Consensus Statement on U.S. Health Care Reform for People with Diabetes

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Diabetes Leadership Council – Coalition Lead
Association of Diabetes Care & Education Specialists
Beyond Type 1 / Beyond Type 2
Certification Board for Diabetes Care and Education
Children with Diabetes
College Diabetes Network
Diabetes Dietetic Practice Group of the Academy of Nutrition and Dietetics
Diabetes Patient Advocacy Coalition
DiabetesSisters
The diaTribe Foundation
JDRF
T1D Exchange
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INTRODUCTION

The COVID-19 pandemic laid bare many of the deep systemic flaws and inequities in the U.S. health care system. People with diabetes, while not at increased risk for contracting COVID-19, have higher risk of severe illness and serious complications from contracting the virus.\textsuperscript{1,2} People with elevated A1c, which measures average blood glucose levels, seniors, and individuals with overweight or obesity are particularly vulnerable.\textsuperscript{3} Communities of color already are disproportionately impacted by diabetes; COVID-19 compounded the burden, adding higher risks of infection, hospitalization and death. Centers for Disease Control data show Latinx and Black U.S. residents were three times more likely than their white neighbors to become infected with COVID-19, and twice as likely to die from the virus.\textsuperscript{4}

Weeks before most Americans had even heard of coronavirus or COVID-19, the diabetes advocacy community was launching a unique collaboration. Anticipating renewed federal-level interest in U.S. health care reform after the November 2020 elections, 12 independent, non-profit national diabetes organizations convened in a virtual working group to align on a patient-centered framework for U.S. health care reform.

The diabetes health care reform (DHCR) working group’s objective:

\textit{Articulate for policymakers and health care system stakeholders how our nation’s complicated health care and coverage system works for – and sometimes against – people with diabetes, and provide tangible ideas for improvement.}

Critical diabetes coverage gains under the Patient Protection and Affordable Care Act (PPACA) served as the foundation of our consensus framework. We use the Act’s full title rather than the frequently abbreviated Affordable Care Act, or ACA, to remind policymakers that patient protections belong at the forefront of any reforms to our nation’s health care coverage and reimbursement systems.
The working group identified and prioritized coverage improvements that matter most to people with diabetes. Several of these improvements were enacted temporarily during the pandemic, providing a unique opportunity for payers, policymakers and others to experience reduced access barriers and new ways to care for and cover 34 million Americans with diabetes.

The pandemic also added urgency to the nation’s dire need to address comprehensive health care reform across the individual, small group, public and employer-based health coverage markets. According to Families USA, 5.4 million American workers lost their health insurance due to job loss or leaving the labor force between February and May 2020. Consequently, millions more of these workers’ family members also lost access to health insurance but their numbers could not be estimated based on the report’s methodology. More than 50 million Americans filed for unemployment since the pandemic began. Today more Americans are jobless than ever before in our nation’s history.

**Diabetes is unaffordable without comprehensive health coverage.** American Diabetes Association research finds people with diabetes have 2.3 times the health care costs of people without the disease – averaging $16,750 annually.

Affordable insulin is the bedrock of diabetes management for 1 in 3 people with diabetes – but insulin is only one piece in a mosaic of medicines, medical devices, software, supplies, services, medical nutrition therapy (MNT) and diabetes self-management education and support (DSMES) the disease demands.

Public and private health plans generally cover long-term diabetes complications, including amputations, blindness, end stage renal disease, heart attack and stroke. **Now is the time to ensure people with diabetes have adequate coverage for individualized care that can prevent or delay the onset of these costly and life limiting complications.** The shift is better for people with diabetes and their families, and a wiser investment of health care dollars for payers, especially in the face of a diabetes epidemic.

The PPACA helped reduce the number of uninsured non-elderly Americans by nearly 20 million in its first years – from 46.5 million (17.8 percent) in 2010 to 26.7 million (10 percent) in 2016. The number of uninsured started climbing again to 27.4 million in 2017 and jumped upward sharply in 2020 due to pandemic-driven unemployment rates.
PPACA’s Medicaid expansion helped millions of Americans in 38 states, the District of Columbia\textsuperscript{11}, Guam, Puerto Rico and U.S. Virgin Islands\textsuperscript{12} find affordable health coverage. Screenings and other preventive care led to more people being diagnosed and therefore treated earlier for diabetes.\textsuperscript{13} People with diabetes in Medicaid expansion states report substantial improvements in access to care, diabetes management and health status compared to their counterparts in non-expansion states.\textsuperscript{14} A more recent study found a 17 percent decrease in amputation risk among non-white people with diabetes living in “early adopter” Medicaid expansion states.\textsuperscript{15}

**Our current system leaves behind too many people with diabetes.** Seven of the 12 states that did not expand Medicaid are in the southeastern U.S. diabetes belt.\textsuperscript{16} Our nation cannot confront the diabetes epidemic when millions of people with or at risk for the disease do not have health coverage for life sustaining care.

7 of the 12 states that did not expand Medicaid are in the southeastern U.S. diabetes belt.\textsuperscript{16}
Employer-provided health insurance plan design can help or hinder the financial stability of American families with diabetes. Health benefit structures that shift costs to patients – including inflated list prices rather than discounted plan rates – create a reverse insurance system that disproportionately burdens people with chronic diseases like diabetes. People across the diabetes community say health benefits drive their career decisions. They are forced to set aside artistic, entrepreneurial and philanthropic passions so they can afford the array of medications and supplies that diabetes requires.

Most other countries with advanced economies have solved this problem. We can and must do better for people with diabetes and all Americans. In the pages that follow, we address our collective concerns and requests on behalf of people with diabetes in the commercial and government insurance sectors, following these basic tenets:

- Everyone deserves access to affordable and effective health care
- Diabetes care is preventive care. Long term health care costs for people with diabetes are lower when they have the medications, devices and services they need to manage their disease.
- National health care reform must address the roles and incentives of major stakeholders in the health care coverage, delivery and reimbursement systems, and realign their practices and obligations in support of patients’ rights to:
  - Understand the terms of their coverage;
  - Compare treatment costs and make informed decisions in collaboration with their health care providers; and
  - Affordably access individualized treatment needed to effectively manage chronic and acute health conditions.

