



United States Office of Management and Budget, Request for Information: *Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government*

Docket No. OMB-2021-0005

Response from the American Diabetes Association

July 6, 2021

Introduction and Background

Thank you for providing the American Diabetes Association (ADA) the opportunity to submit comments to the Office of Management and Budget (OMB) on how the federal government can more equitably serve all Americans, particularly those who are underserved. We appreciate your consideration of this important topic at such a critical time.

The ADA is the nation's leading voluntary health organization fighting to bend the curve on the diabetes epidemic and help people living with diabetes thrive. For more than 80 years the ADA has been driving discovery and research to treat, manage, and prevent diabetes, while working relentlessly for a cure. We help people with diabetes thrive by fighting for their rights and developing programs, advocacy, and education designed to improve their quality of life.

More people in the U.S. have diabetes today than ever have before – and prevalence rates continue to rise. In the last 20 years, the number of American adults diagnosed with diabetes has more than doubled.¹ Nearly 40 percent of the U.S. population, or upwards of 122 million Americans, live with diabetes and prediabetes today.² Rates of underlying chronic disease broadly, many of which stem from and are related to diabetes, mirror this trend – six in 10 U.S. adults now have at least one chronic disease, and four in 10 have two or more.³ Chronic disease is the leading cause of death and disability in America today, and results in more than \$1 trillion in health care expenses annually.⁴

The burden of these rising diabetes rates falls disproportionately on low-income communities, historically underserved Americans, and people of color. Diabetes prevalence today among minority groups is nearly twice as high as it is for white Americans.⁵ Much of this is because the social, economic, and environmental factors that put people at a higher risk for developing diabetes are especially pervasive in America's communities of color. Zip code, educational opportunity, and socioeconomic status often dictate how far someone lives from the nearest grocery store, whether they have access to healthy foods, and whether they have quality health care nearby, putting needed resources out of reach for many of those among us who need them most.

These trends are so prevalent that in the U.S. today, it is impossible to disentangle diabetes from larger systemic questions around health equity; we cannot have a holistic

¹ U.S. Centers for Disease Control and Prevention, "Diabetes Quick Facts," August 6, 2019, <https://www.cdc.gov/diabetes/basics/quick-facts.html>.

² American Diabetes Association, "Statistics About Diabetes," <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>.

³ U.S. Centers for Disease Control and Prevention, "Chronic Diseases in America," <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>.

⁴ Hugh Waters and Marlon Graf, *The Cost of Chronic Disease in the U.S.*, The Milken Institute, August 2018, https://milkeninstitute.org/sites/default/files/reports-pdf/ChronicDiseases-HighRes-FINAL_2.pdf.

⁵ ADA, "Statistics About Diabetes."

conversation about the causes and effects of one without discussing the other. It is for this reason that the ADA is dedicated to helping improve health equity in the United States, and by extension, racial and socioeconomic equity writ large – today’s health disparities are rooted in centuries of structural racism, resulting in systemic barriers to health care and other resources that over time have compounded the disadvantages faced by Americans of color and other historically underserved communities, at the expense of both health and personal well-being.

The COVID-19 pandemic provided a striking illustration – and exacerbation – of this tragic pattern. It has been widely reported that the novel coronavirus is more dangerous for minority groups: according to the Centers for Disease Control and Prevention (CDC), not only are Black, Hispanic, and American Indian or Alaska Native Americans three times as likely to be hospitalized with COVID than their white peers, they are also more than twice as likely to die of the virus.⁶ COVID has also taken a disproportionate toll on Americans living with diabetes: our community accounts for 40 percent of virus fatalities nationwide, despite making up just 10 percent of the U.S. population.⁷ What has not been as widely written about is that these two groups – people with diabetes and people of color – largely overlap, and often do so in low-income and underserved communities. When we consider that more than three in four Americans living in poverty today are people of color, and that income-related inequities in diabetes prevalence have steadily widened over the past decade, it becomes clear how the disparities this pandemic has brought to light have not only persisted but continue to intensify.⁸

While COVID has cast a needed spotlight on these issues, it is imperative that we strive to make the U.S. an equitable place for all – irrespective of race, income, zip code, age, education, gender, or health status – both through the end of this pandemic and beyond. To address this system-wide problem, we must look toward system-wide solutions. For too long, those of us working in this space – government agencies,

⁶ U.S. Centers for Disease Control and Prevention, “Risk for COVID-19 Infection, Hospitalization, and Death By Race/Ethnicity,” June 17, 2021, <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-race-ethnicity.html>.

⁷ Erin K. Stokes et al., “Coronavirus Disease 2019 Case Surveillance—United States, January 22–May 30, 2020,” *Morbidity and Mortality Weekly Report (MMWR)*, U.S. Centers for Disease Control and Prevention, June 15, 2020, https://www.cdc.gov/mmwr/volumes/69/wr/mm6924e2.htm?s_cid=mm6924e2_w#T1_down; Karena Yan, “1 in 10 People with COVID and Diabetes Die Within Seven Days of Hospital Admission,” *diaTribe Learn*, June 22, 2020, <https://diatribe.org/1-10-people-covid-and-diabetes-die-within-seven-days-hospital-admission>; Jonathan M. Wortham et al., “Characteristics of Persons Who Died with COVID-19 — United States, February 12–May 18, 2020,” *Morbidity and Mortality Weekly Report (MMWR)*, Centers for Disease Control and Prevention, July 10, 2020, <https://www.cdc.gov/mmwr/volumes/69/wr/mm6928e1.htm>; ADA, “Statistics About Diabetes.”

