



National Clinical Care Commission

Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications

2021

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Information and opinions in this report do not necessarily reflect the opinions of each member of the Commission, the U.S. Department of Health and Human Services, or another component of the federal government.

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Executive Summary

The United States is confronting the COVID-19 pandemic. At the same time, another health crisis challenges the U.S.: diabetes mellitus.* Since the last federal commission on diabetes issued its report in 1975, the diabetes epidemic has accelerated and grown, affecting more individuals and families, and contributing to greater health care costs. With appropriate population-wide strategies and individual-level interventions, diabetes can be prevented in many cases and its consequences mitigated. The 2021 National Clinical Care Commission Report to Congress and the Secretary of Health and Human Services outlines recommendations to leverage federal programs to prevent type 2 diabetes and control diabetes complications. The report contains evidence-based recommendations for (1) reducing diabetes-related risks and preventing type 2 diabetes in the general population, (2) preventing type 2 diabetes in targeted populations at high risk for its development, and (3) treating and managing diabetes and its complications to improve the health outcomes of individuals with the disease. Implementation of these recommendations will help improve the health and quality of life of millions of Americans affected by diabetes, and help control the rising costs of diabetes and its complications in our nation.

Prevalence and Health Impact

In 2018, more than 34 million Americans (about one in 10 Americans of all ages including one in seven adults¹) had diabetes, and 88 million American adults (approximately one in three) had prediabetes, a state of increased risk for type 2 diabetes and cardiovascular disease in which blood glucose levels are higher than normal but not high enough to be diagnosed as diabetes.² If current trends continue, one in three Americans will develop diabetes in their lifetime.³ In the U.S., diabetes is a leading cause of blindness in adults, kidney failure, and lower-limb amputations and is a major contributor to death including death from COVID-19. Individuals with poorly controlled diabetes have at least a two-fold greater risk of death from COVID-19. Both diabetes and its complications are more common and more severe in low-income Americans and Americans of color.

Economic Burden

The cost of diabetes poses a financial burden on the U.S. health care system and on society. The total cost of diabetes was \$327 billion in 2017, including \$237 billion in direct medical

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costs and \$90 billion in reduced productivity.² About 67% of diabetes costs were paid by Medicare and Medicaid.⁴ Caring for people diagnosed with diabetes accounts for one of every four health care dollars, making diabetes the most costly chronic condition in the U.S.^{4,5}

Diabetes Is a Medical and a Societal Problem

Type 2 diabetes can be prevented in many cases and medical care can help individuals with diabetes avert many of its complications. However, the social and environmental conditions that shape people's daily experiences have a huge impact on whether people will develop diabetes or suffer from its consequences. Thus, the Commission approached its charge through the lens of a socioecological and an expanded chronic care model. It was clear that diabetes in the U.S. cannot simply be viewed as a medical or health care problem, but also must be addressed as a societal problem that cuts across many sectors, including food, housing, commerce, transportation, and the environment. The Commission believes that to effectively improve the health outcomes of people at risk for or affected by diabetes, all of these elements must be taken into account. As a result, many of the Commission's recommendations are aligned with what is known as a "health-in-all-policies" approach.

The Commission's Recommendations

Based on the information gathered and synthesized through a federal data call, stakeholder input, public comments, and extensive literature searches and reviews, the Commission developed evidence-based, actionable recommendations to address (1) diabetes prevention and control in the general population, (2) diabetes prevention in populations who are at high risk of developing type 2 diabetes, and (3) treatment of diabetes and its complications.

Overarching Recommendations

Historically, diabetes prevention and treatment have been considered to be medical problems requiring medical treatment. Limited attention has been paid to the social and environmental conditions that contribute to diabetes and make managing diabetes more challenging.

To improve diabetes awareness, prevention, and treatment, additional federal efforts are needed to improve access to health care, address the social determinants of health, and improve trans-agency collaboration. Accordingly, to formulate its recommendations, the National Clinical Care Commission focused on each of these cross-cutting issues and made the following recommendations:

- To coordinate and monitor federal efforts relevant to diabetes and to ensure trans-agency collaboration, an Office of National Diabetes Policy should be created and

given responsibility to develop and implement a national diabetes strategy across health care and non-health focused federal agencies.

