out of control and is beyond the reach of many.

First of all, it's important to note that people with diabetes have medical expenses approximately 2.3 times higher than those who do not have diabetes[5] and that ADA research has shown that, for one in four insulin users, cost has impacted their use,[6] leading to rationing, decreasing or skipping doses of insulin, which is unsafe and can lead to costly and preventable emergency room and hospital visits.

Kentucky took an important first step to address this issue with the passage of HB 95 in 2021. Effective January 1 of this year, state employees and those Kentuckians on state-regulated health plans saw their cost-sharing for insulin reduced to no more than $30 for a 30-day supply.

I'll discuss next steps the legislature should consider in a moment, but I'll focus now on patient assistance programs that have been put in place by drug manufacturers.

Patient Assistance Programs

ADA manages a website, www.insulinhelp.org, that serves as a clearinghouse – or a one-stop shop – for people to learn about these manufacturer-sponsored programs.

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Whereas patient assistance programs may be helpful for some, and that's why we offer the website as a resource, the ADA does not view them as a long-term solution to the challenges of insulin affordability for a number of reasons:

- There are limits to who is eligible for many assistance programs.
- Eligibility and application requirements vary from program to program which can often make applying difficult or confusing and wait times for approval can be long.
- There may be a cap on how much a program will provide and that cap might be based on list price so people would reach the limit quickly.
- Manufacturer programs are not a permanent solution and can be ended or revised anytime at the discretion of the manufacturer.

The Kentucky Prescription Assistance Program (KPAP) is operated by the Cabinet for Health and Family Services and, by all accounts, is a valuable resource, but its success depends greatly on the quality of the manufacturer programs.

Insulin Affordability Initiatives

Because Kentucky's insulin co-pay cap only applies to state employees and those on state-regulated health plans, there are additional steps that need to be taken to more fully address the insulin affordability crisis.

This past session, Rep. Danny Bentley introduced two measures that would have dramatically changed the landscape for Kentuckians who rely on insulin to live by creating two new programs that would benefit others who rely on insulin.

These programs would resemble those created in Minnesota through the enactment of what has become known as the Alec Smith Insulin Affordability Act. Alec was the young man who, after aging off his parents' health insurance, began rationing his insulin due to the high cost and, sadly, passed away from diabetic ketoacidosis in 2017.

Urgent Need Insulin Program

Too often, insulin-dependent individuals may find themselves unexpectedly near the end of their insulin supply. This could be due to a lack of financial resources or a broken vial. Unless they are able to obtain additional insulin, they risk devastating complications that could otherwise be avoided.

HB 42 would have established a program whereby a 30-day supply of insulin would be provided to an eligible person with an urgent need, meaning someone with less than a seven-day supply of insulin on hand.

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The urgent need program may be accessed once in any 12-month period, unless extenuating circumstances exist.

Continuing Access to Insulin Program

HB 42 would have also established a Continuing Access to Insulin Program to provide insulin for an ongoing need throughout the year. Under such an initiative, each insulin manufacturer would be required to make a patient assistance program available to any eligible individual.

An individual's eligibility for this program is valid for 12 months.

As envisioned by HB 42, both the Urgent Need and Continuing Need programs would be administered by the Board of Pharmacy who would develop the applications and information sheets for each program.

An applicant for either program would submit a completed application as well as a valid insulin prescription and proof of residency to a pharmacy. The pharmacist would dispense a 30-day supply of insulin and could collect a co-payment of $25. The pharmacist could submit a claim for payment to the drug manufacturer or accept a replacement supply of the insulin in the same amount that had been dispensed.

Cap Cost-Sharing for Certain Diabetes Devices and Supplies

Another bill sponsored by Rep. Bentley, HB 90, would have built off the insulin co-pay cap and established a $30 per month co-pay cap on non-insulin medications used to treat diabetes as well as certain diabetes equipment and supplies.

Members, Kentucky has long been a leader in diabetes advocacy – from enacting the nation's first Diabetes Action Plan legislation, to keeping students with diabetes safe at school, and being one of now 21 states (plus DC) to have enacted an insulin co-pay cap. You have an opportunity next session to provide further critical relief for people with diabetes and I encourage you to maximize this opportunity.

I appreciate your attention this morning and will be happy to try to answer any questions you might have.

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[1] https://www.cdc.gov/diabetes/data/statistics-report/index.html
[2] https://diabetes.org/sites/default/files/2022-04/ADV_2022_State_Fact_sheets_all_rev_KY-4-4-22.pdf
[3] Iglay, K., "Prevalene and co-prevalence of comorbidities among patients with type 2 diabetes mellitus," Current Medical Research and Opinion, Vol. 32, Issue 7 (2016). Available at https://www.tandfonline.com/doi/full/10.1185/03007995.2016.1168291
[4] Centers for Disease Control and Prevention https://www.cdc.gov/diabetes/prevention/why-participate.html
[5] https://diabetes.org/sites/default/files/2022-04/ADV_2022_State_Fact_sheets_all_rev_KY-4-4-22.pdf
[6] American Diabetes Association, Insulin Affordability Survey, 2018, available at http://main.diabetes.org/dorg/PDFs/2018-insulin-affordability-survey.pdf

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