THE OUTWARD MANIFESTATIONS OF SEGREGATION IN HEALTH CARE HAVE BEEN REMOVED BUT THE INEQUALITIES HAVE NOT. THE PANDEMIC HAS OPENED THAT UP.

Gary Puckrein, PhD
National Minority Quality Forum
SCOPE AND LIMITATIONS

Working groups focused discussions on features of the U.S. health care system to preserve or reform to better meet the needs of people with diabetes. We captured specific policy or legislative suggestions as they came up in discussions and include them as examples throughout this consensus statement, but our main focus was what needs to happen, not specifying how to do it. We welcome the opportunity to collaborate with federal and state policymakers, health plan sponsors and other system stakeholders, lending patient perspectives to the development of specific regulatory or legislative solutions.

In addition, we focused our attention on the commercial health insurance market, Medicare and Medicaid. Most Americans with diabetes are covered by these three systems. We will address health care needs of active duty military and veterans with diabetes in the future.

Throughout the working sessions and editorial process, participants made a concerted effort to leave no person with diabetes behind. We applied a series of lenses (see Appendix B) to examine problems and potential solutions from diverse perspectives and experiences within the diabetes community. Every person’s diabetes journey varies but there is no refuting the troubling inequities in diabetes burden, access to care and health outcomes affecting communities of color. Americans in rural areas or Tribal lands may not have broadband internet access needed for a telemedicine visit or to connect online with their peers for learning and support. A woman with gestational diabetes may wait weeks during pivotal stages of fetal development for insurance to approve even the most basic diabetes management tools.

SOME OF OUR PATIENTS DRIVE 4 TO 8 HOURS TO COME SEE US. THE COVID-19 PANDEMIC RESPONSE ALLOWED US TO BEGIN USING HOME TELEMEDICINE FOR THE FIRST TIME, WHICH IS A GREAT TOOL TO IMPROVE HEALTH CARE ACCESS FOR OUR PATIENTS DURING THIS PERIOD AND BEYOND

G. Todd Alonso, MD
Barbara Davis Center, University of Colorado
Collectively the 12 participating national diabetes organizations represent all people with diabetes. The resulting consensus recommendations are a first step toward addressing health inequities but are by no means all encompassing. The Health Equity Collaborative’s July 2020 report to the Centers for Medicare & Medicaid Services (CMS) provides a thorough overview and recommendations to address health inequities among people with or at risk for type 2 diabetes.\(^1\)

**Finally, diabetes is non-partisan, as are the consensus findings and recommendations that follow.** Broad adoption would markedly improve our national approach to the diabetes epidemic, emphasizing lifelong affordable, comprehensive health coverage. This evidence-based reallocation of our nation’s precious health care dollars shifts investment toward earlier diabetes care and education to help delay or prevent the onset of costly diabetes complications later in life. People with diabetes and their families certainly benefit from improved quality and quantity of life.

The nation gains more stable marketplaces for private and public coverage, irrespective of party control of the White House and Congress.
**CONSENSUS FINDINGS**

1. **PRESERVE PPACA GAINS**

   Coverage gains afforded under PPACA must be preserved:
   a. Pre-existing conditions coverage
      i. Guaranteed issue – prohibit insurance denials based on health
      ii. Community rating – prohibit higher premiums based on health
      iii. Prohibit coverage exclusions for pre-existing and related, co-occurring conditions
   b. Qualified health plan structure
      i. Essential health benefit (EHB) requirements
      ii. Prohibit annual or lifetime coverage limits
      iii. Annual consumer out-of-pocket maximums
      iv. Minimum actuarial value
      v. Affordability requirement based on a percentage of household income
      vi. Subsidies incentivizing healthy individuals to enroll before getting sick or injured

2. **ESSENTIAL DIABETES HEALTH BENEFITS (EDHBs)**

   Future U.S. health care reform efforts should further define a set of chronic disease management or Essential Diabetes Health Benefits (EDHBs) to be covered pre-deductible, including safe harbor for High Deductible Health Plans (HDHPs) with and without Health Savings Accounts (HSAs). See Appendix C for recommendations. All U.S. health plans should provide first dollar coverage for insulin, glucagon, and other health care products and services prescribed to manage an insured’s diabetes or diabetes-related conditions or complications. This includes prescription medicines, medical devices, software, services, supplies, medical nutrition therapy (MNT) and diabetes self-management education and support (DSMES).

3. **PREDICTABLE COST SHARING**

   People with diabetes should have no or low, predictable cost sharing for diabetes management tools and education, commensurate with other preventive care.

4. **REBATE & DISCOUNT PASS THROUGH**

   Patient out-of-pocket costs at the point-of-sale, particularly for medicines and devices, should fully reflect all related discounts and rebates negotiated or mandated across the supply chain. Rebate pass-through will help reduce patient costs in the near-term, but further national reforms are needed to eliminate or modify rebate policies, and the misaligned incentives they cause in our health care system.
Reverse insurance, spread pricing or otherwise requiring patients to pay more than net price can make essential medicines like insulin unaffordable to people with diabetes. Prescription drug coverage should mirror coverage for office visits, lab tests and other facets of care where patient cost sharing reflects discounted plan rates.

5. LIMIT DELAYS IN DIABETES CARE

Health care utilization management methods, like step therapy and prior authorization, unnecessarily restrict access to appropriate, individualized diabetes care when they are based on health insurer or pharmacy benefit manager (PBM) financial incentives rather than evidence-based clinical practice guidelines. Utilization management for prescribed diabetes products or services should be eliminated or strictly limited to avoid delays in care and ease administrative burdens on patients and providers. All diabetes coverage determinations should be adjudicated within 24-72 hours.

6. PATIENT & PRESCRIBER PREVAIL

All U.S. health plans should cover medically necessary prescription medications to treat diabetes and its complications or comorbidities, including non-formulary or non-preferred products. Given the complex and individualized nature of diabetes management regimens, product selection should be a shared decision between the person with diabetes and their health care provider. The prescriber’s determination that a product is medically necessary and warranted should be final, consistent with their reasonable professional judgment and clinical documentation of accepted use of such products.

