PROTECTING ACCESS TO DIABETES CARE

A WHITE PAPER FROM THE **DIABETES THERAPY ACCESS WORKING GROUP**

Almost 1 in 10 Americans – men, women, and children of all ethnicities and income levels – has diabetes.[1] One of the most common medical conditions in America, diabetes has become more widespread in recent years, increasing by more 1 million people between 2012 and 2015 alone.[2]

Diabetes can occur as type 1, in which the body does not make insulin, or type 2, in which the body either does not produce a sufficient amount of insulin or the insulin made does not work appropriately. It can also manifest in pregnant women as gestational diabetes.

The disease can have a multifaceted impact on patients. Its effect on the vascular system may cause heart attack or stroke, as well as eye, kidney, and nerve problems. The disease can increase adults' risk of heart disease and can affect circulation to the extremities, sometimes leading to amputation.[3] People with diabetes are also three times more likely to be diagnosed with depression.[4] Complications vary based on the type of diabetes patients have and how successfully they are able to manage it.

Not surprisingly, diabetes is an expensive disease. In 2017 diabetes cost the United States $237 billion in direct medical costs and $90 billion in reduced productivity, accounting for about one in every four health care dollars spent. People with diabetes incurred an average per-patient cost of $16,750 a year.[5]

The U.S. economy and society at large also pay a price. Full-time workers with diabetes miss, on average, 5.5 extra workdays per year, costing employers $20.4 billion annually.[6]

Diabetes' impact and prevalence demand policies that allow people to access appropriate medications and effective health care.

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ACCESS CHALLENGES

Patients and their physicians can manage diabetes symptoms through diet and lifestyle changes and prescription medications. Educating patients about self-management techniques can have a significant impact on their ability to control symptoms and avoid complications. But progress is limited if health plan policies do not adequately cover the therapies that physicians recommend.

Prior Authorization

Insurers often require patients to get prior authorization before they will cover a prescribed medication that's appropriate to the patient's condition. Otherwise, the insurer can deny payment, leaving the patient to cover the entire price out of pocket. Patients and their health care professionals can appeal if the insurer rejects the requested prescription, though the insurer can reject the appeal as well.

The process is time consuming, requiring patients to wait days or even weeks for medication they need immediately. It can take some insurance companies as long as a month to approve an authorization request.[7]

Prior authorization is also expensive for the health care system, saddling clinicians with significant, unreimbursed costs. A study conducted in 2009 found that, on average, primary care physicians spent 1.1 hours per week fulfilling prior authorization requests, along with additional nursing staff time of 13.1 hours and 5.6 hours of clerical staff time. In total, prior authorizations increase costs for the U.S. health care system by an estimated $23-$31 billion each year.[8]

Step Therapy

Sometimes the insurer's authorization is contingent upon step therapy. Also known as "fail first," this is where an insurance company requires patients to try less expensive alternatives to the drugs their physician has prescribed. Only when patients have tried the alternative medication and found it to be ineffective will the insurance company cover the original prescription.

This process of trying and failing on one or more alternative drugs takes time, during which a patient's disease severity may worsen. And there is little evidence that step therapy actually diminishes costs long-term. The combined expense of additional office visits, more treatments, and even expensive hospitalizations due to failing on less expensive medications can exceed any savings at the pharmacy. And this does not even take into account the personal and societal costs of missed workdays, ongoing disability, or other impacts of uncontrolled symptoms.

Some health plans make my patients fail off-label drugs before they can get one of the FDA-approved therapies that I prescribed. For the health plans, it's all about cost.

John Anderson, MD

Non-Medical Switching

Health plans sometimes try to move patients from their prescribed medication to one that is less expensive for the insurer by increasing out-of-pocket costs. They can do this by placing medications on higher-cost tiers, increasing the co-pay, or sometimes eliminating coverage completely – even if the drug was originally covered when the patient bought the insurance policy. This practice is known as non-medical switching, because patients switch from one drug to another not for better care but to reduce costs to the payer.

A non-medical switch affecting many patients with diabetes occurred in 2016, when several health plans announced they were dropping coverage for certain insulin products. Diabetes patients who depended upon those products were left scrambling to find alternative treatments, or to pay out of pocket for their existing, effective medication.[9]

Health plans often base coverage decisions on the amount of manufacturers' rebates; thus, treatment options for patients can vary from year to year based on price negotiations. This practice does not support the continuity needed to manage a lifelong disease such as diabetes.

COST ISSUES

Medications for diabetes can be expensive. All people living with type 1 diabetes and about 25 percent of those with type 2 diabetes depend upon insulin to control their blood glucose levels.[10]

"Patients get flipped between insulins, and – as often as not – the one that works for them ends up in the high-cost tier."

Jeff Hitchcock, Children with Diabetes

Insulin prices have skyrocketed in recent years, more than tripling between 2002 and 2013.[11]

Medical devices used by diabetes patients can be expensive as well. These can include tools such as blood glucose meters and strips, continuous glucose monitors, insulin pumps and injection pens.[12] The high cost of devices, especially disposable test strips, which many diabetes patients must use multiple times a day, has led to an online black market in which patients with no or insufficient insurance coverage can buy strips at below market rates. The sellers buy strips from insured patients (or Medicare or Medicaid recipients, although it is illegal to resell strips paid for by those programs) who have extras or simply need money, and then resell them at a profit. Buying secondhand strips can put patients at risk of receiving inaccurate results from testing supplies that are past their expiration date or were stored incorrectly.[13]

Like diabetes itself, the financial issues confronting diabetes patients are complicated, influenced by multiple interconnected factors. One factor is the additional cost incurred by the presence of pharmacy benefit managers. These supply-chain middlemen can drive up drug prices by urging manufacturers to compete for a preferred spot on the health plan formulary by providing bigger and bigger rebates. Pharmaceutical manufacturers may hike list prices to offset increased rebate outlays. The interplay can become a vicious cycle.[14]