⁸ Kaiser Family Foundation, “Poverty Rate by Race/Ethnicity,” <https://www.kff.org/other/state-indicator/poverty-rate-by-raceethnicity/?currentTimeframe=0&sortModel=%7B%22colld%22:%22Location%22,%22sort%22:%22asc%22%7D>; American Diabetes Association, “Income-Related Inequalities in Diabetes Have Widened Over Past Decade, CDC Study Finds,” June 28, 2021, <https://www.diabetes.org/newsroom/press-releases/2021/income-related-inequalities-in-diabetes-have-widened-over-past-decade-cdc-study-finds>.

private entities, and nonprofit groups alike – have preferred short-term approaches that, while well-intended, have failed to remedy the source of these issues, especially when it comes to diabetes. It is for this reason that while one-dimensional policy interventions – like raising the cost of certain “unhealthy” foods or beverages – may boost revenue and reduce some consumption of those items, they ultimately do not address the causes of health discrepancies in minority and low-income communities or provide system-wide approaches to the challenges that people with diabetes and prediabetes face. We must instead ask ourselves what can be done to create resources and facilitate the consumption of better alternatives in communities whose food resources are limited and largely bereft of nutrients; whose economic resources are inadequate to cover the cost of healthy food options; and whose institutions regularly serve foods that fail to account for the unique nutritional needs of people with or at high risk for diabetes.

To generate this type of structural change, we need to look further upstream and address the cause of these problems rather than just the symptoms. That is why the ADA launched our Health Equity Now campaign last year and published our Health Equity Bill of Rights, a set of principles guiding the ADA’s ongoing efforts to take on, through policy and programmatic action, the systemic barriers to health and health care that persist in our country today.⁹ Through this work, we aim to ensure that no person with diabetes or at risk for developing diabetes, regardless of who they are, where they are from, or what they look like, lacks the resources they need to stay safe and healthy – a bare necessity that has remained out of reach for far too many for far too long.

While no silver bullet can reverse the grim effects of hundreds of years of racial injustice, structural inequality, and systemic barriers to health care, there is much we can do to ensure that nobody is forced to go without the resources they need to live a healthy life. It is our hope that, in addition to considering the policy recommendations enclosed in this response, OMB and the Biden administration more broadly will partner with and keep the diabetes community top of mind as we work to build a more equitable future for all.

Area 1: Equity Assessments and Strategies

Approaches and methods for holistic and program- or policy-specific assessments of equity for public sector entities, including but not limited to the development of public policy strategies that advance equity and the use of data to inform equitable public policy strategies.

One of the most consequential issues for the diabetes community today – and among the greatest barriers to health and well-being for Americans living with diabetes – is the cost of health care. Ever-rising prices across our health care system are shouldered disproportionately by people with diabetes, who interact with health care providers,

⁹ American Diabetes Association, “#HealthEquityNow,” <https://www.diabetes.org/healthequitynow>; American Diabetes Association, “Health Equity Bill of Rights,” https://www.diabetes.org/sites/default/files/2020-08/Health%20Equity%20Bill_2nd_v2.pdf.

pharmacies, and hospitals significantly more often than the average person. Given these realities, it should be little surprise that diabetes is the most expensive chronic disease in the U.S.; that Americans with diabetes spend two and a half times more on health care than those who do not have diabetes; that people with diabetes account for \$1 in every \$3 spent on prescription drugs, and 25 cents of every dollar spent on health care, in America today; and that one in four insulin-dependent Americans report rationing their insulin supply due to financial difficulty.¹⁰ The cost of living with diabetes is not only high, but also continues to rise – since 2014, insulin list prices have surged by more than 50 percent, while list prices for non-insulin diabetes medications have spiked by over 75 percent – a much steeper increase than costs for all drugs, which increased by just 30 percent over the same period.¹¹

The soaring cost of diabetes care not only makes the condition hard to manage medically, but oftentimes next to impossible for the many low-income Americans living with the condition. As the press has widely reported, the economic burden of diabetes forces large numbers of individuals in our community to choose between obtaining life-sustaining medications and meeting other basic needs. Since the COVID-19 pandemic began, nearly one in five people with diabetes report needing to choose between buying food and filling one or more of their prescriptions, a trend that is likely to continue in the absence of meaningful change.¹²

Although we recommend specific policy changes to bring down the cost of health care within four discrete domains – lowering the cost of prescription drugs and devices, health insurance coverage practices, Medicare and Medicaid coverage and access, and hospital and provider care – we must also recognize that impediments to care are cross-system barriers, and that systemic solutions require engaging across the health care continuum. Health care in America is an extraordinarily complex and often opaque marketplace, and we must hold all players accountable for their business practices and the impact of those practices on Americans with diabetes.

¹⁰ American Diabetes Association, “Economic Costs of Diabetes in the US in 2017,” *Diabetes Care* 41, no. 5 (2018): 917-928, <https://care.diabetesjournals.org/content/41/5/917>; Sarah Stark Casagrande and Catherine C. Cowie, “Health Insurance Coverage Among People With and Without Diabetes in the US Adult Population,” *Diabetes Care* 35, no. 11 (2012): 2243-2249, <https://care.diabetesjournals.org/content/35/11/2243>; U.S. Centers for Medicare and Medicaid Services, “National Health Expenditure Data – Historical,” NHE Tables, December 16, 2020, <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical>; American Diabetes Association, “The Cost of Diabetes,” <https://www.diabetes.org/resources/statistics/cost-diabetes>; Darby Herkert et al., “Cost-Related Insulin Underuse Among Patients with Diabetes,” *JAMA Internal Medicine* 179, no. 1 (2019): 112-114, <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499>.

¹¹ Amanda Nguyen and Katie Mui, “The Staggering True Cost of Diabetes,” GoodRx Research, April 2020, <https://www.goodrx.com/blog/wp-content/uploads/2020/04/Diabetes-Cost-White-Paper.pdf>.

¹² American Diabetes Association and Diabetes Daily, “Effects of the COVID-19 Pandemic on People with Diabetes,” December 23, 2020, <https://www.diabetes.org/sites/default/files/2020-12/ADA%20Thrivable%20Data%20Deck.pdf>.