THE CHALLENGE IS OUR HEALTH CARE SYSTEM IS REALLY BASED ON MANAGING FINANCIAL RISK, WHICH ELEVATES PATIENT RISK. PUT PRESSURE ON THE SYSTEM TO MANAGE PATIENT RISK – FOR HOSPITALIZATIONS, EMERGENCY ROOM VISITS, DISABILITY AND MORTALITY – WHILE IMPROVING QUALITY OF LIFE.

THAT’S WHERE THE CHANGE IN THE SYSTEM HAS TO BEGIN.

Gary Puckrein, PhD
National Minority Quality Forum
7. **NON-MEDICAL SWITCHING**

Non-medical switching – therapy changes prompted by insurance formularies rather than medical necessity or clinical efficacy – rarely provides clinical value to patients and instead disrupts stable treatment regimens. Rebate-driven formulary changes prioritize plan revenue without necessarily reducing consumer costs. Health plans should not require people with diabetes to switch away from using products that work for them.

8. **PATIENT-CENTERED VALUE**

Transitioning our health care system from fee-for-service that pays for quantity of care to a system that pays for value or quality of care must utilize measures that patients value, particularly in chronic disease care. Value-based insurance design (VBID) in diabetes will fall short if payers and providers emphasize A1c but neglect time in range, reducing hypoglycemia, cardiovascular and renal protection, behavioral health, improved quality of life and other measures that people with diabetes value.

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**CONSENSUS FINDINGS**

**Non-Medical Switching**

For the purposes of this consensus statement, “non-medical switching” refers to therapeutic substitution compelled by formulary changes:

A) Driven by financial interest rather than medical necessity or clinical efficacy; and

B) Prompting patients to switch from a currently prescribed medication to a therapeutic alternative that is not FDA-approved as its generic substitute, in the case of small molecule drug products, or “interchangeable” for biological products.

For example, compelling a person with diabetes who is stable on insulin aspart to switch to insulin lispro meets this working definition of non-medical switching.

Moving them from insulin glargine to a biosimilar or follow-on biologic approved as interchangeable with the reference product under Section 351 of the Public Health Service Act does not meet this working definition.
U.S. CHRONIC DISEASE CARE, COVERAGE & VALUE

Overview

Despite significant dialogue around value-based coverage, the U.S. health care system is still primarily a fee for service model with certain specialties getting a disproportionate share of the overall spend. About 60 percent of American adults live with a chronic disease and 40 percent live with multiple chronic conditions.20 As one of the most prevalent and costly chronic conditions, diabetes understandably attracts a lot of attention in payment reform efforts. The nation spends 1 in 4 health care dollars caring for people with diagnosed diabetes – with more than half of this expenditure directly attributable to diabetes.8

However, direct medical costs do not fully capture diabetes impact on society. In 2017, diabetes cost the nation an estimated $327 billion, including $237 billion in direct medical expenditures and $90 billion from reduced productivity.8 It is in these indirect costs that we see how the current system fails to confront the growing diabetes epidemic:

- **$26.9 billion** from reduced productivity and $3.3 billion in absenteeism among the working population
- **$37.5 billion** from inability to work due to disease-related disability
- **$19.9 billion** in lost productivity due to premature death

67% of the nation’s diabetes costs are paid by Medicare, Medicaid or the military8

Diabetes requires a different lens than many other chronic, progressive conditions. It is self-managed and highly individualized. Diabetes care teams across multiple disciplines provide vital care, education and support, but it is ultimately the person with diabetes, their parent or guardian making day-to-day diabetes care decisions.

As advocates, we have seen how people with diabetes who have “good coverage” fare compared to the uninsured or underinsured. Diabetes care is by nature preventive; as a nation, we need to cover it as such, with earlier investment that delays far more costly disease progression and complications later in life. We should eliminate barriers to diabetes care and coverage, rather than placing it beyond reach through high deductibles, exposure to list prices rather than net prices, restrictive formularies and administrative hoops.
Before moving to review the commercial insurance, Medicare and Medicaid systems and recommending ways to better meet diabetes needs within them, we urge consideration of the following recommended options to improve the economic viability of the chronic health care service and supply chain:

**Health Care Provider Access**
It is essential that the pipeline of health care workers is adequate to meet the growing demand for multidisciplinary diabetes care.

- Review reimbursement levels by specialty to ensure economic viability of the service and supply chain, especially:
  - Endocrinologists, especially pediatric endocrinologists
  - Diabetes care and education specialists
  - Registered dietitians and other authorized providers of medical nutrition therapy
  - Behavioral health professionals
  - Social workers
- Make acceptance of telehealth permanent
- Eliminate or strictly limit utilization management for prescribed diabetes products or services to avoid delays in care and ease administrative burdens on patients and providers

**Faster Care Decisions**
- Develop “fast track” diagnosis and claims adjudication for gestational diabetes and type 1 diabetes to minimize roadblocks such as step therapy and benefit appeals. People with these conditions do not have the luxury of time to be denied prescribed medications and services.
- All diabetes coverage determinations should be adjudicated within 24-72 hours
- Develop a reporting channel between pharmacies and prescribers to notify them of unfilled prescriptions within 15 days of prescribing
  - Chronic disease management is most effective when the patient has access to and takes the medications prescribed for their condition. Health care providers too often learn months later that a patient has not been able to afford their medications and didn’t fill the prescriptions
- Support treatment adherence and persistence by giving people with diabetes and their prescribers real-time cost data that allows them to compare treatment costs and make informed decisions, and individualize affordable treatment needed to effectively manage diabetes

**Coverage and Care Connections**
- Increase open enrollment periods to a minimum of 60 days and provide a 60-day retroactive enrollment similar to COBRA
- Expand navigator programs to help the uninsured and underinsured identify subsidized individual coverage, Medicaid or other programs for which they are eligible but not yet enrolled
Affordable Access to Innovation

- Cover as preventive care, with no or low patient cost sharing, continuous glucose monitors (CGMs), smart devices, and closed loop CGM+pump or “artificial pancreas” systems that provide data that supports diabetes management decisions.
- Provide people with diabetes access to the devices that work best for them. One-size-fits-all coverage for insulin pumps and other technologies compromises the individual’s ability to make diabetes management decisions. People with diabetes need affordable access to the products and technologies that work best for their bodies – not reimbursement schemes that limit their options.
- Maintain a level competitive landscape among manufacturers, insurers and PBMs so people with diabetes benefit from price competition.