- Federal policies and programs should ensure that people at risk for or with diabetes have access to comprehensive, high-quality, and affordable health care.
- Health equity should be considered in every new or existing federal policy or program that impacts people at risk for or with diabetes. This is essential to eliminate unintended and adverse impacts on health disparities.

Recommendations for Diabetes Prevention in the General Population

To delay, prevent, and control diabetes, and to reduce racial, ethnic, and income-related disparities in diabetes outcomes, changes need to take place in the social and environmental contexts in which U.S. residents live, learn, work, and play. Fostering such change cannot be left only to those federal agencies that are accountable for health care. Large-scale success can only be achieved by also engaging those federal agencies whose primary focus is not on health but whose policies and programs play an important role in shaping the social and environmental contexts that influence diabetes incidence and complications.

To address this critical need, the National Clinical Care Commission recommends

- Updating and increasing funding to the U.S. Department of Agriculture's nutrition assistance programs to promote both food security and dietary quality;
- Increasing breastfeeding rates through effective federal programs and paid maternity leave;
- Implementing federal strategies to encourage the consumption of water over sugar-sweetened beverages in the U.S. population;
- Updating the Food and Drug Administration's food labeling policies and practices to prevent and control diabetes;
- Providing the Federal Trade Commission with the authority and resources to regulate the food and beverage industry's marketing and advertising to children;
- Modifying federal department and agency policies to reduce environmental exposures associated with diabetes in the ambient environment (air, water, land, and chemical) and improve the built environment by enhancing walkability, green spaces, physical activity resources, and active transport opportunities;

- Expanding housing opportunities in health-promoting environments for low-income individuals and families through the Department of Housing and Urban Development's programs; and
- Optimizing and expanding research programs that will enhance our understanding of the social and environmental conditions associated with a greater risk of diabetes and its complications, and evaluating the effects of changes in these conditions on diabetes-related outcomes.

Recommendations for Diabetes Prevention in People at High Risk

The Commission focused on several factors that have the greatest likelihood of preventing the development of type 2 diabetes and its complications in those who are at high risk for type 2 diabetes, specifically people with prediabetes. There are effective methods, in particular lifestyle change programs, for reducing the risk of developing type 2 diabetes. However, 85% of the 88 million Americans with prediabetes are not aware they have the condition, and most people with prediabetes are not engaged in preventive interventions. The Commission recommends

- Increasing awareness of prediabetes and availability of effective lifestyle intervention programs, in particular the National Diabetes Prevention Program (National DPP);
- Promoting better coverage of screening tests for prediabetes; and
- Adopting clinical quality measures that support screening for prediabetes and targeted interventions to delay or prevent type 2 diabetes.

The Commission also recommends improving access to, participation in, and sustainability of type 2 diabetes prevention interventions. These recommendations include

- Providing adequate insurance coverage for all effective delivery modalities for diabetes prevention (that is, in-person, telehealth, and virtual);
- Approving the Medicare Diabetes Prevention Program (MDPP) as a permanent covered benefit;
- Continuing efforts to streamline the recognition and payment processes for type 2 diabetes prevention programs;
- Improving payment models and payment levels for MDPP providers;
- Incentivizing state Medicaid programs to provide coverage for the National DPP; and

- Providing additional support for federal programs that focus on type 2 diabetes prevention.

The Commission also recommends supporting research to develop new and better methods for preventing both type 1 and type 2 diabetes.

Recommendations for Diabetes Treatment and Complications

The Commission focused on several factors that have the greatest likelihood of improving the delivery of high-quality care to all persons with diabetes. The biggest gap in diabetes treatment and preventing its complications is mismatch between available resources and the needs of persons living with diabetes. The Commission's recommendations for diabetes treatment and complications are designed to bridge this gap.

- At the patient level, the Commission recommends reducing barriers and streamlining administrative processes for receipt of diabetes self-management training and diabetes technologies and devices, expanding access to virtual care, and ensuring insulin is affordable and accessible.
- At the practice level, the Commission recommends enhancing programs that support team-based care and developing capacity to support technology-enabled interventions.
- At the health care system level, the Commission recommends aligning health care workforce needs with programs funded by the Department of Health and Human Services.
- At the health policy level, the Commission recommends ensuring pre-deductible insurance coverage for high-value diabetes treatments and services and developing a quality measure that enhances patient safety and reduces risk of hypoglycemia.

