

Improving Insulin Access and Affordability

Krista Maier and Meghan Riley • May 2018

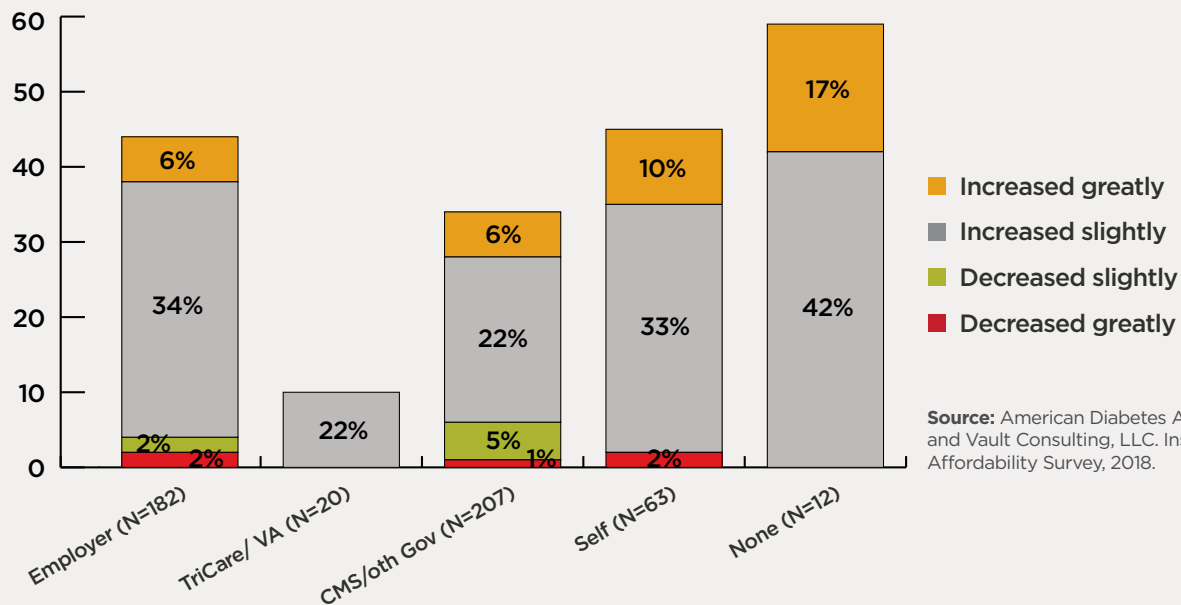
INTRODUCTION

There are more than 30 million Americans with diabetes.¹ Now the nation's most expensive chronic disease, diagnosed diabetes accounts for an estimated \$327 billion in costs per year.² Achieving glycemic control and managing cardiovascular risk factors have conclusively shown to reduce diabetes complications, comorbidities and mortality. Today, many classes of medications and many formulations of insulin are available to effectively manage the metabolic abnormalities for individuals with diabetes. However, the affordability of medications in general, and insulin specifically, is of great concern to people with diabetes, their families and healthcare providers. For millions of people living with diabetes, including all individuals with type 1 diabetes, access to insulin is literally a matter of life and death. The average list price of insulin has skyrocketed in recent years, nearly tripling between 2002 and 2013.³

KEY TAKEAWAYS

- Insulin costs have been steadily increasing, forcing many people with diabetes to choose between purchasing this life-sustaining medication or paying for other necessities.
- Earlier this month, the ADA's Insulin Access and Affordability Working Group released findings from their research and stakeholder discussions.
- This Public Policy Statement provides an array of short-term and long-term recommendations to help shed light on the issue, to combat increasing insulin costs, and to improve affordable access to medications, including:
 - Streamlining the biosimilar approval process;
 - Increasing pricing transparency throughout the insulin supply chain;
 - Lowering or removing patient cost-sharing for insulin;
 - Increasing access to health care coverage for all people with diabetes.

**PAST YEAR INSULIN PRICE CHANGE BY INSURANCE TYPE
(AMONG THOSE USING INSULIN 1+ YEARS)**



Source: American Diabetes Association and Vault Consulting, LLC. Insulin Affordability Survey, 2018.

As the price of insulin continues to rise, so do patient costs. Individuals with diabetes are often forced to choose between purchasing their medication or paying for other necessities, exposing them to serious short- and long-term health consequences.⁴

The reasons for the increase are not entirely clear, but are due in part to the complexity of the drug supply chain. Even though insulin is unique, the path it takes from manufacturer to patient is the same as for most drugs. So too, are the negotiations between the different supply chain entities—manufacturers, wholesalers, pharmacy benefit managers (PBMs), health plans and pharmacies.

In order to solve this escalating problem of insulin affordability, there must be a better understanding of the transactions throughout the insulin supply chain, the impact each entity has

on what people with diabetes pay for insulin, and the relative efficacy of therapeutic options. As the nation’s leading voluntary health organization whose mission is “to prevent and cure diabetes

and to improve the lives of all people affected by diabetes,” the American Diabetes Association (ADA) is committed to helping find solutions for individuals and families who lack affordable access to insulin.

In November of 2016 the ADA launched its Make Insulin Affordable campaign, which calls

for all entities in the insulin supply chain to be transparent about the pricing process. Increasing transparency is the first step toward identifying viable, long-term solutions. More than 300,000 people have signed a petition calling for increased transparency in the insulin supply chain and for Congress to hold hearings to identify the reasons for the dramatic increases in insulin costs.⁵

“**We [budget], but I have to ask relatives to give us money each month so we can afford to pay our bills. How can it be that two college-educated, hard-working people with health insurance cannot afford insulin?**”
—Megan M.