- Health plan contracting that excludes generic and biosimilar competitors, or automatically places them in specialty or non-preferred tiers, negates competitive forces that will help reduce prescription drug prices. Follow-on biologic and biosimilar analog insulins have finally entered the U.S. market. For people with diabetes to benefit from these competitive forces, newer products available at lower net cost cannot be placed out of reach – either by formulary exclusions or high tier placement – in favor of products with higher rebates that are retained by health plans or plan sponsors. Health plans and PBMs should not be incentivized to favor higher rebated products over lower net cost alternatives that are therapeutically equivalent.
- With rebates now taking hold in the diabetes device and technology space, coverage and reimbursement policies should allow access to all FDA-approved products based on their clinical value to people with diabetes, rather than favoring large rebate-high list price products over lower list price products that do not provide rebates.

FOR A FEW PENNIES (ESPECIALLY FOR INSULIN) INSURANCE COMPANIES JUST CHANGE WHAT THEY’LL PAY FOR EVERY YEAR USUALLY IN MARCH/APRIL. WE NEED TO HAVE STAFF JUST TO DO THE CHANGES IN ALL THE SCRIPTS, OR DO PRIOR AUTHORIZATIONS, WHICH TAKES FOREVER. IT’S NONSENSE. ONCE THE DRUG IS APPROVED AND THE PATIENT IS USED TO IT, LET THE PHYSICIAN AND PATIENT CHOOSE

Satish Garg, MBBS, MD, DM
Barbara Davis Center, University of Colorado
Value Based Coverage

The concept of shifting our health care spend away from fee-for-service that pays for quantity of care to a system that pays for value or quality of care has merit and the potential to improve diabetes outcomes if done effectively. However, it is essential that value-based insurance design (VBID) utilizes measures that patients value, particularly in chronic disease care. For example, VBID in diabetes will fall short if payers and providers emphasize A1c but neglect time in range, reducing hypoglycemia, cardiovascular and renal protection, behavioral health, improved quality of life and other measures that people with diabetes value.

Let’s start with the basics of what people with diabetes need and value to manage their condition:

- **Access to medicine**
  - Affordable out-of-pocket cost
  - No forced non-medical switching
  - Continuity of care periods following formulary changes so patients can continue using prescribed medications that are proven successful for them, avoiding additional office and lab visits that are not medically indicated
  - Eliminate or mitigate barriers to access (e.g., step therapy, prior authorizations, quantity limits, etc.)

- **Access to technology and supplies (including insulin pumps, meters, strips, CGMs)**
  - Affordable out-of-pocket cost
  - Access to choice of technology products to meet individual patient needs
  - Eliminate or mitigate barriers to access (e.g., policies that favor large rebate-high list price products rather than lower list price products that do not rebate)

- **Access to care**
  - Affordable out-of-pocket cost
  - No lifetime maximums
  - Adequate availability of health care providers for covered populations
    - Removal of treatment barriers and bias
    - Especially in underserved and minority populations
  - Include education and nutrition counseling
  - Include behavioral health care
  - Eliminate or mitigate barriers to access (e.g., minimize prior authorizations)
  - Patient participation in care decisions

- **Resources for and access to type 2 diabetes onset prevention**
  - Screening and preventive care
  - Diabetes Prevention Program
  - Coverage for prevention of diabetes-related complications should be first dollar coverage in all plans including HDHPs
  - Coverage for overweight and obesity medical treatment

- **Reduce burden of living with diabetes**
  - Quality of life and psychosocial outcomes are important metrics beyond A1c for value-based arrangements
One of the largest concerns from a patient perspective in implementing a VBID model that pays for outcomes is that a patient who is struggling with their diabetes management gets left behind or may be “fired” by their health care provider. People who struggle to manage diabetes need more not less assistance. There is a proven return on investment to health plans for improving treatment adherence and persistence. VBID models must incentivize this effort. If not structured appropriately a VBID model could easily exacerbate the existing gaps in care experienced by minority and low income communities.

Outcome measures for people with diabetes also need to ensure that standards of care are being met for all patients in a practice and must have a long-term perspective of value to enable a true return on investment for the preventive care provided. Quality adjusted life years (QALYs) should not be used as a measure for who receives access to care or levels of treatment. This discriminatory practice is already prohibited in Medicare and should be eliminated from all health plans.

Acceptable outcome measures should include:

- A1c
- Time in range
- Hypoglycemia
- Hyperglycemia
- Psychosocial metrics (e.g., diabetes distress, psychological comorbidities, lack of social and economic resources)\(^23\)
- Blood pressure
- Atherosclerotic cardiovascular disease (ASCVD) risk score
- Number of in-person or virtual visits or touch points
- ADA Standards of Care, including foot and eye exams
- Screens and appropriate treatment for gestational diabetes
- Screens and appropriate education for pre-diabetes
In 2018, 65 percent of Americans obtained private health insurance coverage through commercial markets, most often through an employer (58 percent) or other sources like the individual insurance market. Fundamentally these policies must be affordable and cover the essential needs of chronic disease management in order to provide the level of care and desired health outcomes that each covered person requires.

Employer coverage is still the mainstay for most Americans, however rising unemployment and the growth of the small business sector (who often cannot afford to provide health coverage to their employees) and gig economy place more emphasis on having a viable individual market across the country.

Individual Markets
Individual markets are essential to enable Americans to pursue their career dreams without being dependent on employer-based coverage. Unfortunately, these marketplaces are not strong enough in all geographies across the country. Many have no or few plans to choose from.

We urge consideration of the following recommended options to improve and strengthen individual markets:

- Increase market risk pool support to ensure adequate offerings in all areas of the country
- Expand exchange subsidies to reduce impact on “working poor”
- Consider expanding Medicare eligibility or buy-in for individuals below age 65 who want it
- Allow employers to provide pretax subsidies for employees to buy qualified individual coverage. Exempt employers with >50 employees who provide such subsidies from any penalties for not providing their own plan.
Commercial Insurance Coverage

People who buy commercial health insurance from whatever source (individual or employer) have the fundamental right to expect that the coverage will meet minimum standards of care, including the costs of managing a chronic disease. It is far less expensive to pay for diabetes management (regardless of type) than to pay the cost of devastating complications. People who resort to rationing components of diabetes standards of care are at significantly greater risk of more costly and serious diabetes complications like amputation, heart attack, stroke, blindness or kidney failure. The key to lowering health care costs for chronic disease is to invest in health education and management.