The Commission also identified several areas that need additional research.

To improve the health outcomes and quality of life of individuals at risk for or with diabetes; to protect the wellbeing of all American people; and to control our nation's rapidly rising health care cost, the Commission urges Congress and the Secretary of Health and Human Services to take action to make certain that the Commission's recommendations are implemented and the results monitored.

Chapter 1: Background

Diabetes in the United States

Diabetes Mellitus

Diabetes mellitus is a heterogeneous group of disorders characterized by high blood glucose levels (hyperglycemia). Most people with diabetes can be classified as having type 1 diabetes or type 2 diabetes.

Type 1 diabetes accounts for five to 10 percent of diabetes in the U.S. It tends to affect children and adolescents but it may be diagnosed at any age. In type 1 diabetes, destruction of the insulin-producing cells in the pancreas leads to insulin deficiency. At clinical presentation, people with type 1 diabetes often have marked hyperglycemia and its attendant symptoms and signs including increased thirst, increased urination, and unintentional weight loss. When a person is symptomatic, the fasting plasma glucose is usually unequivocally elevated and the diagnosis of diabetes is straightforward. Insulin is the only therapy for type 1 diabetes and it is necessary for survival.

Type 2 diabetes accounts for 90% to 95% of diabetes in the U.S. Racial and ethnic minority populations are at substantially increased risk for type 2 diabetes as are older adults and those with obesity, hypertension, high triglyceride and low high-density lipoprotein (HDL) cholesterol levels, and family histories of type 2 diabetes. Women with histories of gestational diabetes are also at substantially increased risk. Type 2 diabetes is often preceded by prediabetes, a state of increased risk for type 2 diabetes and cardiovascular disease where blood glucose levels are higher than normal but not high enough to diagnose diabetes. Type 2 diabetes is caused by a combination of resistance to insulin action and inadequate compensatory insulin secretion. In type 2 diabetes, hyperglycemia sufficient to cause complications affecting the eyes, kidneys, and nerves may be present without clinical symptoms. During this asymptomatic period, prediabetes and type 2 diabetes may be diagnosed by measuring fasting plasma glucose, plasma glucose after an oral glucose load, or hemoglobin A1c (HbA1c), a measure of average glucose levels over the preceding three months. Both lifestyle interventions and medications can delay or prevent progression from prediabetes to type 2 diabetes, and both lifestyle interventions and an array of oral and injectable medications, including insulin, may be needed to control blood glucose levels in type 2 diabetes.

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are pertinent to all types of diabetes, this report uses the general term “diabetes.” For statements that are specific to type 1 or type 2 diabetes, this report uses the term “type 1 diabetes” or “type 2 diabetes.”

Diabetes Prevalence

Someone in the U.S. is diagnosed with diabetes every 20 seconds. In 2018, more than 34 million Americans (about one in 10 Americans of all ages^{2,6} including one in seven adults¹) had diabetes. Of these, 26.9 million were diagnosed and 7.3 million were undiagnosed. In addition, 88 million American adults (more than one in three) had prediabetes.²

The prevalence of diabetes increases with age such that 24.2 million or more than one in four Americans 65 years of age and older have diabetes. In recent years, the prevalence of both type 1 and type 2 diabetes has increased substantially among American youth.⁷ In 2016, nearly one in five adolescents had prediabetes, increasing their risk of developing type 2 diabetes, comorbidities, and complications.⁸ Type 2 diabetes is more common among low-income people and people of color, in whom prevalence rates are often twice of their white counterparts. As such, diabetes is an important contributor to health inequities in the U.S. If current trends continue, one in three Americans will develop diabetes during their lifetimes.³ One of five Americans with type 2 diabetes and four of five Americans with prediabetes are unaware of their condition.