I. Lowering the Cost of Prescription Drugs and Devices

The skyrocketing cost of prescription drugs has levied an outsized burden on everyday Americans from all walks of life. But for people with diabetes, and particularly for the disproportionate number of low-income, underserved Americans who live with the disease, this financial barrier can mean the difference between life and death. We value the work of many drug makers to reinvest substantial funding into research and development for new and improved drugs, but it is urgent that policy and practice changes be implemented to support therapeutic innovation on one hand and drive affordability on the other. Manufacturers, middlemen, and payors all bear a share of the responsibility for the unsustainable cost of diabetes drugs and devices today, and we urge changes among all three. More fundamentally, the types of adjustments that are most important to underserved Americans are those that change the costs for patients themselves. Shifting economics between other industry stakeholders does not ensure any reduction in cost to patients – the latter being where we urge the administration to prioritize its efforts in this space.

Today, 98 percent of Americans with diabetes require one or more prescription drugs, yet the cost of many drugs has grown out of reach for people with diabetes, especially given the continued increase in our community of low-income individuals.¹³ There are several proposals we recommend which we believe can help to ameliorate the high cost of drugs and devices for people with diabetes.

- *Rebate Reform*

Currently, pharmacy benefit managers (PBMs) and other drug middlemen function at the center of the pharmaceutical supply chain, acting as intermediaries between insurers, manufacturers, and pharmacies. Health insurers hire or own PBMs to handle benefits for their health plans, who then develop lists – or formularies – of the drugs and devices the health insurer will cover. PBMs negotiate prices with drug makers for the products covered on the formulary, and as part of this process, manufacturers offer rebates to PBMs in exchange for preferred formulary placement. As a result, the actual price the PBM pays is lower than the list price – and because what the consumer pays at the pharmacy counter is based on the list price, not negotiated price, it is not clear how, if at all, rebates negotiated by PBMs benefit patients. More fundamentally, there is troubling evidence that current incentives for PBM formularies to favor the most high-cost drugs and devices may encourage the exclusion of lower-cost drugs and devices, putting more affordable options out of reach for our community.

The system in place has created perverse incentives and led to increased costs to consumers, which is why the ADA is calling for rebate reform. Simply put, savings

¹³ Georgetown University Health Policy Institute, “Prescription Drugs,” <https://hpi.georgetown.edu/rxdrugs/>.

negotiated by PBMs for prescription drugs should be shared with consumers, and those with unusually high launch prices where other lower-cost options are available, should be subject to a full pass-through of rebates to consumers so that they are not given preferential treatment that limits or blocks access to lower-cost options.

Notably, these types of rebates are not exclusive in this sense to drugs; they are also applicable to a limited number of devices – like diabetes management technologies, for example – that are sold directly to consumers, rather than to providers. We believe opportunities to expand rebate reform are meaningful in the diabetes device marketplace as well. As with prescription drugs, device manufacturers typically pay rebates to middlemen like PBMs to carry their products, and the rebates similarly have a market-distorting impact that inherently reduces access to lower-priced, more cost-effective devices. Diabetes device focused PBM rebate reform can bring needed pricing transparency, reduce costs at the counter, and bolster patient access.

- *Curbing Aggressive Drug Pricing Tactics*

The current regulatory environment allows some manufacturers to increase the list price of insulin and other drugs at rates that seem to defy justification.¹⁴ Where drugs whose prices in the Medicaid and/or Medicare programs are increased at rates beyond the annual rate of inflation, manufacturers should be subjected to additional reporting on their net prices and true margins. Additionally, policymakers should consider disincentives for manufacturers that regularly set or increase their prices overly aggressively.

- *Building a Competitive Biosimilars Marketplace*

With steady growth in the numbers of Americans who are insulin-dependent, policy change should target lowering barriers to meaningful competition to drive down drug prices.¹⁵ One key opportunity is promoting broader availability of safe and effective biosimilar medications, including advancing measures which address biosimilar-blocking patent abuse; creating faster U.S. regulatory approval tracks for certain biosimilars which are approved in trustworthy third country markets; and boosting provider, patient, and pharmacy education on biosimilars to build awareness and confidence in products deemed to be safe, effective, and interchangeable with reference products. Other reforms targeted at commercial payor practices are also appropriate and are discussed in more detail below.

¹⁴ Juliette Cubanski and Tricia Neuman, “Price Increases Continue to Outpace Inflation for Many Medicare Part D Drugs,” Kaiser Family Foundation, February 4, 2021, <https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs/>.

¹⁵ Andrew W. Mulcahy, Zachary Predmore, and Soeren Mattke, *The Cost Savings Potential of Biosimilar Drugs in the United States*, RAND Corporation, November 3, 2014, https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

- *Ensuring Patients Benefit from 340B Discounts*

The 340B Drug Pricing Program was intended to provide low-income patients who are underinsured or uninsured access to extremely affordable prescription drugs. Its significant economic benefit to hospitals, however, has spurred an explosion of 340B hospitals around the nation, and this growth has not been accompanied by meaningful new benefits to patients or reductions in patient costs.

While we recognize that 340B discounts are needed to help many community and academic health care systems offset what may be high public charity expenses, not all hospitals are providing high levels of charitable care, and are gaming the system to create new, significant 340B revenue streams. It is imperative that we find a better balance between covering steep operating costs for providers that care for large numbers of indigent or uninsured patients on the one hand and passing through savings to patients on the other.

II. Health Insurance Coverage Practices

Though insurance should have the effect of making health care more accessible, some practices by commercial health insurers can have the opposite effect – a reality that is exacerbated by health plans commonly used by lower-income Americans, where out-of-pocket costs can be particularly steep. Though most Americans living with diabetes are covered by some type of health insurance – just 10 percent are uninsured, and nearly 20 percent depend on Medicaid – they are nonetheless hampered in accessing affordable care by cost-saving insurance practices that can do more harm than good.¹⁶ Targeting these practices is an immediate opportunity to improve affordability and expand access to care for those we most urgently need to reach.

