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Introduction

This report was prepared by the Diabetes Patient Advocacy Coalition (DPAC), a 501(c)4 organization working collaboratively to improve the health of people with diabetes through public policy initiatives.

Diabetes directly affects 37.3 million Americans – one in five people don’t know they have it. Regardless of its form (e.g., type 1 diabetes, type 2 diabetes, gestational diabetes, or pre-diabetes – see Exhibit A), the disease demands serious solutions from policymakers at all levels of government and power in America. The cost of inaction grows every day and ignoring it risks the loss of more lives. We can and must do better to provide citizens access to the diabetes care they require.

<table>
<thead>
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<th>Exhibit A: Understanding the Types of Diabetes</th>
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<tbody>
<tr>
<td><strong>Type 1</strong></td>
</tr>
<tr>
<td>Type 1 diabetes is an autoimmune disease that stops the body from producing insulin. Approximately 5-10% of the people who have diabetes have type 1.</td>
</tr>
<tr>
<td><strong>Type 2</strong></td>
</tr>
<tr>
<td>With type 2 diabetes, the body doesn’t use insulin well and can’t keep blood sugar at normal levels. About 90-95% of people with diabetes have type 2.</td>
</tr>
<tr>
<td><strong>Gestational Diabetes</strong></td>
</tr>
<tr>
<td>Gestational diabetes develops during pregnancy in women, affecting blood sugar levels which could put the baby at higher risk for health problems. 2% to 10% of pregnancies in the United States are affected by gestational diabetes.</td>
</tr>
<tr>
<td><strong>Pre-diabetes</strong></td>
</tr>
<tr>
<td>A pre-diabetes diagnosis suggests blood sugar levels are higher than normal, but not high enough for a type 2 diabetes diagnosis. More than 1 in 3 Americans have pre-diabetes.</td>
</tr>
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Introduction

This living document, the State Legislative Diabetes & Obesity Handbook, exists to help policymakers, advocates, and the community identify state and national tools to consider replicating to combat diabetes and its risk factors.

DPAC will update this guide periodically whenever a new policy solution emerges to encourage policymakers to take similar actions.

The Need for The Diabetes Policy Handbook

Diabetes presents macro health system and government budget challenges but also family financial challenges when it comes to managing and preventing the disease. Challenged by patient medical expenses approximately 2.3 times higher than average, the financial impact of diabetes equals $1 out of every $4 in U.S. health care costs – with billions spent by state and federal entities. \(^{i*}\)

The condition is at pandemic-level proportions as 11% of Americans are diagnosed with either type 1 or type 2 diabetes, and another 40% live with pre-diabetes or are undiagnosed. Further, up to 10% of pregnancies in the U.S. are affected by gestational diabetes, with 50% of those women going on to develop type 2 diabetes. \(^{ii}\)

Patients continue to encounter barriers to care – be it too few providers in their community, lack of comprehensive health coverage, exposure to high prescription drug costs, utilization management tactics, or predatory copay accumulator programs.

When considered alongside potential comorbidities like obesity, heart disease, or nerve damage – the fiscal strain, health resources used, and lost productivity associated with diabetes cannot be overstated.

\(^{*}\text{For citations, please reference Endnotes in the Appendix}\)
Amid longstanding commitments to public health departments and legislative advancements such as copayment limitations, increased price transparency and coverage mandates, the question we are most often asked by key leaders: What else can we do?

This handbook offers state policymakers a sampling of models which with broad adoption would markedly improve patients' access and affordability, solutions which deliver economic benefits like lower costs and a healthier, more productive workforce. Appendix A provides an addendum of related policies for your reference.

State vs. Federal: How legislative impact varies

**Congressional and state jurisdictions vary, meaning legislation at both levels impacts different populations of people. What's the difference?**

**FEDERAL IMPACT**

Federal jurisdiction covers the Medicare program, portions of Medicaid, Tricare for military personnel, and the Employee Retirement Income Security Act of 1974 (ERISA), which includes most voluntarily established retirement and health plans in private industry ~ 85% of Americans. Only Congress may legislate to enact changes.