The increasing prevalence of type 2 diabetes in the U.S. has been associated with dramatic increases in the prevalence of obesity, which, like type 2 diabetes, can result from unhealthy social and environmental conditions. In 1975, 14.5% of U.S. adults had obesity and 1.3% had extreme obesity.⁹ By 2020, 42.4% of U.S. adults had obesity and nearly 10% had severe obesity.¹⁰ Rates of childhood obesity have also increased over the years, with nearly 20% of American youth two to 19 years of age having obesity.¹¹

Health Impact

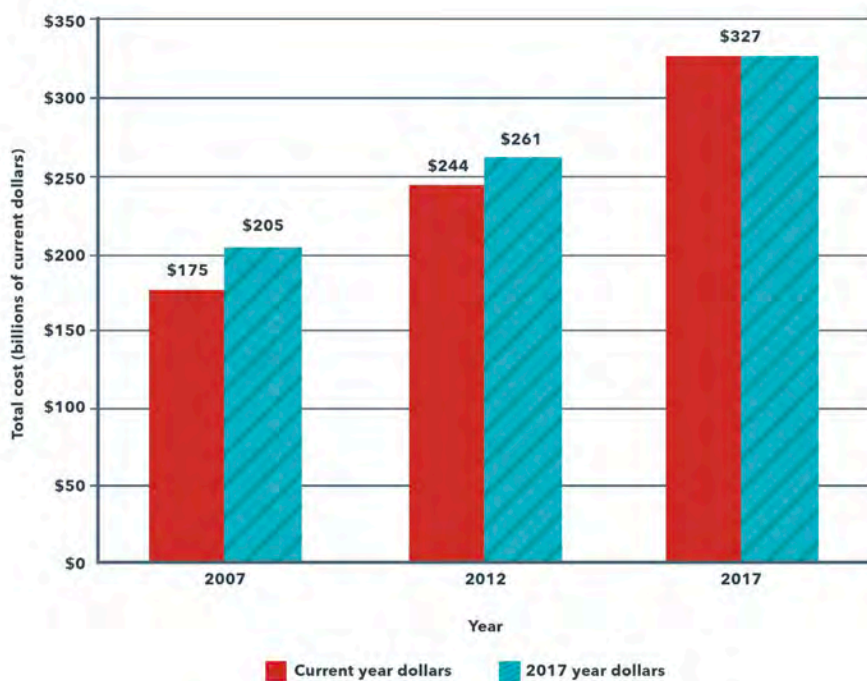
Diabetes can affect the whole body. It is associated with a two- to four-fold increased risk of cardiovascular disease, including stroke and heart attack, and causes unique complications affecting the eyes (diabetic retinopathy), kidneys (diabetic nephropathy), and nerves (diabetic neuropathy). In the U.S., diabetes is the number one cause of adult blindness, kidney failure, and lower-limb amputations, and is a major contributor to heart disease and death. Diabetes also contributes to death from infectious diseases. As an example, diabetes increases the risk of death from COVID-19 by two- to three-fold.

Economic Burden

The cost of diabetes in the U.S. is enormous and poses a substantial burden to the health care system and to society (Figure 1). The total cost of diabetes in 2017 was estimated to

be \$327 billion. This included \$237 billion in direct medical costs (the costs of medical care for people with diabetes) and \$90 billion in indirect costs (the costs to society of lost productivity due to illness, disability, and premature mortality).² Two-thirds of direct costs of diabetes were paid by Medicare or Medicaid.⁴ Caring for people with diabetes in the U.S. accounted for one of every four health care dollars, making diabetes the most costly chronic disease.^{4,5}

Figure 1. Change in total economic costs of diabetes in the United States, adjusted for inflation, 2007-2017⁴



History of Federal Efforts to Combat Diabetes in the U.S.

In 1974, “The National Diabetes Mellitus Research and Education Act” (Public Law 93-354) established the National Commission on Diabetes. It formulated the Long-Range Plan to Combat Diabetes in the United States.¹² The plan and subsequent federal actions made a substantial impact on diabetes research, diabetes programs, and treatment for diabetes and its complications. Basic biomedical research advanced knowledge of the fundamental causes of diabetes and its complications and facilitated the development of effective new therapies. Clinical trials proved that hyperglycemia causes the microvascular and neuropathic complications of type 1 diabetes, and that intensive diabetes treatment can delay or prevent those complications.¹³ Similarly, the Diabetes Prevention Program

demonstrated the effectiveness of intensive lifestyle intervention and metformin to delay or prevent the development of type 2 diabetes in high-risk individuals with prediabetes.¹⁴ Advances have also been made in devices and technologies to improve glucose control, including insulin pumps and continuous glucose monitors. Exciting new treatments have been developed to reduce the incidence of blindness, end-stage kidney disease, and amputations.