- *Step Therapy Reform*

Step therapy, also known as “fail first,” is a process used by health insurers to control costs. It requires patients to try one or more medications specified by the insurance company, typically a generic or lower-cost medicine, to treat a health condition before an insurer will cover a more costly drug. These policies can force patients to switch from drugs that work to keep them healthy to ones that do not – and even to drugs a patient has tried before and knows will not work – before their insurer will cover the appropriate, recommended medication, frequently overriding what the prescribing clinician believes to be in the patient’s best clinical interest.

These types of needless treatment alterations can have grave consequences for people with diabetes. Indeed, just days before the submission of this document to OMB, an

¹⁶ Casagrande and Cowie, “Health Insurance Coverage Among People With and Without Diabetes”; Sarah Stark Casagrande and Catherine C. Cowie, “Chapter 42: Health Insurance and Diabetes,” in *Diabetes in America*, 3rd Edition (Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases, 2018), <https://www.ncbi.nlm.nih.gov/books/NBK567967/>.

article in *NJ.com* told the story of a 13-year-old boy with type 1 diabetes whose insurer refused to cover the insulin his doctor prescribed and instead insisted that the boy try another type of insulin instead.¹⁷ Although his family already knew the child was sensitive to switching insulins, and despite multiple prior authorization requests from his doctors, he was still forced to “fail first” – and it nearly killed him. According to the boy’s parents, “Using the new insulin our insurer preferred, he experienced severe hypoglycemia ... To bring his blood sugar back up to level, we spent over 15 minutes pumping sugary juices down his throat to no avail, and then ultimately had to resort to the use of an emergency glucagon injection to ensure his survival. Most diabetics go their entire lives without ever having to resort to using this emergency glucagon injection. This is what the insurer preferred insulin did to our son.”¹⁸

Insurance coverage and formulary decisions must be based on clinical evidence and the direction of health care providers, not driven by profits. Additionally, patients must be equipped with tools like a clear appeals process for instances in which these types of strategies may be harmful or otherwise keep patients from the drugs their prescribers recommend.

- *Restrictive and Costly Tiering Practices*

Reforming insulin and other drug tiering practices represents another opportunity to improve access and lower costs. To put drugs out of reach for patients, insurers can force them to pay more of the cost of the drugs by putting them on so-called “specialty” tiers, where out-of-pocket costs are typically significantly higher. For example, though several follow-on insulins are already on the market, many of them have been placed by private payors on specialty tiers, where patients must pay more of the costs, and through which potential out-of-pocket savings for patients are effectively erased. In the Medicare Part D program, for calendar year 2022, participating insurers will be allowed to include a “preferred” specialty tier that explicitly permits them to shift more of the cost of high-cost drugs to patients.

The ADA urges the Centers for Medicare and Medicaid Services (CMS) to monitor payors participating in the Part D program to ensure they are acting transparently so that enrollees have a true picture of their prescription drug benefit plan. As finalized in the Medicare Advantage and Medicare Prescription Drug Benefit Programs Policy and Technical Changes rule on January 19, 2021 (file code: CMS–4190–F2), CMS will require Part D plans to offer a real-time benefit comparison tool beginning in 2023, so enrollees can obtain information about potential lower-cost alternative therapies under their prescription benefit plans. If implemented fully and effectively, this tool can empower enrollees to find the most cost-effective prescription drugs for their health needs before they are standing at the pharmacy counter.

¹⁷ Liz Parlett Butcher, “My Son Nearly Died Because of Step Therapy,” *NJ.com*, June 20, 2021, <https://www.nj.com/opinion/2021/06/my-son-nearly-died-because-of-step-therapy-opinion.html>.

¹⁸ *Ibid.*

In addition, we urge the federal government to work with state policymakers to prohibit insurers from placing biosimilar insulins and other commonly needed drugs for people with diabetes on high cost-sharing tiers or using other utilization practices, and instead ensure that lower-priced alternatives are accessible at a reduced cost for our community. And finally, as more biosimilars come to market, the ADA urges the Biden administration to create a new, designated generic tier for biosimilar drugs to ensure patient savings.

- *Out-of-Pocket Caps*

Although we appreciate that there is no quick and easy solution to bringing down the cost of prescription drugs, implementing out-of-pocket caps for insulin and other diabetes drugs, devices, and supplies would make a substantial difference in the lives of those struggling to afford their care. Such out-of-pocket spending limits have already been signed into law by governors in 19 states and the District of Columbia, and similar policy changes at the federal level would help bridge gaps in affordability and access that have persisted for far too long.¹⁹

Additionally, exempting insulin, other diabetes drugs, and supplies from deductibles would provide people with diabetes first dollar coverage, eliminating exorbitant costs for these life-saving items, particularly at the beginning of each plan year when the deductible limit resets.

III. Medicare and Medicaid Coverage and Access

Having health insurance is the strongest single predictor of whether adults with diabetes are likely to receive high quality diabetes care – but still, one in 10 people with diabetes in the U.S. today go without.²⁰ Compared with insured adults with diabetes, the uninsured have 60 percent fewer office visits with health care providers, are prescribed 52 percent fewer medications, and have 168 percent more emergency department visits.²¹

As is the trend for most other health care resources, access disparities fall along predictable lines – both low-income communities and Americans of color are historically more likely to be uninsured than whiter, wealthier peers.²² Although the Affordable Care

¹⁹ American Diabetes Association, “American Diabetes Association Applauds Texas as it’s Added to Growing List of States Working to Reduce Cost-Sharing on Insulin,” June 15, 2021, <https://www.diabetes.org/newsroom/press-releases/2021/ada-applauds-TX-added-to-growing-list-states-working-reduce-cost-sharing-insulin>.

²⁰ Felicia Hill-Briggs et al., “Social Determinants of Health and Diabetes: A Scientific Review,” *Diabetes Care* 44, no. 1 (2021): 258-279, <https://care.diabetesjournals.org/content/diacare/early/2020/10/31/dci20-0053.full.pdf>; Casagrande and Cowie, “Health Insurance Coverage Among People With and Without Diabetes.”