In addition to the right to adequate coverage, a person who pays a premium for insurance has the fundamental right to receive the benefit of all cost savings negotiated by the plan including all discounts and rebates on drugs, supplies or services. The insurance company or employer should never make a windfall profit when a paying plan participant purchases a covered item during their deductible period. Cost, access and clinical need for people with diabetes must be the deciding factors in coverage decisions, not hidden price increases or rebating practices.

Also, we must improve the consumer insurance literacy and demystify insurance plans so they can make appropriate, informed choices for their personal situations, including simpler examples to help people with diabetes weigh premium costs against their pre- and post-deductible cost sharing burdens.

Jumping Through Hoops

Prior authorization, refill limits and other utilization management techniques impose a heavy burden on people with diabetes or other chronic conditions, who require multiple prescriptions.

Diabetes advocate and journalist Mike Hoskins chronicled his efforts to refill just one prescription for blood glucose test strips:

- **31 days** from the day the refill was requested to the day it was delivered by mail order
- **12+** physician’s office, insurer or PBM staff involved
- **120 minutes** on the phone
- **$184** out-of-pocket because the delayed prescription was finally filled after his deductible reset

**REMEMBER, THIS WAS FOR JUST ONE PRESCRIPTION REFILL, OF THE HUNDREDS I’VE NEEDED IN MY 30+ YEARS WITH DIABETES, NOT TO MENTION ALL THOSE I HAVE TO LOOK FORWARD TO.**

Mike Hoskins
Accordingly, we urge consideration of the following recommended options to improve the availability, transparency and cost effectiveness of commercial health coverage for people with diabetes:

- Expand dependent coverage eligibility to age 30
  - Average glycemic levels for people with diabetes under the age of 30 are higher than any age demographic. Poor access to health care contributes to this effect as many Americans in the early part of their career are in jobs that do not offer employer provided health care coverage or they cannot afford the coverage. Expanding dependent eligibility to age 30 will provide an important bridge for this population. Note the states of Florida and New York already have an extended eligibility requirement to age 30 and Ohio has an eligibility requirement of age 28.

- Increase open enrollment periods to a minimum of 60 days and provide a 60-day retroactive enrollment option similar to COBRA
  - Insurance selection is a daunting process for many if not most Americans. We need to provide a broader window of time to make the appropriate choices for their individual and family needs.
  - Retroactive coverage would help young people newly diagnosed with diabetes, effectively recognizing it as a qualifying event outside the open enrollment period.

- Require rebate and discount pass through to the consumer at the point of sale on all prescription drugs, medical devices, supplies or services during the deductible phase
  - A plan member should never pay more for a covered product or service than the plan would pay if the plan were paying 100 percent of the cost.
  - For example, a vial of insulin lists at approximately $300 but the net cost to the plan after rebates and discounts is closer to $70. The insurer or employer literally makes a $230 windfall profit when a covered participant pays list price for this lifesaving medication during the deductible period. This is simply wrong.

- Chronic disease management coverage should bypass the deductible and be treated as preventive care in all commercial plans. This investment in prevention will improve health outcomes, save lives and save health care dollars. It will also improve the general health of people entering the Medicare system when they reach age 65. Essential coverage should include:
  - Prescribed medicines, medical devices including blood glucose meters, insulin pumps, continuous glucose monitors and the related supplies and software
  - Diabetes self-management education and support (DSMES), medical nutrition therapy (MNT) and behavioral health care
- To maintain continuity of care, a stable patient with a chronic disease should not be forced to switch to a different medication or device due to a change in formulary, or non-medical switching. Patients on previously approved products should be grandfathered for those treatments at no additional cost, avoiding setbacks in disease management.

- Eliminate or ban co-pay accumulator, adjustment and maximizer programs for medications with no generic alternative that are prescribed as medically necessary.

- To improve consumer insurance literacy, the Center for Consumer Information and Insurance Oversight should update and simplify examples required in the Summary of Benefits to provide real life scenarios for chronic disease management. Current language is not specific enough to be of use to readers and it is too often buried on pages 8-12 of the unwieldy document.

- Eliminate surprise medical bills for out of network charges incurred through in network services.
  - 16 percent of U.S. hospital stays have at least one out of network charge. Hospitals are relying on third party subcontractors to provide ancillary services such as nursing, anesthesiology, therapy, etc. These third-party contractors are not currently required to accept the reasonable and customary charges negotiated by insurance plans. Patients have no control over these service providers but are too often being balance billed for out of network charges.
  - People with diabetes are more likely to see multiple care specialists due to underlying conditions and comorbidities and are similarly more likely to encounter these surprise charges.

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**Co-pay Assistance**

Co-pay accumulator, adjustment or maximizer programs effectively eliminate the benefit of patient assistance programs and redirect the funds that were intended for the patient to the insurer.

As an example: A patient is prescribed a medication with no generic equivalent that costs $1,000 but has access to a patient assistance program during their deductible period that reduces their cost to $100.

- **Without a co-pay accumulator:** The patient pays $100 for the medication and the program pays $900 at point of sale for the balance of the cost during the deductible period. The patient gets $1,000 credited to their deductible for the purchase of their medication. The $900 credit effectively reduces the net funds received by the manufacturer for the drug.

- **With a co-pay accumulator:** As before, the patient pays $100 for the medication and the program pays $900 at point of sale for the balance of the cost; however, the patient gets no credit for the $900 toward their deductible. The patient must then pay an additional $900 toward the deductible when the assistance plan ends or if the patient is started on additional therapies, which is often unaffordable. The insurer effectively diverts funds intended for the patient to the plan itself, which raises costs for patients by keeping them in the deductible period longer than they would be otherwise.
MEDICARE

Each year millions of Americans look forward to reaching the age of Medicare eligibility, when their insurance is no longer tied to their job or a partner’s. For people with diabetes, the transition from employer-provided coverage to Medicare can lead to significant disruptions in care.