Meanwhile, the Affordable Care Act stopped insurance companies from charging higher premiums to people with pre-existing conditions such as diabetes. To protect their bottom line, insurance companies may increase the patient's cost sharing for medications and medical care. A 2017 Consumer Reports study found that a quarter of 1,000 prescription-taking patients surveyed were paying more for medications than they paid the previous year. Fifteen percent of them experienced annual increases of at least $100.[15]

As a result, patients may be forced to cut back on prescribed doses or make tough choices between paying for basic necessities such as food or rent and buying insulin. The aforementioned survey also found that out-of-pocket cost increases led 14 percent of patients to forgo filling their prescriptions.[16]

Deviating from one's diabetes management regimen generates significant costs, not only in terms of the patients' health but also for the overall economy. The National Institutes of Health estimates that the U.S. economic impact of medication nonadherence in 2015 was somewhere between $100 billion and $290 billion.[17]

I have patients tell me, "I can either eat, or I can buy my insulin."

Eda Cengiz, MD

Co-Pay Accumulator Adjustment Programs

Complicating patients' cost-sharing challenges, some health plans have changed the way they count prescription drug payments toward patients' annual deductibles.

Some patients rely upon co-pay coupons from the drug manufacturer to help cover the out-of-pocket cost of expensive medications or specialty drugs. This does not include patients enrolled in federal health care programs, including Medicare Part D, who are prohibited by law from using coupons. In the past, the coupon helped, over a period of time, to pay down the patient's annual out-of-pocket deductible. Under new accumulator adjustment programs, however, health plans do not count the coupon's value toward the patient's deductible or maximum out-of-pocket obligation.[18]

When the coupons run out, patients may discover that they still owe most or all of their annual deductible. Depending upon the cost of their drug, that amount could be due in full on a single visit to the pharmacy.

In its impact, an accumulator adjustment program resembles non-medical switching. The program increases out-of-pocket costs for patients, often to the point where they can no longer afford the drug prescribed by their physician.

Patients may not realize this additional expense is coming until they are handed a big co-pay bill at the pharmacy. That puts them in a tough spot, because they've likely already adjusted to the medication. They may be forced to try to find another, "cheaper" treatment, cut back on dosages, stray from their physician's recommendations, or attempt to squeeze the family budget to cover the cost of stabilizing their condition. Financial issues related to co-pay accumulator programs can drive people with diabetes to forego their regular management routine, causing health problems.

POLICY SOLUTIONS

Policymakers at both the state and federal level are becoming more aware of the dangers of these tactics. Some are taking steps to protect patients.

State Efforts

One national advocacy group has crafted model state legislation addressing step therapy for patients with chronic diseases. The group emphasizes that health plan policies should rely on current clinical data, be transparent, and offer clear and concise exceptions to step therapy protocols based on medical necessity. As of early 2018, 18 states had adopted step therapy regulations crafted along those precepts. Efforts in support of similar bills were underway in at least 11 more states.[19]

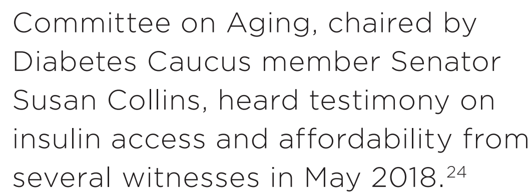
Legislation addressing non-medical switching has also received approval in multiple states. To date, 10 states have adopted regulations on non-medical switching, and other state legislatures are considering their own plans to protect patients.[20]

Federal Efforts

At the federal level, the Affordable Care Act caps out-of-pocket expenses for covered services. Once the maximum payment limit on deductibles, copayments, and coinsurance is reached, the health plan pays 100 percent of the cost of covered benefits. For the 2018 plan year, the out-of-pocket limit for a plan purchased on the exchange is $7,350 for an individual and $14,700 for a family.[21]

Meanwhile, the White House has acknowledged the role pharmacy benefit managers and manufacturer rebates play in high drug prices. In a May 2018 address on prescription drug affordability, President Donald Trump specifically mentioned pharmacy benefit managers, calling them middlemen who increase out-of-pocket costs for patients.[22]

The Congressional Diabetes Caucus, which includes more than 300 senators and U.S. representatives is also exploring the challenges and access barriers posed by diabetes costs.[23] The Senate Special



Committee on Aging, chaired by Diabetes Caucus member Senator Susan Collins, heard testimony on insulin access and affordability from several witnesses in May 2018.[24]

In other federal policy efforts, the 115th Congress is considering legislation to address step therapy. With 44 Republican and Democratic cosponsors in the House of Representatives, The Restoring the Patient's Voice Act of 2017 would require insurance companies to establish a clear protocol for exceptions to step therapy. Patients could request an exception by meeting one of five circumstances that make their situation unsuitable for a fail first process.[25]

CONCLUSION

With 1.5 million Americans newly diagnosed each year, diabetes presents a long-term challenge for patients and public health alike.[26]

Meeting that challenge means giving people with diabetes every chance to manage their condition. It also means instituting policies that respect the physician-patient relationship's role in quality care and acknowledge the individual health care needs of people with diabetes.

Clinicians, people with diabetes, private sector employers, insurers and policymakers must work together to ensure access to care and to reduce unmanageable out-of-pocket expenses related to this serious, but manageable, disease.

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The Diabetes Therapy Access Working Group is a unique network for clinicians and advocates interested in public policy surrounding access to treatments for diabetes. Members identify access challenges and share their perspective with policymakers, the media and the public through education and advocacy initiatives.

To learn more, visit www.AllianceforPatientAccess.org.

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