²¹ Hill-Briggs et al., “Social Determinants of Health and Diabetes.”

²² Samantha Artiga, Kendal Orgera, and Anthony Damico, “Changes in Health Coverage by Race and Ethnicity since the ACA, 2010-2018,” Kaiser Family Foundation, March 5, 2020, <https://www.kff.org/racial->

Act (ACA) resulted in considerable coverage gains for groups that had previously struggled with structural barriers to care, there is still more to be done when it comes to democratizing access to health insurance.

- *Medicare Prescription Drug Coverage*

Diabetes affects roughly one in five Medicare beneficiaries aged 65 and older, or more than 12 million people.²³ Still, the program could be updated, and thus better aligned with the needs of the diabetes population. Medicare drug coverage provides a specific example: as an outcropping of the ACA, weight loss drugs proven to help control and facilitate better management of type 2 diabetes are excluded from Medicare Part D coverage. The exclusion of these types of drugs not only threatens to leave many fixed- and low-income Medicare beneficiaries with diabetes worse off health-wise, but also raises health system costs as patients are denied access to medications that would help them better manage their condition and avoid costly and often unnecessary complications.

- *Expanding Access to Diabetes Technologies*

Technologies like insulin pumps and continuous glucose monitors (CGMs) have transformed the diabetes management landscape, making the condition easier to live and thrive with for people with diabetes. But for many who stand to benefit most from these breakthroughs, access remains financially out of reach. Much like other medical advances, diabetes technology is frequently unavailable to those who live in less affluent zip codes – this includes large numbers of minority individuals, who comprise the lion’s share of low-income Americans. Black and LatinX young adults living with type 1 diabetes, for example, are significantly less likely than white peers to be able to get diabetes management technologies that can offer them tremendous benefits – a trend that pervades along predictable fault lines.²⁴

While important progress has been made to expand access to medical technology for Medicare beneficiaries with diabetes – like CMS’s recent, permanent removal of a four-times-a-day testing requirement that has long been a barrier to qualify for a CGM under

[equity-and-health-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/](https://www.kff.org/equity-and-health-policy/issue-brief/changes-in-health-coverage-by-race-and-ethnicity-since-the-aca-2010-2018/).

²³ Jennifer Hasche, Christopher Ward, and Nicholas Schluterman, *Diabetes Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over*, U.S. Centers for Medicare and Medicaid Services, September 2017, https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/downloads/diabetes_databrief_2017.pdf; Kaiser Family Foundation, “State Health Facts: Total Number of Medicare Beneficiaries,” <https://www.kff.org/medicare/state-indicator/total-medicare-beneficiaries/?currentTimeframe=0&selectedDistributions=total&sortModel=%7B%22collid%22:%22Location%22,%22sort%22:%22asc%22%7D>.

²⁴ Michael Monostra, “Black Young Adults with Type 1 Diabetes Less Likely to Use CGM, Insulin Pump,” *Healio*, January 4, 2021, <https://www.healio.com/news/endocrinology/20201231/black-young-adults-with-type-1-diabetes-less-likely-to-use-cgm-insulin-pump>.

Medicare – more is still needed. Specifically, we hope to see CMS take further action to lower Medicare’s CGM coverage requirements that limit access for low-income and minority people with diabetes.

For low-income people with diabetes who rely on Medicaid, the diabetes management technology they need may not be covered adequately, or at all. With Medicaid coverage often determined on a state-by-state basis, there are wide variances in diabetes technology access from one state to another.²⁵ Given both the short and long-term health benefits of using a CGM and insulin pump for those with poor glycemic control, the federal government can and should take steps to drive more uniform, expanded coverage policy for diabetes technology and supplies within Medicaid as a common-sense health equity measure. In doing so, we can ensure significant long-run health system savings as more people with diabetes can control their condition and avoid unnecessary health complications.²⁶

- *Coverage to Ensure Amputation Prevention*

In the United States, a limb is amputated due to diabetes every four minutes – a rate that has increased by 75 percent since just 2014.²⁷ This reality is particularly acute for minorities, who experience amputations up to four times as often as non-minorities.²⁸ This inordinate burden shouldered by people of color becomes even more tragic when considering that as many as 85 percent of diabetes-related amputations are preventable, making clear that the challenge lies not in biology, but in access to preventative health care. Worse still, amputees with diabetes see elevated risks of mortality following the loss of a limb – one in 10 dies within 30 days of surgery, and one in six lose their lives within 90 days.²⁹

Recent years have seen meaningful medical progress in this realm – we now have the ability to intervene with patients suffering from peripheral arterial disease (PAD) and critical limb ischemia (CLI) to prevent amputations. Minimally invasive procedures are now available for at-risk patients that can help improve blood flow, address lower limb neuropathy, and ultimately save limbs and lives. But the reality is that these procedures

²⁵ John E. Anderson, James R. Gavin, and Davida F. Kruger, “Current Eligibility Requirements for CGM Coverage Are Harmful, Costly, and Unjustified,” *Diabetes Technology & Therapeutics* 22, no. 3 (2020): 169-173, <https://www.liebertpub.com/doi/10.1089/dia.2019.0303>.

²⁶ “Black Young Adults with Type 1 Diabetes Less Likely to Use CGM,” *Healio*.

²⁷ U.S. Centers for Disease Control and Prevention, *National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States*, <https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>; U.S. Centers for Disease Control and Prevention, *National Diabetes Statistics Report 2014*, https://www.healthandenvironment.org/docs/cdc_23442_DS1.pdf.

²⁸ Kerianne H. Holman et al., “Racial Disparities in the Use of Revascularization Before Leg Amputation in Medicare Patients,” *Journal of Vascular Surgery* 54, no. 2 (2011): 420-426, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3152619/>.