In the spring of 2017, the ADA Board of Directors convened an Insulin Access and Affordability Working Group (Working Group) to ascertain the full scope of the insulin affordability issue. Throughout 2017 and early 2018, the Working Group assembled existing public information about insulin prices and patient cost-sharing, and held discussions with multiple stakeholders at every level of the insulin supply chain to discuss how each entity affects the cost of insulin for the consumer. In May 2018, the U.S. Senate Special Committee on Aging held a hearing titled Insulin Access and Affordability: The Rising Cost of Treatment, during which the Working Group's Chair and ADA Chief Scientific, Medical and Mission Officer, Dr. William T. Cefalu, discussed the Working Group's findings.⁶ The Working Group's findings can be accessed in the June 2018 issue of Diabetes Care.⁷ This Policy Statement utilizes the conclusions and recommendations of the Working Group to propose public policies that will help improve affordability of insulin and increase transparency throughout the insulin supply chain.

ADA'S PREVIOUS PUBLIC POLICY ACTIONS

One of the core public policy priorities for the ADA is to ensure health insurance options provide adequate and affordable access to the care people with diabetes and prediabetes need. As part of that work, the ADA has actively worked to enact legislation and influence regulations improving or protecting access to and affordability of health care at the state and federal levels. Much of this work has addressed coverage for and affordability of prescription drugs for people with diabetes, including insulin. In addition to our work related to access to health insurance in general, the ADA's work has included support of:

- Limits on prescription drug cost-sharing;
- Formularies without co-insurance;
- Excluding prescription drugs from the deductible;

- Oversight and enforcement of Affordable Care Act's (ACA) non-discrimination rules;
- Closing the Medicare Part D coverage gap;
- Prohibition of mid-year formulary changes;
- Requiring utilization management protocols to be evidence-based and consumer-friendly.

PUBLIC POLICY CHANGES RECOMMENDED BY ADA

Based on the findings of the Working Group and research conducted by the ADA, we recommend the following public policies to help improve the affordability of insulin. The ADA recognizes no single action will solve the complex problems that contribute to the high cost of insulin, but recommends an array of changes that can help address the issue. This paper includes recommendations specific to insulin as well as recommendations to improve access to and affordability of medications in general. Some of the recommendations are continuation of the ADA's previous work, while others are new proposals emerging from the Working Group's findings.

INSULIN-SPECIFIC RECOMMENDATIONS

Insulin Supply Chain Transparency

Even after the ADA's Working Group held in-depth discussions with multiple stakeholders at every level of the insulin supply chain, they concluded that there is a lack of transparency throughout the insulin supply chain. They also noted it is unclear precisely how the dollars flow through the supply chain and how much each intermediary profits. Without additional information about insulin pricing and patient costs, it is difficult to prescribe long-term, sustainable solutions that will address the underlying systemic problems. To be useful, the information must provide a full picture of the insulin supply chain.

Each entity in the supply chain impacts patient costs in some way. The list price for insulin is set by the manufacturer and is the starting point for negotiations among the manufacturer, PBMs, health plans, and others. PBMs negotiate rebates and fees with insulin manufacturers, health plans, and pharmacies and do business with almost every arm of the insulin supply chain. These confidential negotiations have a direct impact on the out-of-pocket costs for individuals with diabetes who need insulin. Out-of-pocket costs of insulin vary widely depending on a number of factors, including the formulary tier placement of the prescribed insulin; whether or not the individual is required to meet a deductible before prescription drug coverage begins; and the cost-sharing required for insulin. In addition to these costs, individuals are also responsible for paying their plan's premium. Therefore, health plan premium calculations and formulary decisions impact patient costs. Finally, most individuals with diabetes regularly receive their insulin either in person or via mail order from a pharmacy. The pharmacy interacts with other entities across the insulin supply chain and dispenses insulin to consumers based on the cost-sharing required by their health plan, the list price set by the manufacturer, or the pharmacy's own price.

RECOMMENDATION

It is imperative that we learn the factors that go into setting the list price, to provide clarity on the starting point for negotiations throughout the supply chain and how changing list prices impact supply chain entities and patients. But transparency from just one entity in the chain will not provide the full picture as to why out-of-pocket costs for insulin users have risen so

dramatically. Similar reporting from all entities in the insulin supply chain is necessary for a comprehensive assessment of the root cause and to identify long-term solutions. For example, to provide a better understanding of how health plans and PBMs impact the cost of insulin for people with diabetes, they should disclose more information about the coverage of and cost-sharing related to insulin. As the consumer-facing arm of the insulin supply chain it is also useful to learn how payments made to and collected by pharmacies impact an individual's out-of-pocket insulin costs.



I have had Type 1 diabetes since 1991. In 1996, when I first started using an analog insulin, my insulin cost \$27 a bottle with a \$10 copay for three months. Today, I am on the same brand of insulin and my 3-month copay is \$2152.... I will die without this medication and must be on it for the rest of my life.

—Kate M.



The ADA recommends increased transparency throughout the full insulin supply chain. To achieve this, we have outlined pieces of information from each entity that would help shed additional light on the factors contributing to high insulin costs for patients. For example:

- **Manufacturers:** Insulin production costs; sales and marketing expenditures for insulin; patient assistance program expenditures for insulin; rebates and fees paid to PBMs for insulin; fees paid to wholesalers for handling insulin; investments in research and development for insulin.
- **Wholesalers:** Payments made to manufacturers to purchase insulin; fees received from manufacturers for handling insulin; description of how handling fees for insulin are calculated; payments received from pharmacies for the sale of insulin.
- **PBMs:** Rebates and fees received from insulin manufacturers; amount of rebates and fees from insulin retained by the PBM; payments made to and received from pharmacies for insulin; payments and fees paid to wholesalers for insulin.

- **Health Plans:** Percentage of premiums attributable to insulin costs; annual changes in plan spending on insulin; average enrollee cost-sharing for insulin; overview of the PBM's responsibilities for the plan; rebates for insulin received from the PBM; description of how PBM discounts factor into patient cost-sharing; fees paid to PBMs.
- **Pharmacies:** Payments received from PBMs and insurers for insulin; payments made to pharmaceutical manufacturers and wholesalers for insulin; total fees paid to PBMs for insulin.

We recognize there are potential consequences in releasing all of this information to the general public, so we recommend the information be provided to an independent third party or parties, such as Congress, state legislatures, state agencies or federal agencies, that can compile and analyze the information to identify changes that will lead to long-term improvement in insulin affordability.