**STATE IMPACT**

State jurisdiction includes individuals covered under individual exchanges, small-group markets, state employee plans, and portions of Medicaid ~ 10-15% of Americans. State legislatures may only act on state-regulated health plans.
Part 1

Reducing Drug Prices for the Uninsured and Underinsured

Chronic disease management is unaffordable without comprehensive health coverage. Better access is in the best interest of lawmakers and patients alike as high costs decrease medication adherence and increase hospitalizations and other costly and life-threatening complications.

Many states have taken measures to reduce the barriers to access for prescription drugs through legislation including copay caps, copay accumulator bans, emergency access laws, and more (see Appendix A). Additionally, low cost options are becoming available through new biosimilars and generics. Still, patients find themselves paying inflated costs at the pharmacy counter.

Now more than ever, we should be doing everything we can to increase affordability of prescription drugs.
The Prescription Assistance Model

This section features an innovative, low budget program, the Kentucky Prescription Assistance Program (KPAP) – its overwhelming success – and how your state could pilot a similar effort.

The American Diabetes Association finds people with diabetes have health care costs that average $16,750 annually. Given millions of people with or at risk for the disease do not have sufficient health coverage for life sustaining care, such high costs hinder the ability to confront the diabetes epidemic.

Reduced cost prescription programs, offered by manufacturers, retailers and other sponsors, are often available for high-cost brand and specialty medications and are used by people with diabetes and other complex chronic conditions. These programs can serve as a lifeline to the uninsured and underinsured who may otherwise be unable to afford their prescription and risk complications from non-adherence.

With the intent to make essential medicines like insulin more affordable, Kentucky has established a program that enables and expands community-based efforts to enroll eligible individuals in these prescription assistance programs. And that’s not all - the program connects people with services and aid available from other organizations. A small budget with an outsized impact for patients, KPAP is a model for the nation.
In 2009 KPAP was established through the legislature’s biannual appropriation bill with $400k in funding.

Taking inspiration from a volunteer-run program assisting local residents access free and reduced cost medicines provided by manufacturers, retailers, foundations, non-profits and other benefactors – the legislative sponsor expanded the model statewide in collaboration with the Kentucky Cabinet for Health and Family Services (KY-CHFS).

The program, now fully operating out of CHFS, is funded by a $600k annual line-item appropriation, and staffed by 2 full-time employees and a contractor. Rather than overburden other professions, such as pharmacists or nurses, or create new programs that rely on existing professionals, KPAP partners with individuals and organizations already active in underserved communities. By working with entities including county health departments, hospitals, food pantries and faith-based organizations — KPAP expands their capacity to all 120 counties without duplicating efforts.

Through KPAP partners, three community consultants are contracted to serve as program liaisons and train the community-based volunteer advocates who operate as prescription assistance program navigators. KPAP provides ongoing support for their partner organizations through weekly virtual office hours, monthly software training, and individual training and troubleshooting as needed.

Today, KPAP is helping more than 4,800 Kentuckians access $47 million in free and reduced cost medications in a single year.
Kentuckians needing help with prescription costs can call a statewide toll-free hotline and be linked with a local KPAP-trained advocate who will meet in-person or virtually with the caller to understand their assistance needs and enter details into Drug Assistant software licensed to KPAP. Through the software, navigators may simultaneously explore enrollment in multiple assistance programs, identify copay cards and other resources to reduce prescription costs, and connect with the state's health coverage system for individuals who are eligible but not yet enrolled in other state assistance programs like Medicaid or CHIP.

Navigators are also available to help patients requiring assistance with appeals and other wraparound services like notifying when a refill is needed. The process reduces the burden of locating free or reduced-cost prescriptions for patients, minimizing paperwork and offering more direct access to the treatment they need to live.

Eligibility for the program is based on income guidelines set by participating entities. While incomes 200 to 400 percent of the federal poverty level often qualify, interested participants with higher incomes or who have insurance may be eligible if their medications are not covered by their benefits. Those ineligible may still reach out to a KPAP navigator to receive consultation about other potential sources of low-cost prescriptions.

SECTION SUMMARY

KPAP's efficient deployment of its annual $600K appropriation may make it the only state program across the nation to deliver a 78-times return on investment. By working through existing prescription assistance programs, Kentucky is prudently stewarding its fiscal resources while helping uninsured and underinsured residents afford prescriptions to manage their chronic conditions.
As the cost of prescription drugs has jumped, state and federal policymakers have worked to bring much needed transparency to the opaque drug pricing system. Manufacturers, insurers, and pharmacy benefit managers (PBMs) alike have come under intense scrutiny, each offering explanations on how their companies deliver lower costs and better patient access and health care outcomes.