²⁹ Jason K. Gurney et al., “Postoperative Death After Lower-Limb Amputation in a National Prevalent Cohort of Patients with Diabetes,” *Diabetes Care* 41, no. 6 (2018): 1204-1211, <https://care.diabetesjournals.org/content/41/6/1204>.

are not widely enough covered by government insurance programs, severely restricting their potential benefit.

To begin reversing this heartbreaking pattern, the ADA urges broadened and enhanced Medicare and Medicaid coverage for earlier interventions, screenings, and diagnoses, and addressing both physical and financial barriers to needed care, services, and treatments. This includes ensuring appropriate and ample coverage for screenings for PAD and CLI, access to regular diabetes foot exams, and ensuring people with diabetes can access appropriate, routine podiatric services.

- *Medicaid*

Access to Medicaid coverage is also crucial for Americans with diabetes who cannot afford an individual marketplace plan or get insurance through an employer. The ACA significantly expanded insurance coverage by making Medicaid available to millions more Americans. Notably, the reduction of uninsured people in the U.S. is mostly attributable to the ACA's Medicaid expansion.³⁰ Unfortunately, 12 states still do not participate in the expanded Medicaid program, leaving millions of Americans without access to insurance coverage they could receive in other states. This problem has become especially dire since the outbreak of COVID-19 – people with diabetes suffered pandemic-driven unemployment at a rate 50 percent higher than the national rate, with more than one in 10 reporting a disruption in their health insurance coverage during the public health emergency.³¹ Worse still, the majority of states that have opted not to expand Medicaid are located in the Diabetes Belt, the area of the country with the highest rates of diabetes prevalence and related complications.

To rectify these gaps in equitable access, which have an acute and dangerous effect on our community, the Department of Health and Human Services (HHS) should identify other ways to offer this option to low-income individuals in non-expansion states. Ways to do so include allowing county health departments and other local entities to access the increased federal funding for Medicaid beneficiaries even if the state does not, or consider mandatory Medicaid expansion across the country.

IV. Hospital and Provider Care

People with diabetes visit the hospital far more often than other populations, and thus comprise a disproportionate share of hospital spending. Our community is estimated to

³⁰ U.S. Department of Health and Human Services, “New HHS Data Show More Americans than Ever Have Health Coverage through the Affordable Care Act,” June 5, 2021, <https://www.hhs.gov/about/news/2021/06/05/new-hhs-data-show-more-americans-than-ever-have-health-coverage-through-affordable-care-act.html>.

³¹ American Diabetes Association and dQ&A, “Diabetes and COVID-19: New Data Quantifies Extraordinary Challenges Faced by Americans with Diabetes During Pandemic,” July 29, 2020, https://www.diabetes.org/sites/default/files/2020-07/7.29.2020_dQA-ADA%20Data%20Release.pdf; <https://www.diabetes.org/newsroom/press-releases/COVID-19-brings-crisis-of-access-for-millions-living-with-diabetes>.

account for more than 40 million hospital days each year, 25 percent of the 162 million recorded annually in the U.S.³² Fully 22.6 million hospital days each year are attributable to diabetes directly, occurring when members of our community are first diagnosed with diabetes, experience severe high or low blood glucose, or suffer from diabetic ketoacidosis, to name a few examples.³³ Hospital inpatient services for people with diabetes alone cost a staggering \$70 billion every year – tied with the cost of prescription medications for the largest driver of health care expenses for the diabetes community – illustrating just how urgently Americans with diabetes need financial relief in this arena.³⁴

- *Surprise Billing*

The steps Congress has taken to end surprise billing are an important start, and we recognize and appreciate the administration's efforts to fully implement the No Surprises Act so that patients are no longer charged enormous medical bills for out-of-network care. However, there is still much more the federal government can do when it comes to ensuring that hospital care is affordable for all who need it.

- *Hospital Pricing Transparency*

In addition, despite recent efforts by Congress on surprise billing, transparency is still a significant issue for patients struggling to navigate an exceedingly opaque hospital billing system. Patients should be able to access pricing information quickly and easily for the services and treatments they receive in a hospital setting, and we hope the Biden administration will take steps to ensure a more transparent hospital pricing system in the future.

- *Diversity in Clinical Trials and Among Health Care Providers*

Despite the fact that chronic diseases such as diabetes strike communities of color most acutely, and that people with diabetes account for perhaps the single largest share of drug spending of any disease group in the nation, people of color and people with diabetes in general are sorely underrepresented in drug trials. This disconnect between our community's reliance on existing and new drug innovations and our exclusion from the process of evaluating so many of the same drugs we may need calls for thoughtful interventions by the government, the nonprofit community, and the private sector.

Among other challenges, the lack of information between people with diabetes and their health care providers about appropriate drug trials can be addressed through more robust public awareness efforts. Currently, the limitations of the National Institutes of Health (NIH) clinical trials website – which is available to those who have internet

³² ADA, "Economic Costs of Diabetes in the US in 2017."

³³ Ibid.

³⁴ ADA, "Economic Costs of Diabetes in the US in 2017"; ADA, "The Cost of Diabetes."

access only, and even then, is not always intelligible (or even in a language that online users may speak) to appropriate candidates – are significant.

To bridge these gaps, we ask that the Biden administration prioritize disseminating multilingual and multicultural information about clinical trial participation in ways that are likely to reach marginalized audiences. The federal government should also be cognizant of the myriad barriers faced by the underrepresented communities we aim to include – for example, low-income participants are more likely than higher-earning peers to face constraints when it comes to taking time off from work, securing childcare, or obtaining means of transportation to and from any given clinical trial should they wish to take part. These restraints could be addressed in part by add-on payment vouchers or other such tools. Moreover, clinician education, especially at the community care level, urgently needs to be improved, be it through Continued Medical Education Training or other federal programs with analogous goals.