Competition and Biosimilar Insulins

In the broader prescription drug landscape, the availability of multiple generics reduces prices by 50%–80%.⁸ These dramatic price decreases occur because generics are easily substituted for the brand at the pharmacy, which is often reinforced by laws mandating generic substitution.^{9,10} Insulin is a biologic medication made from living cells, so the regulatory process for introduction of “generic” versions (called “biosimilar” or “follow-on biologics”) is different from traditional generic drugs. To date, three follow-on biologic insulins have been approved by the U.S. Food and Drug Administration (FDA),^{11,12,13} and two are available for sale in the U.S. Those medications were introduced with list prices approximately 15% lower than the original version.^{14,15,16} More importantly, none of the follow-on biologic insulins have been approved as substitutable or interchangeable for the branded original versions. To be deemed interchangeable with the original medication, the manufacturer must go through the biosimilar



For more than 25 years, I've wondered why insulin manufacturers cannot offer a generic alternative for this life-saving medication. Every other medication gets a generic equivalent in about 7 years, but we insulin users have been paying for brand name medication for my whole life.

—Brenda W.



approval pathway and provide additional data to the FDA that show the biosimilar medication is expected to produce the same clinical result as the original and that switching between the biosimilar and original will not increase safety risks or reduce effectiveness.¹⁷ State laws vary regarding whether interchangeable biosimilars can be automatically substituted for the original version at the pharmacy.¹⁸

RECOMMENDATION

While it is still unclear whether and how introduction of additional follow-on or biosimilar insulins will impact prices,^{19,20} increasing available options could lead to lower costs for patients. Recently, the FDA published a list of medications no longer under patent protection that do not have generic or biosimilar alternatives.^{21,22} The FDA will expedite review of applications for products on the list. The FDA list includes one type of insulin that is off-patent but for which there are no alternative versions available. The ADA recommends the FDA continue its efforts to encourage additional competition within the insulin landscape, including fostering biosimilar competition.

Health Plan Design and Patient Cost-Sharing

The ACA changed the health insurance landscape through numerous health insurance protections that improved access to coverage for people with diabetes, as well as the quality



When I was first diagnosed with diabetes, I was on an insurance plan through my employer that was not designed for diabetics, and there was no alternative plan that was better.... The insurance I had didn't cover prescriptions until after my deductible was met, and that deductible was outrageously high. In fact, I couldn't meet it most years. That meant that I had to try to pay for insulin out of pocket, which [was], at minimum, \$500 for a one-month supply, sometimes more.... I got some assistance now and then from my family, but **months went by where I wouldn't take one of my insulin prescriptions; most of the time, I only took one because that's all I could afford.**

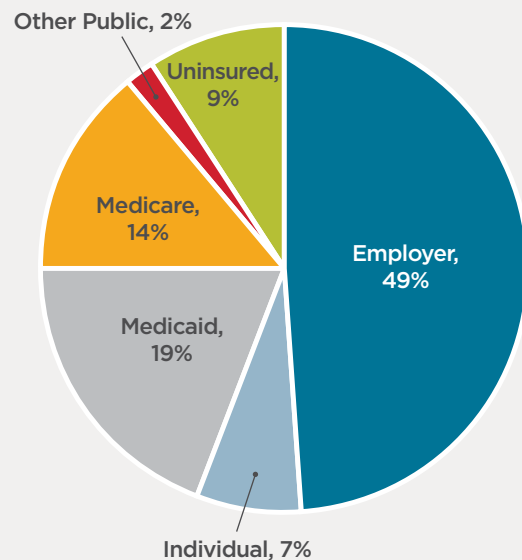


—Charles L.

of that coverage. Yet we know challenges with affordability persist. In addition, the ACA primarily modified the individual and small group health insurance markets. Only about 7% of Americans purchase their own insurance directly from an insurer or through state health insurance exchanges (called individual market insurance).²³ Almost half of Americans have health insurance provided through their employer or a family member's employer.²⁴ Medicaid, a health insurance program for low-income individuals, covers almost 20% of Americans.²⁵ Medicare, the federal health care program for Americans over age 65, people with disabilities under age 65 and people with end-stage renal disease, covers about 14% of Americans.²⁶ Roughly 2% of Americans are covered under other government programs like military or Veterans Administration coverage.²⁷

Many factors impact how much people with diabetes pay for insulin, but one of the largest is the health insurance plan and design of the pharmacy benefit. Health insurance plans, PBMs and government health care programs determine which drugs will be covered by the plan and how much patients pay. The coverage decisions are informed by a variety of factors, including price negotiations between manufacturers and PBMs. Health plans often utilize high patient cost-sharing or exclude medications from the formulary to encourage patients and prescribers to use medications that cost the plan less.

HEALTH INSURANCE COVERAGE BY TYPE, 2016



Source: State Health Facts, Health Insurance Coverage of the Total Population, 2016, Kaiser Family Foundation, available at: <https://www.kff.org/other/state-indicator/total-population>.

When people are not able to afford the medications, tools, education and care necessary to manage their diabetes, they scale back or forego the care they need.^{28,29} Specifically, in one study, after a large employer changed its employee health benefit plan to a health savings account (HSA) eligible high-deductible health plan (HDHP), employee spending on health care decreased, including a 15%–17% reduction in

pharmaceutical spending. Essentially all of the spending decrease was attributed to a decrease in receipt of care and services.³⁰ Unfortunately, for people with diabetes who need insulin to live, taking less insulin than prescribed can have serious and potentially deadly consequences