PBMs don’t have a fiduciary responsibility to the patient, only to their shareholders. Originally created for medical billing of pharmacy transactions, PBMs have evolved to work with, and for, insurers and inserted themselves into the patient-provider relationship - exerting enormous influence on which drugs are prescribed to patients, which pharmacies patients can use, and how much patients ultimately pay at the pharmacy counter. Now vertically integrated with the largest health insurance companies (see Exhibit B) and wholly owned mail order and specialty pharmacies, the three largest PBMs – Express Scripts, CVS Caremark and OptumRx – control approximately 89% of the market and serve about 270 million Americans.
These middlemen face rising criticism as Attorneys General across the country have filed and won suits alleging their business practices have dramatically inflated costs for states’ Medicaid and employee health plans. The Federal Trade Commission has also launched an investigation into PBMs and their role in the rising price of prescription drugs through the fees and rebates received in exchange for formulary coverage.

While it is important to understand and acknowledge the factors inflating patient costs, it is possible for state legislators to do more to provide direct relief to constituents with chronic diseases.

Exhibit B: Vertical Integration of Insurers, PBMs, Specialty Pharmacies, and Providers

*For more information, please visit Drug Channels Institute at: https://www.drugchannels.net/2023/05/mapping-vertical-integration-of.html
The Rebate Reform Model

This section spotlights legislation prioritizing patients over PBMs

West Virginia has enacted a solution providing direct relief to patients at the pharmacy counter alongside much needed transparency in a broken system that is widely acknowledged to be inflating those costs. Through HB 2263, a bill that would be selected onto the Council of State Governments’ 2022 Shared State Legislation Docket, West Virginia became the first state to require rebate pass through.

Rebates – discounts provided by manufacturers to incentivize PBMs and insurance companies to cover their medicines – have risen to create a serious barrier to patient affordability and access. In contrast with the major medical side of health plans, which automatically shares network discounts with plan participants, health insurance coverage of prescription medicines is unique in that PBMs and health plans may pocket these rebates.

Refusal to share these rebates, which average 48% across all brands and exceed 80% in the case of insulin, leave people with chronic conditions, who may rely on multiple medications just to stay alive, paying hundreds of dollars more than their insurer.

Making matters worse, PBMs are negating competitive forces that should deliver reduced prescription drug prices. As follow-on biologic and biosimilar analog insulins come to market, they are increasingly being placed in specialty or non-preferred tiers or being excluded altogether as PBMs and health plans prefer higher priced branded medications which provide them greater amounts of rebates and enhanced profitability. At no point is patient cost-saving included in the calculations.
Patients with high deductibles and coinsurance most often pay the full list price of a medicine rather than the negotiated net price (see Exhibit C), with the middlemen and insurers keeping the profits. As these entities increase premiums, coinsurance requirements and deductibles, shifting more healthcare costs to the patients, it is common sense that the patient receive the benefit of the pricing that the insurance plan has negotiated.

By requiring rebate and discount pass through to the consumer at the point of sale on all prescription drugs, medical devices, supplies or services during the deductible phase – has made prescription drug coverage commensurate with major medical coverage and reduced patient costs at the point of sale. In 2023, Arkansas and Indiana followed suit and enacted pass through legislation while many other states considered action on similar legislation.

Opponents have argued that premiums will exponentially rise, but implementation of the bill did not have that affect in West Virginia whose premiums have risen in line with national averages. Actuarial studies also bear out the negligible impact on overall health plan costs of passing rebates through to patients.