The Long-Range Plan also helped establish several federal programs to address diabetes and its complications. The National Institutes of Health (NIH) established Diabetes Research and Training Centers to conduct research in diabetes, expand the diabetes workforce, offer training programs, and provide continuing education. More recently, NIH's Centers for Diabetes Translational Research have facilitated translation of research into community practice. The Centers for Disease Control and Prevention (CDC), the Veterans Health Administration, and the Indian Health Service also established diabetes health care, education, and control programs. Additionally, the National Diabetes Information Clearinghouse and the National Diabetes Data Group provided accurate statistics on diabetes to support public policy.

In the mid-1970s, CDC funded a demonstration project to build the infrastructure for Diabetes Prevention and Control Programs in seven states. Over the ensuing two decades, these programs expanded to include all 50 states, the District of Columbia, and several U.S. territories and freely associated states in the Pacific and the Caribbean. In 1995, CDC published the first *National Diabetes Fact Sheet* with the collaboration and consensus of more than 10 federal agencies and national diabetes organizations. Today, CDC's interactive *U.S. Diabetes Surveillance System* documents the public health burden of diabetes and its complications at the national, state, and county levels. In 1998, CDC and NIH began the *SEARCH for Diabetes in Youth Program* to address the emerging public health problem of type 2 diabetes in children and adolescents and the *Translating Research Into Action for Diabetes (TRIAD)*, a study of diabetes quality of care, costs, and outcomes in the U.S. CDC and NIH also co-funded the NEXT-D Initiative to evaluate the effects of type 2 diabetes-related health policies and interventions on various populations. In response to findings from the Diabetes Prevention Program (DPP) and subsequent translation studies, CDC launched the National DPP in 2012, with the goal of building a nationwide delivery system for an evidence-based lifestyle change program to prevent or delay the onset of type 2 diabetes in adults with prediabetes.

Remaining Challenges and Emerging Threats

Although the National Commission on Diabetes stimulated progress, it has been nearly 50 years since it issued its report, and there is an urgent need to reassess and update the federal response to the diabetes epidemic. It is time to consider how the federal government can initiate or expand programs and policies to more effectively address the growing problem of diabetes in the U.S.

There has been increasing recognition that social and environmental factors influence the risk of type 2 diabetes and make controlling diabetes more challenging.¹⁵ Individuals who have less education, lower incomes, more food and housing insecurity; and who live in rural areas have higher rates of type 2 diabetes and worse diabetes outcomes. Higher type 2 diabetes risk and worse diabetes outcomes are also associated with physical environments that lack adequate playgrounds, parks, walkability, and transportation. Poor social cohesion, marginalization, and poverty are also associated with diabetes risk.

Efforts to translate the advances in diabetes treatment into routine clinical practice have also stalled. Only one in four adults with diabetes achieves recommended standards of diabetes care,¹⁶ and this level of performance has remained unchanged since 2012.¹⁷ In addition, the improvements in diabetes care have not been evenly distributed across the U.S. population. The same racial and ethnic minority groups and lower-income individuals who experience higher type 2 diabetes prevalence often have higher rates of preventable and costly complications, including heart attacks, strokes, blindness, kidney failure, and amputations.

In the U.S., more than half of the preventable burden of diabetes is attributable to the non-clinical social and environmental factors that shape health behaviors.^{15, 18, 19} The other half is attributable to lack of access to affordable, quality care and to failings in the design of our current health care delivery system—one that is more geared to reactive, acute care than to proactive, team-based care. National efforts to prevent and treat diabetes have been hindered by (1) failure to address social determinants of health; (2) lack of directives for trans-agency engagement of non-health federal agencies and insufficient coordination among all federal agencies (non-health and health agencies); and (3) persistent gaps in access to health care.