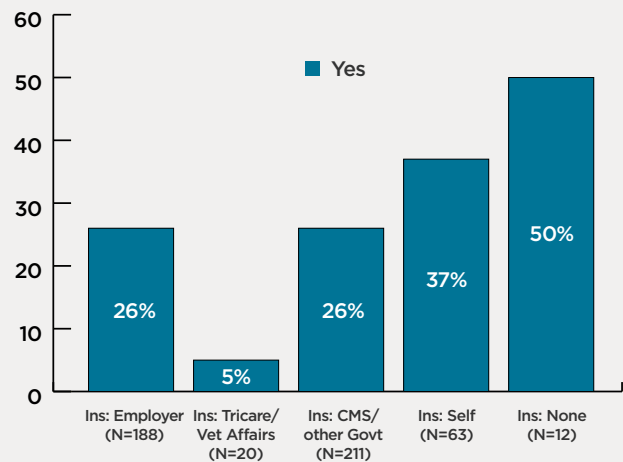
RECOMMENDATION

The ADA recommends that health plans and government programs make changes to their prescription drug benefit designs to ease the financial burden for people with diabetes by covering insulins without cost-sharing. Many health plans are moving toward a value-based insurance design, lowering or removing cost-sharing for high-value clinical services and medications. Providing diabetes medications with low or no cost-sharing has been shown to increase medication adherence and results in better long-term health outcomes.^{31,32}

At minimum, we recommend insulins not be subject to a deductible nor co-insurance, since this exposes people with diabetes to high list prices, often creating financial barriers to accessing the medicine. If cost-sharing is imposed for insulins, it should be a flat dollar amount, which can be more manageable and consistent for consumers.

When there are deductibles or co-insurance for insulins, the ADA recommends all discounts negotiated amongst the various supply chain entities (manufacturers, pharmacies, PBMs) be incorporated into the calculation of patient costs, ensuring patients pay the lowest price available. We recognize health plans attempt to maintain balance between premium costs and patient cost-sharing, and often these discounts are utilized to lower plan premiums for all enrollees. However, premiums are just one aspect of health care expenses for people with diabetes who need affordable access to medications, tools, care and education in order to effectively manage the disease and fend off devastating complications. A health plan with low premiums but exorbitant out-of-pocket costs does not help someone with regular health care needs. Utilizing

PAST YEAR COST HAS IMPACTED PAST YEAR INSULIN PURCHASE/USE (% YES) —BY INSURANCE (AMONG THOSE USING INSULIN 1+ YRS)



Source: American Diabetes Association and Vault Consulting, LLC. Insulin Affordability Survey, 2018.

savings from insulin negotiations to lower the premium costs for all plan enrollees shifts the cost burden to people with diabetes who need insulin to live.

Despite evidence showing that high cost-sharing reduces access to care, health plans imposing high deductibles continue to be widely available, including employer-sponsored insurance plans. To encourage employers to limit out-of-pocket expenses for insulin costs, the ADA recommends the Department of Treasury provide additional guidance to clarify that HSA-eligible HDHPs can exempt insulin from the deductible without impacting the tax status of such plans. Under federal rules, contributions to the HSA are not subject to income tax, so long as the plan meets certain requirements.³³ Under those requirements, HSA-eligible HDHPs can cover primary preventive benefits before the deductible is paid. While health plans and PBMs may often include insulin on their own preventive drug lists and provide coverage without patient cost-sharing, clarification is needed regarding whether exempting insulin from the deductible is permitted in HSA-eligible HDHPs.

IMPROVING ACCESS TO AND AFFORDABILITY OF ALL MEDICATIONS

Limits to Out-of-Pocket Costs

Currently, most health plans must limit the amount enrollees spend out-of-pocket for their health care each year. However, this maximum is generally applied to all health care spending combined. In addition, state individual market plans must meet standards for the average cost of care covered by the plan (actuarial value requirements), but these standards also apply for all types of health care spending combined. Rarely is there a limit to how much patients can be required to spend out-of-pocket for medications.

For example, in the Medicare Part D program, there is no limit on cost-sharing for beneficiaries not eligible for a low-income subsidy. Once these beneficiaries reach the catastrophic phase of the Part D benefit, the cost-sharing under the standard benefit structure is 5% of a drug's cost. For drugs with high list prices, like insulin, even 5% can be unaffordable—especially if the beneficiary reaches the catastrophic phase early in the plan year. Average annual spending on those who reach the catastrophic coverage level is \$16,914 per person, and those who reach the catastrophic coverage level fill on average twice as many prescriptions

and have an average price per prescription more than twice as high as those who do not. This burden disproportionately impacts people with and at risk for developing diabetes. Specifically, among individuals who reach the catastrophic coverage level, gross spending on diabetes medications is the second highest of all therapeutic classes. In addition, Medicare Part D enrollees who reach the catastrophic coverage level are more likely to be African American—a population with high diabetes risk—compared to the general Part D population.³⁶



My husband... has Medicare, but even with that and a very good ... plan our out-of-pocket costs are quite high. We get into and then through the “donut hole” very quickly. Fortunately, once we are in the catastrophic coverage phase we only pay about \$360 for the pens and \$120 for the vials for a 3-month supply. Still, that is \$480 every 3 months and he has many other meds too, of course. Insulin is not a choice, it is a necessity for people with diabetes. We have had to change our lifestyle and forego a lot of things we should be able to do and enjoy at this stage of our life because of these medical costs.

He worked hard all his life until his disability and we saved up a lot of money only to see it gradually get drained by medical bills.

—Debra L.



RECOMMENDATION

The ADA recommends health plans and government programs be required to limit out-of-pocket spending for medications. In the Medicare Part D program, we recommend an annual out-of-pocket limit equal to the catastrophic phase trigger to provide some financial protection for individuals with high annual drug costs. For commercial health plans, this could be implemented as a monthly cost-sharing limit for medications; by applying the

actuarial value standards to all covered benefits independently, including covered prescription drugs; and/or implementing an annual prescription drug out-of-pocket spending limit.