### Exhibit C: Example at the Pharmacy Counter
Here’s how rebate reform would save money for those on a state-regulated health plan*

<table>
<thead>
<tr>
<th></th>
<th>Current State</th>
<th>With Reform</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Retail List Price:</strong></td>
<td>$150</td>
<td>$150</td>
</tr>
<tr>
<td><strong>Rebate:</strong></td>
<td>$72</td>
<td>$72</td>
</tr>
<tr>
<td><strong>Insurance Pays:</strong></td>
<td>$78</td>
<td>$78</td>
</tr>
<tr>
<td><strong>Patient Pays:</strong></td>
<td>$150</td>
<td>$78</td>
</tr>
</tbody>
</table>

*For illustrative purposes, model does not depict pharmacy fees
Diabetes management is unique in that it is almost entirely self-managed by the individual, or their parent or caregiver, rather than by a healthcare provider. A person with diabetes may need to make minute-by-minute adjustments in their management plan, attempting to keep blood glucose levels within a recommended range.

Insulin is the life-saving bedrock of diabetes management for 1 in 3 people with diabetes, yet it is just one piece in a mosaic of medicines, medical devices, software, supplies, and support services the disease demands. While coverage for insulin is routine, access to these other essential diabetes management tools remains inconsistent.

As public and private health plans generally cover long-term diabetes complications, including amputations, blindness, end stage renal disease, heart attack and stroke – so too should they cover the tools that prevent such complications. The shift is better for people with diabetes and their families, and a wiser investment of healthcare dollars for payers, especially in the face of a diabetes epidemic.
The Medicaid CGM Coverage Model

This section discusses legislation ensuring people with diabetes have coverage for individualized care that can prevent or delay the onset of costly and life-limiting complications.

Efforting to provide their constituents adequate coverage, legislators in Arkansas and Louisiana have recently enacted legislation mandating their Medicaid program cover continuous glucose monitors (CGMs) for individuals with diabetes in accordance with guidelines from the Centers for Medicare & Medicaid Services (CMS).

Innovative technologies such as CGMs, smart devices, and closed loop CGM+ pump or “artificial pancreas” systems provide individuals a vital tool to manage their diabetes, quickly adjust behavior and avoid preventable complications and ER visits.

As these innovations become routine and more data is gathered, clinical guidelines have evolved. The American Diabetes Association now recommends CGMs as the standard of care for treating any insulin-dependent adult, regardless of type, as well as for all children with type 1 and type 2 diabetes who use rapid-acting insulin.

Despite these recommendations, Medicaid coverage of CGMs remains a complex patchwork of prescription or durable medical equipment (DME) benefits. Across the country, coverage differentiates between people with type 1 versus type 2 diabetes as well as between children and adults. Some states go further to require prior authorization alongside prescriber requirements and diabetes-specific requirements.
Under this patchwork coverage, studies reveal that Medicaid beneficiaries with diabetes struggle — suffering higher rates of poor diabetes management, worse glycemic control, and facing more acute- and long-term complications related to diabetes.

While federal laws and regulations set standards for coverage under Medicaid for both the traditional and expansion populations, individual states determine the finer points of what is and is not covered, and how programs are administered.

It is important to contain costs wherever possible, but it’s similarly important to design plan coverage to drive overall cost efficiencies versus any single line item. The purpose of CGM coverage is to promote better diabetes management and importantly, to reduce higher cost spend on the major medical side of the plan. One study shows that patient adoption of CGMs for just nine months results in healthcare costs savings of $4,000 compared to a patient without a CGM.

In covering CGMs through Medicaid, Arkansas and Louisiana offer protection to some of their most vulnerable citizens while properly managing its resources by preventing the greater costs associated with diabetes-related hospitalizations and treatment complications.

What's a CGM?

A CGM is a medical device including: (1) a small sensor; (2) a transmitter, which may be embedded in the sensor or be separate; (3) a monitoring system that automatically tracks glucose levels continually and as often as every five minutes. The sensor is inserted by the patient just beneath the skin (usually on a patient’s arm or stomach), which is connected to a transmitter that sends information to a monitor. The CGM can either be synced to an insulin pump that automatically delivers insulin when needed or transmit information to a separate small handheld device or app on a smartphone.
Obesity, a complex health issue often influenced by a combination of genetic, environmental, and behavioral factors, is a significant health crisis affecting more than 123 million adults and children/adolescents in the U.S.\textsuperscript{X} Despite mounting evidence that obesity leads to multiple comorbidities, including type 2 diabetes, cardiovascular disease, and chronic kidney disease, coverage for weight management is commonly limited to counseling in primary care settings only and weight-loss surgery for people with severe obesity.