Establishment of and Charge to the National Clinical Care Commission

In 2018, in response to the National Clinical Care Commission Act (Public Law 115-80), the Secretary of Health and Human Services established the National Clinical Care Commission.²⁰ The Commission included 12 special government employees and 11 individuals representing relevant federal agencies, who collectively provided expertise in the prevention, care, and epidemiology of diabetes and its complications. The Commission was charged with evaluating and making recommendations to Congress and the Secretary of Health and Human Services regarding:

1. Federal programs of the Department of Health and Human Services that focus on preventing and reducing the incidence of complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases;

2. Current activities and gaps in federal efforts to support clinicians in providing integrated, high-quality care to individuals with the diseases and complications;
3. The improvement in, and improved coordination of, federal education and awareness activities related to the prevention and treatment of the diseases and complications, which may include the utilization of new and existing technologies;
4. Methods for outreach and dissemination of education and awareness materials that
 - a. Address the diseases and complications;
 - b. Are funded by the federal government; and
 - c. Are intended for health care professionals and the public; and
5. Whether there are opportunities for consolidation of inappropriately overlapping or duplicative federal programs related to the diseases and complications.

The National Clinical Care Commission's Approach to Its Charge

The National Clinical Care Commission's approach to its charge recognized that diabetes in the U.S. is not simply a health condition that requires medical care but also is a societal problem that requires a trans-sectoral approach to prevention and treatment. Accordingly, the Commission approached its duties using a framework that combines the Socioecological Model²¹ and the Chronic Care Model²² (see Figure 2).

The socioecological model highlights how societal factors, environmental exposures, community attributes, and group characteristics interact to influence the health of individuals. It is not possible to fully understand or improve health outcomes without taking into account all of these elements. Sectors of influence considered by the socioecological model include government, economic development, industry, labor, education, food systems, the environment, housing, transportation, and communication and marketing. Supportive environments at the community, worksite, school, and home levels also influence individual health. And individual factors, including psychosocial factors, stress, trauma, diet, physical activity, age, sex, and socioeconomic position further influence health.

Preventing and successfully treating diabetes is impossible if individuals do not have access to comprehensive, affordable, and high-quality health care. The Chronic Care Model identifies six categories of clinical practice change that can lead to improvements in health outcomes for people with diabetes. These elements are (1) organizational support, (2) clinical information systems, (3) delivery system design, (4) decision support, (5) self-management support, and (6) community resources.

Those elements that are common to both community and clinical settings include health

literacy, access to services and care, self-management support, organized peer support, and the negative impact of discrimination.