The ADA also supports allowing the Secretary of the U.S. Department of Health and Human Services (HHS) to negotiate prices for the Medicare Part D program. The current Medicare

Part D statutes prohibit the Secretary of HHS from interfering with the negotiations between drug manufacturers and Part D plan issuers.³⁷ In addition, the Secretary is prohibited from requiring a particular formulary under Part D.³⁸ Under the standard Medicare Part D benefit design, beneficiary cost-sharing is 25% of the negotiated price of the medication. Generally, lower negotiated Part D prices mean lower beneficiary cost-sharing. However, the overall impact of lower negotiated prices on beneficiary cost-sharing will likely depend on plan design since many Part D plans provide a tiered cost-sharing structure. According to a 2007 Congressional Budget Office (CBO) analysis, “providing broad negotiating authority by itself would likely have a negligible effect of federal spending.”³⁹ In contrast, CBO estimated that the authority “to establish a formulary, set prices administratively, or take other regulatory actions against firms failing to offer price reductions could give the Secretary the ability to obtain significant discounts...”⁴⁰

Continuity of Care

Day-to-day management of diabetes is a heavy burden that rests squarely with the individual living with the disease. Often medication is at the core of daily diabetes management. There are numerous factors people with diabetes and their health care providers consider when choosing a medication, including efficacy, risk of low blood sugar, pre-existing cardiovascular disease, impact

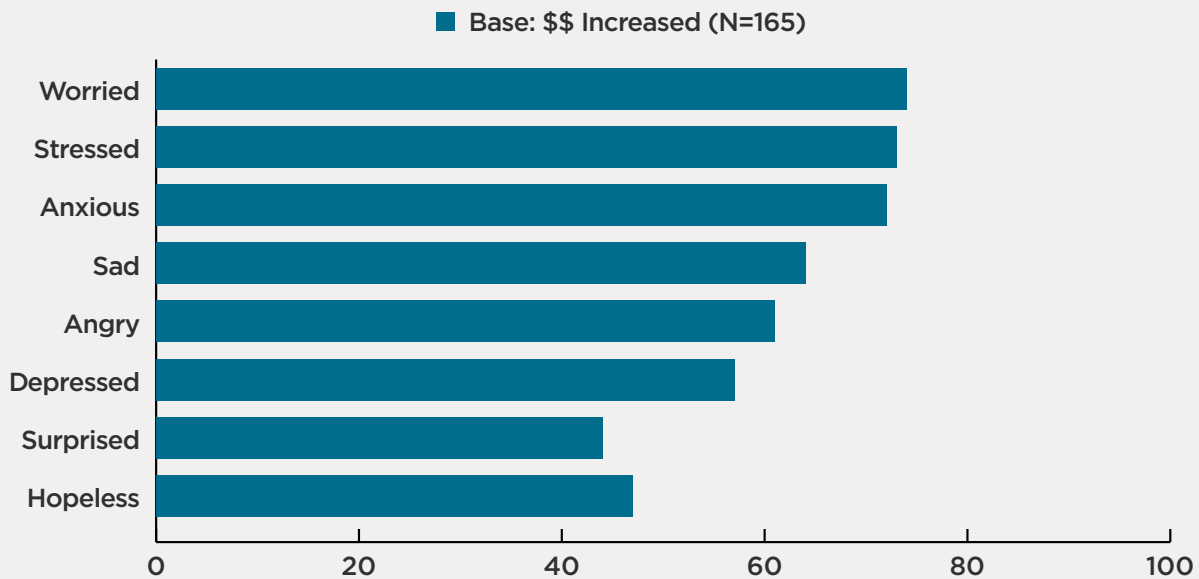


I was on Brand A [insulin]—which was somewhat ok... [Then I] got switched to Brand B which gave me AMAZING results... [T]hen insurance said they would not pay for Brand B as it was not on their “formulary”... and the only one they would pay for was Brand A... regardless of whether it works for the patient or not.

—Lori-Lynne W.



PAST YEAR “FEELINGS” AS A RESULT OF AMOUNT PAID FOR INSULIN (AMONG THOSE EXPERIENCING A PRICE INCREASE)



Source: American Diabetes Association and Vault Consulting, LLC. Insulin Affordability Survey, 2018.

on weight, potential side effects, cost and patient preferences. Excluding a medication from the prescription drug formulary can jeopardize the health of many patients with diabetes. In addition to the possibility that the covered alternative medication is not appropriate for the patient, formulary changes disrupt the continuity of care and burden patients with unanticipated, increased cost-sharing. These additional costs could result in individuals with diabetes being unable to afford medications essential to maintaining their health. Formulary changes made during the plan year are particularly troubling because most individuals do not have the option of changing to a different insurance plan that would cover his or her prescription medication.

RECOMMENDATION

Since most individuals with diabetes rely so greatly on medications to manage their diabetes and prevent complications, the ADA recommends all health plans and government health care programs be prohibited from removing medications from formularies or moving medications to a higher tier during the plan year, except when the FDA calls into question the clinical safety of the drug. This prohibition should apply regardless of whether the pharmacy benefit is managed by a third party, like a PBM. This practice is prohibited in Medicare Part D, and some states have implemented similar restrictions for state-regulated health plans. The ADA recommends this prohibition be applied to all health plans and government health care programs.

Formulary Development Process

Whether a medication is covered on a health plan's formulary and on which cost-sharing tier it is placed directly impacts patient costs. Often, these decisions are made by PBMs, who have Pharmacy and Therapeutics Committees (P&T Committees) comprised of pharmacy and medical experts.^{41,42} Sometimes, PBMs will develop a "national" or "standard" formulary they present to their health plan or employer

plan clients, who decide whether to adopt the PBM's national formulary, or customize their own.^{43,44} Regulation of formulary development and composition varies depending on the health plan type, and whether a health plan's designee is developing the formulary.

RECOMMENDATION

Because of the direct impact formulary decisions have on insured people with diabetes, the ADA recommends all health plans and government health care programs as well as the PBMs they work with be required to follow rigorous standards for the development of prescription drug formularies. This includes:

- Requiring formularies to be developed in accordance with evidence-based standards of care and provide coverage for a wide range of options within each therapeutic area;
- Requiring all utilization management protocols to be developed based on evidence-based standards of care;
- Utilizing a transparent process for the development of formularies;
- Requiring a minimum number of P&T Committee members without a conflict of interest and prohibiting members with a conflict of interest from voting on matters for which the conflict exists.