Of course, trust issues loom large in populations of color due to longstanding and shameful mistreatment of minorities by way of health care experiments. One way to help ameliorate trust obstacles is to do substantially more to increase the number of clinicians of color in primary care, community health centers, and in the specialties of endocrinology and diabetology. Likewise, growing the limited pool of researchers and clinical trial investigators of color is a must. Studies have long shown that when it comes to medical care, people trust individuals who look like them and who have experiential commonalities.³⁵ Leveraging existing federal programs like Graduate Medical Education (GME) to better attract minority candidates to priority disciplines would be a great place to start.

Finally, as the Biden administration pursues the exciting opportunities at the core of the proposed new Advanced Research Projects Agency for Health (ARPA-H), we hope that bridging clinical trial gaps for minority participants will be a top priority.

Area 2: Barrier and Burden Reduction

Approaches and methods for assessing and remedying barriers, burdens, and inequities in public service delivery and access.

Given the systemic barriers to health care and other resources faced by communities where diabetes rates are highest, there exist important opportunities for the federal government to lighten the burdens shouldered by underserved populations when it comes to accessing public services and programs. The ADA has included recommendations in this section aimed at remedying barriers and increasing access to food and nutrition and a healthy built environment, essential components of health equity that we hope the Biden administration will take under advisement.

³⁵ Andrew Hill, Daniel Jones, and Lindsey Woodworth, “Physician-Patient Race-Match Reduces Patient Mortality,” SSRN (2018), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3211276.

I. Food and Nutrition Policy Reforms

Nutrition is an indispensable tool when it comes to preventing the onset of prediabetes, delaying or averting the evolution of prediabetes into diabetes, and managing diabetes care after diagnosis. However, like other health care resources, the diabetes community often lacks access to both the healthy foods and nutrition education they need to safely manage their condition, or even prevent onset altogether. Not only do 20 percent of Americans with diabetes report household food insecurity – double the rate of the general population – but living in food deserts, or areas with limited access to affordable and nutritious food, is associated with reliably higher type 2 diabetes rates.³⁶ Greater availability of restaurants and grocery stores and lower availability of fast food and convenience stores is proven to bring down the surrounding community’s diabetes rates.³⁷ Furthermore, in a recent ADA survey, more than one in four Americans with diabetes reported that the COVID-19 pandemic disrupted their ability to obtain healthy food.³⁸

To begin ameliorating the impediments to adequate nutrition and nutrition education faced by far too many Americans, the ADA recommends several federal policy changes.

- *Target Dietary Guidance for Communities Reliant on Institutional Foods*

Federal nutrition guidance has long informed, and in many instances directed, the diet-related recommendations made by health care providers and other experts and advocates.

Yet, our standard guidance often overlooks the dietary needs of those who live with nutrition-related chronic diseases. Given that the Dietary Guidelines for Americans were launched more than 40 years ago, when rates of diagnosed diabetes in the U.S. were just 2.5 percent – a number that has climbed fourfold in the time since – we must rethink federal nutrition guidance to account for the 122 million Americans living with diabetes and prediabetes.³⁹ Moreover, since a disproportionate share of the diabetes community is low-income, we also know that many people with diabetes rely on public feeding programs to eat. In the military and on military bases; among those receiving supplemental school nutrition; and across public and private prisons, millions of Americans with diabetes and prediabetes are being provided food in accordance with dietary guidelines that are designed to prevent disease, but not as part of an approach for those who are already living with one. There is little doubt that the time to act is now, and that nutrition guidance must be created by the federal government that does more than provide recommendations that promote good preventive health when six in 10

³⁶ Hill-Briggs et al., “Social Determinants of Health and Diabetes.”

³⁷ Ibid.

³⁸ American Diabetes Association, “NEW DATA ALERT: COVID-19 Brings Crisis of Access for Millions Living with Diabetes,” December 23, 2020, <https://www.diabetes.org/newsroom/press-releases/COVID-19-brings-crisis-of-access-for-millions-living-with-diabetes>.

³⁹ U.S. Centers for Disease Control and Prevention, Division of Diabetes Translation, *Long-Term Trends in Diabetes*, April 2017, https://www.cdc.gov/diabetes/statistics/slides/long_term_trends.pdf.

American adults suffer from one or more chronic conditions.⁴⁰ Guidance that helps to address the chronic disease epidemic plaguing our country is a critical step toward improving health care in America.

- *Expand and Modernize Existing Federal Nutrition Assistance Programs*

Programs like the Supplemental Nutrition Assistance Program (SNAP) and the Supplemental Nutrition Program for Women, Infants, and Children (WIC) are crucial to helping to bridge the food access disparities that exist in America today. Not only do these types of programs have a substantial influence on the foods that beneficiaries purchase, but they are also well suited to reach food-insecure individuals who have diabetes and prediabetes. An expansion and modernization of federal nutrition assistance – both with respect to who is eligible for these programs and the benefits themselves – is necessary to ensure that Americans with diabetes have enough of the right foods to eat, and to provide for government programs that are fully equipped to address the unique needs of our community.

- *Take on Food Deserts and Food Swamps*

Access to healthy foods is often a problem of proximity, especially for the 23.5 million Americans who live in food deserts – places where access to affordable, healthy food options is limited or non-existent because grocery stores are too far away.⁴¹ The same challenge to healthy food access can occur in geographic areas that face an oversaturation of unhealthy options – or food swamps – where unhealthy foods are very accessible, and healthy alternatives are not.⁴²

Both food deserts and food swamps are more prevalent in communities of color and neighborhoods with greater socioeconomic disparity – places that also tend to experience notably higher diabetes rates. To build upon the progress that has been made through the American Rescue Plan and other recent initiatives, there are economic incentives that the federal government should consider that would encourage a greater supply of nutritious foods to flow into communities most in need. These incentives can come in the form of expanded grants for community development and initiatives that bring healthy alternatives into local establishments, including bodegas and convenience stores.

⁴⁰ U.S. Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, “Chronic Diseases in America,” <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>.