Innovation in diabetes care is advancing at a remarkable pace. There are more medications, devices, software and technology, than ever before. Navigating commercial insurance to access these changing standards of diabetes care is no picnic – but Medicare is a different animal altogether.

Medicare coverage determinations often become the accepted standard for commercial insurers. If Medicare covers it, other insurers are likely to follow. But in diabetes, standards of care change so rapidly – along with individual needs – that Medicare adoption of innovative products often lags behind commercial insurers.

Case in point: Advanced diabetes technology. Increasingly diabetes management decisions are supported by data that CGMs, smart devices, and closed loop CGM+pump or “artificial pancreas” systems provide. Consumer CGMs first launched in the U.S. in 2004. Medicare didn’t cover CGMs until 2017.

In 2015, the FDA approved a Bluetooth enabled CGM that could transmit data to a companion smartphone app. This novel feature freed users from carrying a separate receiver and allowed them to share their data with trusted friends, family and health care providers. Medicare initially would only cover the CGM with smartphone capability disabled which reduced efficacy and safety benefits, and actually increased cost by requiring a separate companion device. It took more than 15 months of continued advocacy before CMS overturned the policy. Only very recently have Medicare beneficiaries had access to artificial pancreas technology even though the FDA approved the first system in 2016.
Each year Medicare spends millions of dollars covering lower limb amputations due to diabetic neuropathy or treatment for blindness from diabetic retinopathy—but steadfastly refuses to cover test strips so Medicare beneficiaries can test blood glucose as often as they and their health care provider agree is appropriate. Medicare requires beneficiaries to test their blood glucose levels four times per day to be eligible for CGM coverage—yet the program covers just three test strips per day for beneficiaries using insulin and only one for beneficiaries who are not on insulin. There is no clinical basis for the one, three or four test strip limits. People with diabetes often test throughout the day, around meals and snacks, physical activity, driving, correcting highs or lows, and more as needed.

People with type 1 diabetes who were diagnosed decades before they age into Medicare are still required to get an antibody or C-Peptide test to confirm their diagnosis. There is no cure for type 1 diabetes and no chance that the diagnosis has changed. This unnecessary practice wastes precious health care dollars and should be eliminated.

The Medicare Competitive Bidding Program (CBP)—an ill-fated attempt to commoditize diabetes care until it was paused in 2019, sparked a “race to the bottom” for self-monitoring of blood glucose (SMBG) suppliers. Thousands of Medicare beneficiaries had to replace reliable meters and strips they had been using with low bid, less accurate products that flooded into the program. Research by the National Minority Quality Forum revealed access disruptions to prescribed diabetes supplies, contributing to poor health outcomes including rising hospitalization rates, longer inpatient stays and mortality. Diabetes advocates are preparing for yet another round of efforts to secure safe and accurate diabetes supplies and devices for Medicare beneficiaries by keeping these products out of the CBP.

G. Todd Alonso, MD
Barbara Davis Center, University of Colorado
Another illustration: Medicare Part D currently does not cover FDA-approved medications for the treatment of obesity, even as evidence mounts that obesity leads to multiple comorbidities, including type 2 diabetes. The American Medical Association and other leading medical societies have recognized obesity as a serious chronic disease since 2013. Clinical guidelines from the American Association of Clinical Endocrinologists, the Endocrine Society, and the American Heart Association/American College of Cardiology all recommend pharmacotherapy as an option for treatment of obesity and prevention of its comorbidities. Today Medicare beneficiaries still lack access to the full range of options to treat obesity – an essential strategy in the prevention of type 2 diabetes.

Medicare has become the nation’s diabetes payer of last resort, covering hospitalizations, emergency room visits and other expensive, often preventable acute care rather than investing in prevention. Sixty percent of Medicare beneficiaries with diabetes have an inpatient hospital stay annually.26 About 90 percent experience an inpatient stay or emergency room visit.27 The program pays about $160,000 per year for the highest utilizers – while benefits like diabetes self-management training (DSMT, the Medicare benefit for DSMES), CGM and insulin pump coverage, adequate testing and supplies are underutilized due to cost, lack of awareness or access to providers.

In 2016, 8.1 million fee-for-service beneficiaries with diabetes had 9.6 million hospital encounters:

- 4.1 million unique hospitalizations and
- 5.5 million unique emergency room visits that did not end in an inpatient stay26

National Minority Quality Forum Diabetes Index
Medicare coverage and reimbursement policy changes can take months or years, so the diabetes community welcomed several CMS regulatory waivers announced in the early days of the COVID-19 public health emergency. Waivers rapidly expanded access to telehealth services and streamlined access to prescriptions and devices by putting “patients over paperwork.” The waivers were introduced to provide necessary flexibility during the public health emergency – but this same flexibility will be just as essential afterward. Barring any safety or quality of care concerns that may surface, these temporary Medicare Section 1135 waivers should be made permanent.

We urge consideration of the following recommendations to strengthen the Medicare system:

- **Medicare Diabetes Prevention Program (MDPP)**
  - Eliminate the once per lifetime benefit. These programs are inexpensive and the return on investment for intervention is strong. Diabetes prevention should be viewed in the same light as smoking cessation programs and encouraged as frequently as needed.
  - Allow MDPP providers to deliver sessions via digital and telehealth

- **Make permanent COVID-19 related waivers:**
  - Coverage and reimbursement for telehealth services
  - Waived video requirement for DSMT, MNT telehealth, allowing delivery by phone or audio only
  - Expanded eligible practitioners that may furnish and bill for telehealth services
  - Waived prior authorization and medical necessity documentation requirements
  - Waived in-person requirements for CGM and insulin pumps, allowing Medicare beneficiaries with diabetes to get their supplies without an in-person visit
  - Waived in-person visit requirement for replacement of durable medical equipment (DME) that is lost, destroyed, irreparably damaged, or otherwise rendered unusable or unavailable
  - Cover 90-day supply of prescription medications
  - Cover 90-day supply of diabetes testing supplies
Expand access to Medicare DSMT\textsuperscript{28}. As noted above, DSMT refers to the Medicare benefit for diabetes self-management education and support (DSMES). Investment in training is inexpensive and the strongest path to reducing spending away from hospitalizations for the complications of diabetes.