Value-Based Insurance Design

The ADA supports many public policies consistent with the concept of value-based insurance design. With value-based insurance design, the amount of cost-sharing for a medical treatment or service is set according to its value rather than its cost. Value-based insurance design provides coverage for evidence-based treatments that improve health by lowering or eliminating patient cost-sharing. Efforts to encourage value-based insurance design, wherein cost-sharing is linked to population health outcomes, may improve adherence and lower patients' financial burden.⁴⁵

RECOMMENDATION

When value-based insurance design is implemented, the ADA recommends regulators, health plans and government programs ensure the design is evidence-based and that it includes consumer cost-sharing protections, such as low co-pays and accessible exceptions processes. The ADA recommends continued assessment of value-based models within Medicaid and Medicare, as well as provision of industry guidance regarding the role of Medicaid best price requirements in outcomes or value-based health insurance design.

IMPROVING ACCESS TO ADEQUATE, AFFORDABLE HEALTH CARE

Medicaid Expansion

While the ACA made tremendous positive changes to the availability and affordability of health insurance for people with pre-existing conditions, like diabetes, just over 12% of adults in the U.S. were uninsured at the end of 2017.⁴⁶ This is due in part to the so-called Medicaid gap. The ACA was written with the assumption that every state would extend Medicaid eligibility to individuals earning less than 138% of the federal poverty level (FPL), so the premium and cost-sharing subsidies to help individuals purchase health care coverage through the state health insurance Marketplaces are only available to those earning 100–400% of the FPL. Some states do not provide Medicaid coverage to non-disabled adults—regardless of how low little they earn. Consequently, in states that have not expanded their Medicaid programs, individuals earning less than 100% of the FPL are left without an affordable health care coverage option. Nearly 2.5 million uninsured adults fall within the Medicaid gap in states that have not expanded their Medicaid programs.⁴⁷ A survey of the impact of Medicaid expansion in three states—Kentucky, Arkansas, and Texas—shows that gaining coverage under the ACA was

associated with a \$337 reduction in annual out-of-pocket spending and a 25% increase in blood glucose screening.⁴⁸

RECOMMENDATION

All states should expand Medicaid eligibility to those earning less than 138% FPL. In addition, states should take steps to maintain or improve upon existing consumer protections that ensure people with diabetes have meaningful access to adequate, affordable health insurance coverage.



...I had insurance through ... school that had a discount for prescriptions but no prescription coverage. I thought my insulin would be around \$250 a month. When I filled my prescription for the first time, I burst into tears at the drive-up window when they told me it was \$579. I was living off student loans and a small school stipend. I had to put it on credit cards for the rest of the time I was in school. A year and a half later, I finally just paid off the cost of my insulin.

—Melissa A.



Health Insurance Transparency for Consumers

While the ADA does not expect insulin supply chain transparency itself to directly lead to lower costs for patients, providing consumers additional transparency in their expected costs could. Studies show providing general health insurance coverage information may not result in “smart” health insurance choices,^{49,50,51,52} but providing information on expected cost-sharing more closely tailored to the individual may.⁵³ For example, providing Medicare Part D enrollees a cost estimate based on the medications they take resulted in 5% lower annual costs

for enrollees who chose a different plan after receiving the cost information.⁵⁴

Health insurance literacy impacts patient access to care and out-of-pocket costs.⁵⁵ When people with diabetes do not understand their insurance choices, they risk choosing a plan that does not have adequate or affordable coverage for diabetes care. It is usually easier for individuals to determine their monthly premiums for health care coverage than other health care costs like deductibles, co-insurance and out-of-network charges.⁵⁶ The ACA requires most health plans to provide to enrollees and prospective enrollees a plain-language summary of its benefits (called a Summary of Benefits and Coverage or SBC) to help people better understand its coverage and compare plans. The SBC includes a coverage scenario for a sample patient with type 2 diabetes, which helps consumers make an apples-to-apples comparison of plans, but does not provide an estimate of the individual's actual expected costs under the plan.

RECOMMENDATION

All health insurance plans and government programs should be required to provide consumer-friendly tools to help individuals search for the medications they need and provide specific cost-sharing amounts. Fixed-dollar co-pays make costs clearer for patients than co-insurance. Therefore, we recommend, if a plan imposes co-insurance for insulin or any other medications, it should include the dollar amounts consumers will pay out-of-pocket within the formulary document—not just percentages. For example, if a plan charges 30% co-insurance for a \$100 vial of insulin, the formulary should notify consumers that their cost-sharing will be \$30 per vial, per month.

In addition, health plans and government health programs should be required to post an up-to-date formulary online and make this information available in writing, listing all covered drugs. Formulary documents often include only the most commonly prescribed medications covered by the plan. But this makes it difficult

for individuals trying to determine if medications not listed in the formulary document are not covered by the plan, or if they were not included because they are not among the most commonly prescribed drugs. By requiring the formulary documents to list all covered medications, individuals shopping for and enrolled in coverage will have an accurate and reliable list of which drugs are included on the plan's formulary as well as the expected cost-sharing. In addition, to ensure plan enrollees and those shopping for coverage mid-year have access to the most accurate information, plans should be required to update their published formulary documents at least quarterly to reflect any changes made.

Language Access

Latinos, African Americans, American Indians, Alaska Natives, Asian Americans, Native Hawaiians, and Pacific Islanders have a higher incidence of diabetes and are often less able to obtain the care they need to manage their disease than their Caucasian counterparts. Individuals in these populations are also at higher risk for some diabetes complications, such as diabetic retinopathy, non-traumatic lower-limb amputation, and end stage renal disease. Unfortunately, health insurance literacy is lower for non-whites than whites.^{57,58} Therefore, it is imperative that all individuals in communities at high risk for diabetes have access to, and an understanding of, the health care and health insurance options available to them so they are better equipped to prevent or manage the disease. As discussed above, health insurance literacy helps to lower patient spending on health care. Providing health plan coverage and cost information in non-English languages is critical to ensuring meaningful access to this information for all populations impacted by diabetes.

RECOMMENDATION

The ADA recommends all health plans, government programs, health insurance agents and brokers be required to provide on websites and documents taglines in non-

English languages indicating the availability of language services. These taglines greatly help reduce barriers to obtaining and understanding health insurance, particularly for individuals in populations at high risk for developing diabetes.