⁴¹ Kristen Cooksey-Stowers, Marlene B. Schwartz, and Kelly D. Brownell, “Food Swamps Predict Obesity Rates Better Than Food Deserts in the United States,” *International Journal of Environmental Research and Public Health* 14, no. 11 (2017): 1366, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5708005/>.

⁴² Ibid.

- *Boost Healthy Food and Safe Drinking Water Access for Children*

In the United States today, some 13 million children are food insecure.⁴³ Since schools are sometimes the only places low-income children have access to hot meals daily, it is vital that such programs – including the National School Lunch Program, which feeds 22 million children on an average school day – receive increased support to expand access to nutritious school meals and improve nutrition education.⁴⁴

In addition to the need for augmented federal financial support for child feeding programs, nutrition education in public schools is also lacking. Students today receive an average of less than eight hours of nutrition education each school year, though studies show that it takes at least five times that much to change food behaviors.⁴⁵ Educating children and motivating them to eat more nutritious foods while they are young will build better dietary habits, which is crucial to preventing diabetes onset. To help guarantee that the next generation has all the resources they need to live safe and healthy lives, it is our hope that culturally relevant nutrition education continues to expand and improve in order to ensure that all Americans are able to take advantage of new and existing nutrition resources.

As Child Nutrition Reauthorization (CNR) negotiations continue on Capitol Hill, increased federal support to materially improve access to healthy foods, expand the free and reduced-price school meals programs, and enhance nutrition education is urgently needed.

And finally, with American children spending so much of their time at school, ensuring that our schools can provide safe drinking water is essential to the health of our children. Yet, we know from reports on water testing that a high percentage of schools have water that fails to meet quality standards.⁴⁶ Perhaps worse, a high percentage of school districts lack funding to test water safety at all. Providing students access to safe drinking water can increase students' overall water consumption and increase the likelihood of consumption of water over less healthy sugary beverages that can lead to obesity, a risk factor associated with diabetes. We urge the Biden administration to support policies that increase states' abilities to implement water safety testing and

⁴³ Feeding America, *The Impact of the Coronavirus on Food Insecurity in 2020 & 2021*, March 2021, https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf.

⁴⁴ National Conference of State Legislatures and No Kid Hungry/Share Our Strength, *Feeding Hungry Children: A Guide for State Policymakers*, <https://www.ncsl.org/Portals/1/Documents/cyf/FeedingHungryChildren.pdf>.

⁴⁵ U.S. Centers for Disease Control and Prevention, "Nutrition Education in US Schools," https://www.cdc.gov/healthyschools/nutrition/school_nutrition_education.htm.

⁴⁶ Angie Cradock et al., *Early Adopters: State Approaches to Testing School Drinking Water for Lead in the United States*, Harvard T.H. Chan School of Public Health and University of California Agriculture and Natural Resources, January 2019, https://cdn1.sph.harvard.edu/wp-content/uploads/sites/84/2019/01/Early-Adopters_State-Approaches-to-Testing-School-Drinking-Water-for-Lead-in-the-United-States_2019.pdf.

remediation efforts in their schools and policies that encourage education of students and their families about the health benefits of water consumption.

II. Mitigating Barriers to a Healthy Built Environment

Physical activity offers substantial health benefits essential to managing and preventing diabetes, including helping regulate blood glucose levels, aiding in weight loss, and boosting cardiovascular health. Unfortunately, for many Americans, access to a physically active lifestyle is hampered by a lack of safe, accessible infrastructure in the areas where they live. This is especially – though not uniquely – true for historically underserved communities in urban city centers, who suffer disproportionately high rates of diabetes and other chronic diseases.

The CDC has identified community design as one way to facilitate meaningful improvement to physical activity and recreational opportunities.⁴⁷ In fact, research has shown that adults living in walkable communities – areas where there are opportunities to walk, run, or bike to and from nearby destinations like stores, school, or parks – can increase physical activity by as much as 45 minutes a week compared to those living in less walkable communities.⁴⁸ In addition, children with nearby access to parks and recreation centers are less likely to have obesity compared with those without such access. With these facts in mind, it makes sense that more walkable neighborhoods are associated with lower diabetes incidence and prevalence.⁴⁹

As policies and investments to address our nation’s infrastructure are contemplated, we urge the Biden administration to consider the potential health and economic impacts that come from investing in community design policies that provide for more active neighborhoods across the country. Doing so would make significant progress toward ensuring that all Americans have access to a built environment that promotes health and well-being. Everyone should have access to safe spaces where they can be physically active, and we must invest in ensuring that those living with diabetes or at risk for developing diabetes have the resources they need to exercise and stay healthy where they live, work, and play.

Conclusion

The American Diabetes Association appreciates the opportunity to submit our perspective to the United States Office of Management and Budget on its Request for Information: *Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government*.

⁴⁷ U.S. Centers for Disease Control and Prevention, “Health Places,” <https://www.cdc.gov/healthyplaces/>.

⁴⁸ Lilly Shoup and Reid Ewing, *The Economic Benefits of Open Space, Recreation Facilities and Walkable Community Design*, Active Living Research, May 2010, https://activelivingresearch.org/sites/activelivingresearch.org/files/Synthesis_Shoup-Ewing_March2010_0.pdf.

⁴⁹ Hill-Briggs et al., “Social Determinants of Health and Diabetes.”

On behalf of the diabetes community, we applaud this administration's efforts to shine a light on equity issues that have for too long kept individuals with diabetes, especially those with lesser means, from accessing the necessary drugs, technologies, services, and resources they so urgently need.

We recognize that these comments target specific policy recommendations, and that there are many other steps that the government and organizations such as ours can and should take together to promote health equity, and to knock down many systemic barriers to equitable care and resources that have long existed. We stand ready to partner on these vital endeavors.

Should you have any questions or seek additional information regarding these comments, please reach out to Lisa Murdock (LMurdock@diabetes.org), Senior Vice President.