While lifestyle modifications such as diet and exercise are essential components of obesity management, they may not be sufficient for everyone as meta-analysis reflects that over half of weight lost was regained within two years.\textsuperscript{XI}

Addressing the obesity epidemic therefore requires a multifaceted policy approach that shifts the focus from short-term interventions to long-term, sustainable solutions, beginning with coverage of all obesity treatments, both behavioral and pharmacological. Such access better aligns caring for people with obesity to other chronic diseases, promoting a broader spectrum of care and management to control and mitigate its effects.
We urge consideration of timely prevention and early intervention, offered through Medicaid programs like the Diabetes Prevention Program (DPP) and clinical lifestyle approaches such as intensive behavioral therapy (IBT) and medical nutritional therapy (MNT), which provide medically proven treatment options to aid in weight loss, helping individuals achieve better long-term health outcomes and avoid the onset of obesity-related comorbidities.

Incorporating coverage for anti-obesity medications (AOMs) offers improved outcomes, with enhanced treatment adherence leading to more effective weight management and decreased healthcare costs associated with treating secondary health issues. To date, AOM coverage significantly lags behind more-costly treatments like bariatric surgery which AOMs are designed to prevent.

Legislators may go further and address the unwelcome impact of obesity stigma, negative attitudes undermining the level of support and care received which consequently lead individuals to experience poorer mental health, poor quality of life, disordered eating behaviors, excessive alcohol use, and weight gain.

Understanding the myriad of factors associated with obesity care coverage, DPAC offers such solutions as a means for lawmakers to look further upstream when considering what they can do to help the diabetes community in their districts. Presently, there exists no legislative model to enhance access and awareness to treat and prevent obesity – we look forward to continued engagement on this subject and the creation of such policy.
Appendix

The following offers an overview of patient-centered policies, both referenced models and new, which DPAC endorses and monitors nationwide. Track your state’s progress at diabetespac.org/HANDBOOK

**Rebate Pass-Through:** Requires pharmacy benefit managers (PBMs) to pass through a portion of drug rebates to patients at the point of sale, lowering to lower the cost of prescription drugs.
- **Model Legislation:** Indiana Senate Bill 8 – Enacted 5/4/23

**Comprehensive Medicaid Coverage for CGMs:** Ensures that beneficiaries with diabetes have access to Continuous Glucose Monitors (CGM) and related supplies as part of their healthcare benefits.
- **Model Legislation:** Arkansas Senate Bill 521 – Enacted 4/13/21

**Insulin Copay Caps:** Limits the amount individuals with diabetes have to pay out-of-pocket for insulin by imposing a maximum limit on patient cost-sharing.
- **Model Legislation:** West Virginia Senate Bill 577 – Enacted 5/1/23

**Diabetes Supply Copay Caps:** Set a maximum limit on out-of-pocket costs for various diabetes supplies, such as glucose test strips, lancets, insulin pumps, and continuous glucose monitors (CGMs).
- **Model Legislation:** West Virginia Senate Bill 577 – Enacted 5/1/23

**Copay Accumulator Adjustment Program Bans:** Prohibit health insurers and PBMs from applying copay accumulator programs which prevent third-party copay assistance from counting toward a patient's deductible or out-of-pocket maximum
- **Model Legislation:** Virginia House Bill 2515 – Enacted 3/21/19
**Emergency Access to Insulin:** Permits pharmacists to dispense a 30-day supply of insulin in emergency situations where the prescriber isn’t available.

- **Model Legislation:** Kentucky House Bill 64 – Enacted 3/26/19

**First Dollar Coverage for Diabetes Care:** Patient cost-sharing benefits begin without requiring the insured individual to pay a deductible or other out-of-pocket expenses first, ensuring that essential diabetes-related services, treatments, and medications are covered immediately, minimizing financial barriers for patients.

**Diabetes Action Plans:** Strategic frameworks developed by state entities that include specific goals, strategies, and initiatives aimed at prevention, early detection, better management, and improved healthcare services for individuals living with and at risk for diabetes.

**Legislative Caucuses Focused on Diabetes:** Legislative caucuses focused on diabetes are groups of lawmakers who come together to address issues related to diabetes, such as raising awareness, advancing diabetes-related legislation, and promoting policies that improve diabetes care and management.