CONCLUSION

Insulin is not a luxury to those who rely on it to live. Yet, over the past decade insulin costs have steadily increased, forcing many people with diabetes to make tough choices to afford their insulin. There are many entities in the insulin supply chain that impact how much individuals pay, but not enough is known about the transactions and negotiations among them. Improving pricing transparency throughout the insulin supply chain will help policymakers assess the root cause of increasing patient costs and identify long-term solutions. While this information is important, it alone will not lower costs people with diabetes pay to access this life-sustaining medication. This policy statement provides a wide range of policy recommendations targeting both goals: Increased transparency and lower patient costs. When more is known about the transactions throughout the supply chain, it is likely additional promising public policy proposals will emerge. In the meantime, the ADA recommends policymakers take any steps necessary to ensure all people with diabetes have affordable access to insulin, regardless of where they live, whether they have insurance and how much money they earn. ■

About the Authors

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- ¹ Centers for Disease Control and Prevention, National Diabetes Statistics Report, 2017, available at: <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>.
- ² American Diabetes Association, Economic Costs of Diabetes in the U.S. in 2017, *Diabetes Care*, March 2018, available at: <http://care.diabetesjournals.org/content/early/2018/03/20/dci18-0007>.
- ³ Hua X, Carvalho N, Tew M, et al., Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013, *JAMA*, April 2016, available at: <https://jamanetwork.com/journals/jama/fullarticle/2510902>.
- ⁴ American Diabetes Association, <https://makeinsulinaffordable.org/insulin-stories/>.
- ⁵ American Diabetes Association, <https://makeinsulinaffordable.org/petition/>.
- ⁶ U.S. Senate Special Committee on Aging, Insulin Access and Affordability: The Rising Cost of Treatment, May 2018, available at: <https://www.aging.senate.gov/hearings/insulin-access-and-affordability-the-rising-cost-of-treatment>.
- ⁷ Cefalu WT, Dawes DE, Gavlak G, et al., Insulin Access and Affordability Working Group: Conclusions and Recommendations, *Diabetes Care*, May 2018, available at: <https://doi.org/10.2337/dci18-0019>.
- ⁸ U.S. Food and Drug Administration, Generic Competition and Drug Prices, available at: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.
- ⁹ Shrank WH, Choudru NK, Agnew-Blais J, et al., State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid, *Health Affairs*, July 2010, available at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2009.0424>.
- ¹⁰ U.S. Government Accountability Office, Drug Pricing: Research on Savings from Generic Drug Use, GAO-12-371R, January 2012, available at: <https://www.gao.gov/products/GAO-12-371R>.
- ¹¹ U.S. Food and Drug Administration, Basaglar (insulin glargine injection), December 2015, available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/205692Orig1s000TOC.cfm.
- ¹² U.S. Food and Drug Administration News Release, FDA Approves Admelog, the First Short-Acting "Follow-on" Insulin Product to Treat Diabetes, December 2017, available at: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm588466.htm>.
- ¹³ Merck Press Release, Merck Announces U.S. FDA Grants Tentative Approval for LUSDUNA™ Nexvue™ (insulin glargine injection), a Follow-On Biologic Basal Insulin, July 2017, available at: <http://investors.merck.com/news/press-release-details/2017/Merck-Announces-US-FDA-Grants-Tentative-Approval-for-LUSDUNA-Nexvue-insulin-glargine-injection-a-Follow-On-Biologic-Basal-Insulin/default.aspx>.
- ¹⁴ Ault A, Rising Insulin Costs in US Get Pushback as Basaglar Launches, *MedScape*, December 2016, available at: <https://www.medscape.com/viewarticle/873353>.
- ¹⁵ Ramsey L, A Cheaper Version of the Lifesaving Diabetes Medication Just Launched in the US, *Business Insider*, December 2016, available at: <http://www.businessinsider.com/insulin-cheaper-generic-2016-12>.
- ¹⁶ Sanofi Press Release, New Sanofi Insulin Savings Program Aims to Lower Out-of-Pocket Costs for People Living with Diabetes, April 2018, available at: <https://www.prnewswire.com/news-releases/new-sanofi-insulin-savings-program-aims-to-lower-out-of-pocket-costs-for-people-living-with-diabetes-300624743.html>.
- ¹⁷ U.S. Food and Drug Administration, How Drugs are Developed and Approved, available at: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/>.
- ¹⁸ Cauchi R, State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars, National Conference of State Legislatures, April 2018, available at: <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>.
- ¹⁹ Baghdadi R, Kesselheim A, Wilensky GR, Tollen L, Biosimilars, *Health Affairs Health Policy Brief*, July 2017, available at: <https://www.healthaffairs.org/doi/10.1377/hpb20170721.487227/full/>
- ²⁰ Hakim A, Ross JS, Obstacles to the Adoption of Biosimilars for Chronic Diseases, *JAMA*, May 2017, available at: <https://jamanetwork.com/journals/jama/article-abstract/2625049>
- ²¹ U.S. Food and Drug Administration, FDA Works to Encourage and Optimize Drug Competition with Transparency, December 2017, available at: <https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm589275.htm>
- ²² Edney A, FDA Targets Insulin for Increased Competition to Lower Prices, *Bloomberg*, December 2017, available at: <https://www.bloomberg.com/news/articles/2017-12-15/fda-targets-insulin-for-increased-competition-to-lower-prices>
- ²³ State Health Facts, Health Insurance Coverage of the Total Population, 2016, Kaiser Family Foundation, available at: <https://www.kff.org/other/state-indicator/total-population>
- ²⁴ Ibid.
- ²⁵ Ibid.
- ²⁶ Ibid.
- ²⁷ Ibid.
- ²⁸ Premiums and Cost-Sharing in Medicaid: A Review of Research Findings, Kaiser Commission on Medicaid and the Uninsured, February 2013, available at: <https://www.kff.org/medicaid/issue-brief/premiums-and-cost-sharing-in-medicaid-a-review-of-research-findings/>.
- ²⁹ Brot-Goldberg ZC, Chandra A, Handel BR, Kolstad JT, What Does a Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities and Spending Dynamics, *The National Bureau of Economic Research*, October 2015, available at: <http://www.nber.org/papers/w21632>.
- ³⁰ Ibid.
- ³¹ Blumenthal DM, Goldman DP, Jena AB, Outcomes-Based Pricing as a Tool to Ensure Access to Novel but Expensive Biopharmaceuticals, *Annals of Internal Medicine*, February 2017, available at: <http://annals.org/aim/article-abstract/2592775/outcomes-based-pricing-tool-ensure-access-novel-expensive-biopharmaceuticals>.