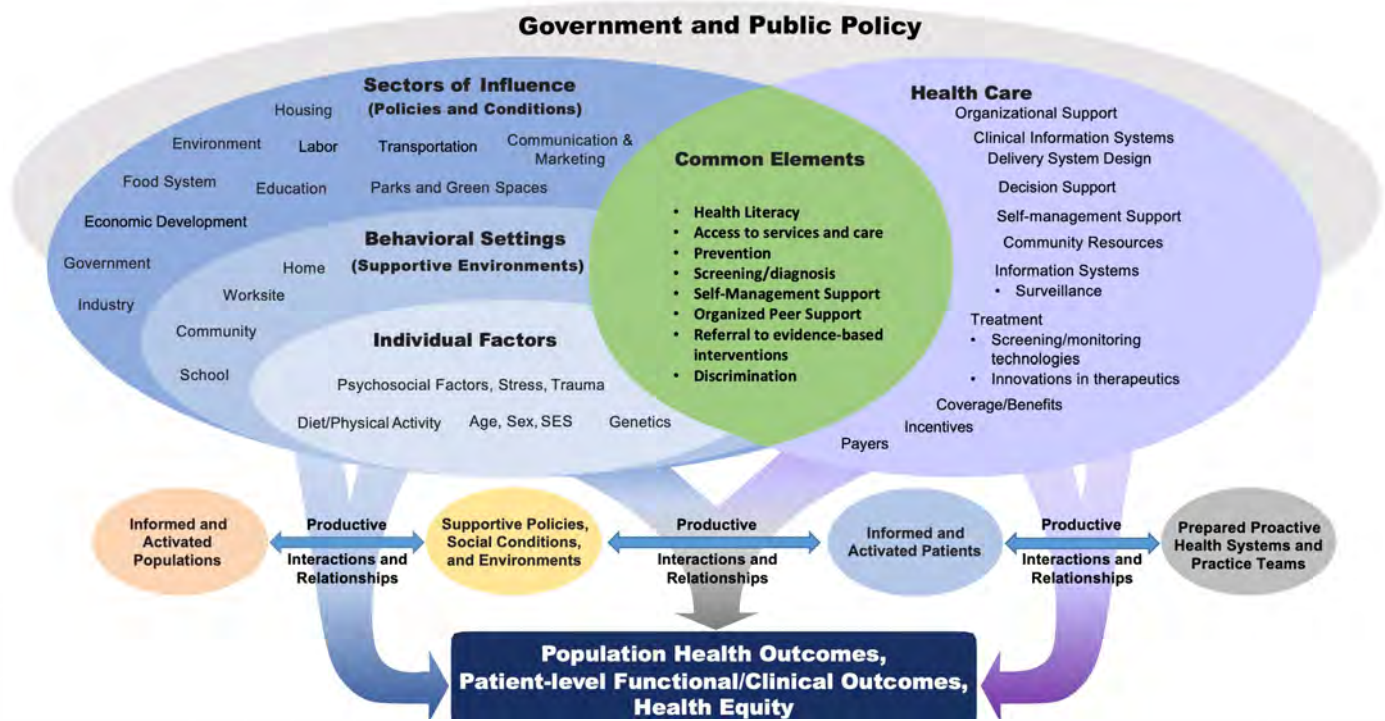


Figure 2. The National Clinical Care Commission Framework for Diabetes Prevention and Control: The Combined Socioecological and Chronic Care Model for Diabetes

The logic of the National Clinical Care Commission Framework is that diabetes can be prevented or controlled only through supportive policies, social conditions, and environments and by promoting more prepared, proactive health systems and practice teams that enable informed and activated patients. The intended outcomes of these structures and processes include improved clinical outcomes and quality of life for individuals at risk for or with diabetes; better diabetes-related population health; and greater diabetes-related health equity.

In the chapters that follow, the Commission first provides a set of overarching recommendations that address federal efforts to ensure coordination of federal policies and programs to improve the social and environmental conditions that influence diabetes risk and outcomes, promote access to health care, and advance health equity. The subsequent recommendations of the Commission are structured around the work of three subcommittees that have addressed (1) diabetes prevention and treatment through federal policies and programs that affect the general population; (2) diabetes prevention through

federal policies and programs that target individuals at high risk for type 2 diabetes; and (3) federal policies and programs that can improve the treatment and reduce the complications of diabetes. Each of these subcommittees also has addressed unmet research needs. Finally, the Commission provides a matrix that summarizes all of its recommendations, explicitly defining how, within its framework, the Commission has addressed each of the specific duties stated in its charge.

Chapter 2: Methods

To develop evidence-based, actionable recommendations to Congress and the Secretary of Health and Human Services (HHS), the National Clinical Care Commission formed three subcommittees and gathered information through a federal data call, a systematic literature search and review, stakeholder input, and public comments.

Commission Structure

Membership

The National Clinical Care Commission consisted of 23 members: 12 non-federal members representing diverse disciplines and views and 11 ex-officio federal members. The non-federal members included primary care physicians, clinical endocrinologists, non-physician health care professionals, clinical pharmacists, patient advocates, and public health experts. The federal members represented the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Indian Health Service, the Department of Veterans Affairs, the National Institutes of Health, the Food and Drug Administration, the Health Resources and Services Administration, the Department of Defense, the Department of Agriculture, and the Office of Minority Health. (See Appendix A: Commission Members).

Commission Chair and Subcommittees

At its first public meeting on October 31, 2018, the Commission elected a Chair and discussed potential focus areas to establish subcommittees. After the meeting, the Commission refined their focus areas and established four subcommittees.

- Prevention–General Population Subcommittee
- Prevention–Targeted Population Subcommittee
- Treatment and Complications Subcommittee
- Case Finding, Outreach, and Education Subcommittee

Commission members volunteered to participate in at least one of the subcommittees. Each subcommittee had two volunteer co-chairs: one public member and one federal Commission member (see Appendix B: Subcommittees).

As the subcommittees gathered information and prepared to develop draft recommendations, it became clear that the work of the Case Finding, Outreach, and

Education Subcommittee overlapped with the other three subcommittees. To reduce duplication, the Commission decided in May 2019 to dissolve the Case Finding, Outreach, and Education Subcommittee and address outreach- and education-related topics through the other three subcommittees. Members of the Case Finding, Outreach, and Education Subcommittee volunteered to join other subcommittees.