- Allow the initial 10 hours of DSMT during the first year to remain available until fully utilized. If there is a determination of medical necessity, then an additional 6 hours of training/education may be added.
- Allow 6 hours of DSMT in subsequent years, up from 2 hours.
- Remove the restriction related to coverage of DSMT and Medical Nutrition Therapy (MNT) services furnished on the same day. These services are often provided in parallel and this practice should be encouraged not limited.
- Exclude DSMT services from Part B cost-sharing and deductible requirements.
- Permit physicians and other qualified practitioners who are not directly involved in managing an individual’s diabetes to refer them for DSMT services. Examples include podiatrists, physician assistants, advanced practice nurses, specialists treating a comorbidity like gangrene or vision loss, or an emergency room physician.
- Revise the Medicare Benefit Policy Manual to allow DSMT services to be provided in a community-based location.
- Add DSMT/DSMES programs, eligible to furnish Part B services, to the list of eligible telehealth practitioners.

Expand diabetes prevention efforts by establishing coverage for obesity treatments

- Revise the Part D plan guidance that currently prohibits coverage for anti-obesity medications so that Medicare beneficiaries have access to FDA-approved treatments for obesity.
- Improve coverage for intensive behavioral therapy services for patients with obesity in Medicare Part B, e.g., by expanding the range of providers that may be reimbursed for these services.
Medication, testing supplies and Durable Medical Equipment (DME) coverage:
- Cover test strips per medical orders, not limited to 3 per day for patients on insulin and 1 per day for patients not using insulin
- Prohibit non-medical switching of drugs or devices on stable patients
- Prohibit step therapy or fail-first requirements
- Make permanent $35 capped cost sharing for insulin per the Part D Senior Savings Model
- Cap patient cost sharing for other diabetes medications and supplies, including SGLT-2s, GLP-1s, DPP-4 inhibitors and other innovative therapies that may be approved
- Require rebate and discount pass through on all prescription drugs during the deductible phase and throughout the plan year. A Medicare beneficiary should never pay more for a covered product or service than the plan would pay if the plan were paying 100 percent of the cost
- Eliminate the 4 finger stick requirement for CGM coverage
- Eliminate the basal bolus insulin requirement for CGM coverage, extending access to Medicare beneficiaries on basal insulin
- Cover artificial pancreas systems in a way that will allow for interoperable systems and coverage of software algorithms to enable them
Medicaid is an essential piece of the national health care safety net. The PPACA recognized and enhanced the program’s role, prompting 38 states, the District of Columbia, Guam, Puerto Rico and U.S. Virgin Islands to expand Medicaid eligibility to more low income Americans.

The Medicaid program serves low income Americans, so access challenges are different than in other insurance markets. Cost sharing is low or eliminated, but it can be difficult to find providers who participate in the program and accept below-market reimbursement rates. Social determinants of health – access to education, housing, nutrition, transportation, etc. – are additional factors impacting diabetes care in the Medicaid population.

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

It is rare for national advocacy organizations to engage on prescription coverage issues under Medicaid. Insulin, in particular, is so steeply rebated that most products are available for free or nearly free on a net basis to states under Medicaid and the federal 340B program.

Advocates are frequently called upon to engage on “penny wise, pound foolish” issues when states try to limit access to newer products and technologies despite the value to patients and their longer term health outcomes. For example, some state Medicaid programs will cover insulin in vials but not pens. Insulin pens may cost more than vials on a per-unit basis, but they are significantly easier to use and carry, and thus more likely to be used as needed. Insulin pens provide tactile and auditory feedback when selecting a dose, which is essential for people with vision limitations or impairments in their hands due to arthritis.
Medicaid coverage for diabetes devices and durable medical equipment, notably CGMs and insulin pumps, remains a concern for several national advocacy organizations. Eleven state Medicaid programs do not yet have a published CGM coverage policy. CGM coverage in the other 39 states are a patchwork of prescription or DME benefits. States set eligibility criteria, typically for specific patient populations (e.g., pediatric, adult, type 1 diabetes, type 2 diabetes) not according to clinical guidelines.

11 state Medicaid programs do not have a published CGM coverage policy
Diabetes management is unique among chronic diseases. It is almost entirely self-managed by the individual, or their parent or caregiver rather than by a health care provider. A person with diabetes makes minute-by-minute adjustments in their management plan, trying to keep blood glucose levels within a recommended range. Increasingly these decisions are supported by data that CGMs, smart devices, and closed loop CGM+pump or “artificial pancreas” systems provide. Restricting coverage for these products in Medicaid hinders the individual’s ability to manage their diabetes, and perpetuates health inequities. Furthermore, restricting coverage of these innovative devices has the potential to increase cost because of additional complications.

**Time in Range**

A sample Ambulatory Glucose Profile (AGP) report from the International Diabetes Center illustrates how a person with diabetes and their care team can use time in range data to inform diabetes decision-making.

For example, CGM data can help identify hyperglycemia and hypoglycemia events, where blood glucose levels are very high or low respectively, putting the person with diabetes at immediate risk.

CGM data can guide immediate or gradual adjustments in insulin or other medication dosing, food intake, physical activity and other variables that influence glycemic levels.

People with diabetes feel better and can improve their long-term health outcomes when they have the right tools to maximize their time in the green target range, with fewer peaks and valleys.
Medicaid buy-in is another state option with potential to reduce the rate of uninsured and underinsured among people with diabetes. This option also encourages people who are able to join the workforce to go back to work without the fear of losing their coverage. The Kaiser Family Foundation explains:

The Medicaid buy-in program for working people with disabilities is an option authorized under the Ticket to Work and Work Incentives Improvement Act that allows working individuals with disabilities whose income and/or assets exceed the limits for other eligibility pathways to “buy-in” to Medicaid coverage. This option provides people with disabilities the opportunity to work and access the health care services and supports they need, without having to choose between working and qualifying for Medicaid.29

Diabetes is a chronic endocrine system disorder and qualifies as a disability under the Social Security Act, Americans with Disabilities Act, and Individuals with Disabilities Education Act. States may be able to allow uninsured people with diabetes who meet other eligibility requirements to obtain coverage by buying into Medicaid.