-
- ³² Spaulding A, Fendrick AM, Herman WH, et al., A Controlled Trial of Value-Based Insurance Design - the MHealthy: Focus on Diabetes (FOD) Trial, *Implementation Science*, April 2009, available at: <https://www.ncbi.nlm.nih.gov/pubmed/19351413>.
- ³³ Internal Revenue Service, Publication 969, Health Savings Accounts and Other Tax-Favored Health Plans, 2017 available at: https://www.irs.gov/publications/p969#en_US_2017_publink1000204025
- ³⁴ Kaiser Family Foundation, The Medicare Part D Prescription Drug Benefit, October 2017, available at: <http://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit>.
- ³⁵ Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System, June 2016, available at: <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>. Includes spending by all parties, including Medicare, Part D plan, and enrollee.
- ³⁶ Ibid.
- ³⁷ 42 U.S.C. §1395w-111(i).
- ³⁸ Ibid.
- ³⁹ Congressional Budget Office, Letter to Senator Wyden, April 2007, available at: <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf>.
- ⁴⁰ Ibid.
- ⁴¹ Academy of Managed Care Pharmacy, Formulary Development, November 2009, available at: <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298>
- ⁴² Pharmaceutical Care Management Association, What is a Formulary?, available at: <https://www.pcmanet.org/pcma-cardstack/what-is-a-formulary/>
- ⁴³ Express Scripts, How We Build a Formulary, July 2016, available at: <http://lab.express-scripts.com/lab/insights/drug-options/how-we-build-a-formulary>
- ⁴⁴ Brennan T, 2018 Formulary Strategy: Targeted Management, Expanded Cost Control Options, CVS Health, August 2017, available at: <https://payorsolutions.cvshealth.com/insights/2018-formulary-strategy>
- ⁴⁵ Lakdawalla D, Eber MR, Forma FM, Sullivan J, et al., Measuring the Value of Better Diabetes Management, *American Journal of Managed Care*, April 2013, available at: <http://www.ajmc.com/journals/evidence-based-diabetes-management/2013/2013-1-vol19-sp2/measuring-the-value-of-better-diabetes-management?p=2>.
- ⁴⁶ Auter Z, U.S. Uninsured Rate Steady at 12.2% in Fourth Quarter 2017, Gallup-Sharecare Well-Being Index, January 2018, available at: <http://news.gallup.com/poll/225383/uninsured-rate-steady-fourth-quarter-2017.aspx>.
- ⁴⁷ Garfield R, Damico A, The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid, Kaiser Family Foundation, November 2017, available at: <https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/>.
- ⁴⁸ Sommers BD, Maylone B, Blendon RJ, et al., Three-Year Impacts of the Affordable Care Act: Improved Medical Care and Health among Low-Income Adults, *Health Affairs*, May 2017, available at: <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.0293>.
- ⁴⁹ Brown V, Russell M, Ginter A, et al., Smart Choice Health Insurance©: A New, Interdisciplinary Program to Enhance Health Insurance Literacy, *Health Promotion Practice*, March 2016, available at: <https://www.ncbi.nlm.nih.gov/pubmed/26721502>.
- ⁵⁰ Bhargava S, Loewenstein G, Sydnor J, Do Individuals Make Sensible Health Insurance Decisions? Evidence from a Menu with Dominated Options, National Bureau of Economic Research, Working Paper No. 21160, May 2015. Available at: <http://www.nber.org/papers/w21160>
- ⁵¹ Austin Frakt, Why Consumers Often Err in Choosing Health Plans, *New York Times*, November 2015, available at: <https://www.nytimes.com/2015/11/02/upshot/why-consumers-often-err-in-choosing-health-plans.html>.
- ⁵² Barnes AJ, Hanoch Y, Rice T, Determinants of Coverage Decisions in Health Insurance Marketplaces: Consumers' Decision-Making Abilities and the Amount of Information in their Choice Environment, *Health Services Research*, February 2015, available at: <https://www.ncbi.nlm.nih.gov/pubmed/24779769>.
- ⁵³ Bartholomae S, Russell MB, Braun B, McCoy T, Building Health Insurance Literacy: Evidence from the Smart Choice Health Insurance™ Program, *Journal of Family and Economic Issues*, June 2016, available at: <https://link.springer.com/article/10.1007/s10834-016-9482-7>.
- ⁵⁴ Kling, J., S. Mullainathan, E. Shafir, et al., Comparison Friction: Experimental Evidence from Medicare Drug Plans, *The National Bureau of Economic Research*, September 2011, available at: <http://www.nber.org/papers/w17410>.
- ⁵⁵ Rasu RS, Bawa WA, Suminski R, et al., Health Literacy Impact on National Healthcare Utilization and Expenditure, *International Journal of Health Policy and Management*, November 2015, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4629700/>.
- ⁵⁶ Norton M, Hamel L, Brodie M, Assessing Americans' Familiarity with Health Insurance Terms and Concepts, Kaiser Family Foundation, November 2014, available at: <https://www.kff.org/health-reform/poll-finding/assessing-americans-familiarity-with-health-insurance-terms-and-concepts/>.
- ⁵⁷ Long SK, Goin D, Large Racial and Ethnic Differences in Health Insurance Literacy Signal Need for Targeted Education and Outreach, *Urban Institute Health Policy Center*, February 2014, available at: <http://hrms.urban.org/briefs/literacy-by-race.html>.
- ⁵⁸ Villagra VG, Fifield J, Coman E, et al., Health Insurance Literacy in Connecticut, UConn Health, Health Disparities Institute, April 2017, available at: <https://health.uconn.edu/health-disparities/health-insurance-literacy-survey-report/>.
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