We urge consideration of the following recommendations to improve Medicaid coverage and eligibility:

- Expand Medicaid in the remaining 12 states
- Qualify diabetes as a disability eligible for Medicaid buy-in for low- and moderate-income workers
- Preserve Medicaid expansion at current state-federal cost sharing ratios
- Provide 12-month eligibility determination and continuous coverage for adults similar to CHIP protections for children to eliminate coverage loss due to fluctuations in household income
- Expand coverage for needed supplies and devices especially for people with type 2 diabetes or gestational diabetes
- Ensure coverage of digital diabetes prevention programs, allowing for telehealth, virtual and in-person options
- Cover all forms of insulin, including pens, vials, inhaled and other products that may eventually be approved
- Cover telehealth services, including video, phone and audio-only delivery
### APPENDIX A: PARTICIPATING ORGANIZATIONS AND DELEGATES

<table>
<thead>
<tr>
<th>Organization</th>
<th>Delegates</th>
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| **Diabetes Leadership Council** – *Coalition Lead* | - Larry Ellingson, RPh  
- Erika Benke Emerson  
- Karen Grishaber  
- Edward Hawthorne  
- George Huntley  
- Hunter Limbaugh, JD  
- Stewart Perry  
- Donna Ryan, MPH, RN, CDCES, FADCES  
- Larry Smith  
- Alyce Thomas, RDN  
- Janel Wright, JD  
- Desmond Schatz, MD  
- John Anderson, MD |
| * formerly the National Diabetes Volunteer Leadership Council |                                                                          |
| **Association of Diabetes Care & Education Specialists** | - Teresa Martin, MS, RD, DCES, LD  
- Mandy Reece, PharmD, CDCES, BC-ADM, BCACP, FADCES  
- Kate Thomas |
| **Beyond Type 1 / Beyond Type 2** | - Christel Marchand Aprigliano  
- Thom Scher |
| **Certification Board for Diabetes Care and Education** | - Jasmine Gonzalvo, PharmD, BCPS, BC-ADM, DCES, LDE |
| **Children with Diabetes** | - Jeff Hitchcock |
| **College Diabetes Network** | - Dan Browne  
- Christina Roth |
| **Diabetes Dietetic Practice Group of the Academy of Nutrition and Dietetics** | - Charlene Dorsey, MS, LDN, LMNT, CDCES  
- Jennifer Okemah, MS, RD, BC-ADM, CDCES, CSSD |
| **Diabetes Patient Advocacy Coalition** | - Julie Babbage |
| **DiabetesSisters** | - Anna Norton, MS |
| **The diaTribe Foundation** | - Emily Fitts  
- Julia Kenney |
| **JDRF** | - Campbell Hutton  
- Jackie LeGrand |
| **T1D Exchange** | - Rebecca Parkes |
APPENDIX B: DIVERSITY AND INCLUSION LENSES

1) COVID-19 & Diabetes
   a. What was learned during the pandemic that should inform health care reform going forward
   b. Were temporary policy changes enacted that should be made permanent or studied more formally?

2) Insurance status
   a. Commercially insured
      i. Employer sponsored
      ii. Individual
   b. Medicare
   c. Medicaid
   d. Military
   e. Uninsured

3) Diabetes type
   a. T1D
   b. T2D
   c. Gestational
   d. Latent Autoimmune Diabetes of Adulthood (LADA)
   e. Maturity Onset Diabetes of the Young (MODY)

4) Diverse Diabetes Populations
   a. Communities of color
   b. Socioeconomic
   c. Age
      i. Children
      ii. Young adults & caregivers
      iii. Working age adults
      iv. Seniors/retired
   d. Gender
   e. Pregnant women with preexisting diabetes or gestational diabetes
   f. LGBTQ+
   g. Disabled/differently abled
   h. Co-occurring conditions/comorbidities
   i. Urban/Rural/Suburban
APPENDIX C: DIABETES ESSENTIAL HEALTH BENEFITS

Recommend pre-deductible coverage with no or low patient cost sharing for treatment of diabetes and related conditions or complications consistent with national clinical guidelines, published by:

- American Diabetes Association
- American Association of Clinical Endocrinology
- Endocrine Society
- American College of Obstetrics and Gynecology
- American Academy of Pediatrics

The services below reflect diabetes care required in addition to general preventive care or annual wellness (e.g., well woman) visits. Services and frequencies noted reflect guidelines as of October 2020.

DIABETES MANAGEMENT

- HCP office visit (in person or telemedicine) and medication review every 3 months
- Medical Nutrition Therapy (MNT) with a registered dietitian, including 3-6 MNT encounters in the first six months after diabetes diagnosis and as needed afterward
- Diabetes self-management education and support (DSMES) with a diabetes care and education specialist (DCES) during the four key times to implement DSMES: at diagnosis, annually or when not meeting treatment targets, when complications develop, and when transitions in life occur.\(^{30}\)
- Covered medication, devices, software and supplies
- A1c test every 3 months
- Gestational diabetes screening

COMPLICATION SCREENING AND PREVENTION

- Annual physical exams
  - Dilated eye exam
  - Foot
- Screening (every 3-6 months or per guidelines)
  - Blood pressure
  - Behavioral health, including depression
  - AVCVD risk
  - Microalbumin
  - Cholesterol/Triglycerides
  - Pulse
  - Weight
- Celiac disease screening at diagnosis of type 1 diabetes, and thereafter according to pediatric and adult clinical guidelines
- Dental exam and cleaning 2x per year
- Vaccinations: pneumococcal, influenza, shingles, Hepatitis B

DIABETES PREVENTION

- Screening individuals at high risk (e.g., overweight or obesity, age, family history)
- Coverage of and support for the National Diabetes Prevention Program
- Medical Nutrition Therapy with a registered dietitian for individuals with prediabetes
- Medication coverage for prediabetes
ENDNOTES


6 Ibid.


10 Ibid.


National Minority Quality Forum Diabetes Index. 2017 Medicare Fee-for-Service data.

Ibid.


U.S. HEALTH CARE REFORM FOR PEOPLE WITH DIABETES

CONSENSUS WORKING GROUP MEMBER ORGANIZATIONS

CORRESPONDING AUTHOR: Diabetes Leadership Council
info@diabetesleadership.org
Consensus statement download available at diabetesleadership.org