Information Gathering and Assessment

The Commission collected information on federal policies and programs relevant to diabetes through a formal data call, literature searches, key informant and stakeholder input, and public comments. The Commission also developed an overarching National Clinical Care Commission Framework for Diabetes Prevention and Control and reviewed relevant research that could inform their recommendations (see Figure 2, Chapter 1).

Each subcommittee developed a framing statement, identified priority focus areas, reviewed federal agencies' responses to the data call, sought clarifications and additional information from the agencies, consulted subject matter experts, and conducted literature searches. The subcommittees conducted regular meetings to hear stakeholder and expert presentations and to discuss progress.

Relevant Agencies

To meet its charge, the Commission reviewed relevant programs and policies of federal agencies and departments that deliver or pay for health care, conduct diabetes-related research, perform administrative roles that impact diabetes care, or support diabetes-related public health efforts. Recognizing that the diabetes epidemic in the U.S. is driven in part by socioeconomic and environmental factors, the Commission also obtained information from non-health agencies whose policies and programs affect diabetes risk. The Commission considered the policies and programs of the following agencies relevant to diabetes risk, prevention, and treatment.

Health Agencies

- Administration for Children and Families
- Agency for Healthcare Research and Quality
- Centers for Disease Control and Prevention
- Centers for Medicare & Medicaid Services
- Department of Veterans Affairs
- Food and Drug Administration
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health
- Office of Minority Health

Non-Health Agencies

- Department of Agriculture
- Department of Defense
- Department of Education
- Department of Housing and Urban Development
- Department of Labor
- Department of Transportation
- Department of Treasury
- Environmental Protection Agency
- Federal Bureau of Prisons
- Federal Communications Commission
- Federal Trade Commission

Federal Data Call and Presentations

To gather information on federal policies, programs, and research relevant to diabetes, the Commission developed a survey to systematically collect information. The data call was distributed at the end of 2019 to the following agencies and departments.

- Centers for Medicare & Medicaid Services
- Centers for Disease Control and Prevention
- National Institutes of Health
- Food and Drug Administration
- Office of Minority Health
- Agency for Healthcare Research and Quality
- Health Resources and Services Agency
- Indian Health Service
- Federal Bureau of Prisons
- Department of Agriculture
- Department of Veterans Affairs
- Department of Defense

All of the agencies and departments that received the data call provided responses in the first quarter of 2020. The subcommittees reviewed the agencies' responses. When needed, the subcommittees sought clarifications and requested additional information from the agencies.

The subcommittees also reached out to relevant agencies and departments that did not receive the data call. Agencies and departments that responded to the Commission's request and provided information through presentations and written communications include the Administration for Children and Families, the Environmental Protection Agency, the Federal Communications Commission, the Federal Trade Commission, and the Department of Transportation.

The information gathered through the data call, subsequent communications, and presentations helped the subcommittees formulate their recommendations.

Literature Search and Review

Each subcommittee developed a list of questions to guide literature searches relevant to their focus areas. Librarians at NIH conducted a series of literature searches based on these questions and identified an extensive list of peer-reviewed publications. Subcommittees reviewed the publications relevant to their work and used the findings to assess the federal programs and develop recommendations.

Stakeholder Input

The subcommittees identified several stakeholder organizations whose missions overlapped with the Commission's charges. Input from these stakeholders was sought through conference calls and written communication. Some stakeholders also provided comment at the Commission's public meetings and in response to Federal Register Notices. In May 2021, the Commission sent their draft recommendations to all stakeholders with whom subcommittees had interacted for their review and comment. The subcommittees reviewed and discussed stakeholders' written comments, and addressed them in their recommendations or in the report, when appropriate.

Key Informant Presentations

The subcommittees also consulted key informants whose subject matter expertise was relevant to the work of the subcommittees. From 2019 to May 2021, the Commission consulted more than 50 experts through conference calls and written communication.

Public Comments

In compliance with Federal Advisory Committee Act (FACA) requirements, the Commission provided the public with opportunities to provide comments through several channels.

- Verbal comments at Commission public meetings: At Commission public meetings, time was allocated for the public to provide comments. Each individual had three minutes to provide oral comments.
- Written comments submitted prior to Commission's public meetings: Prior to each Commission meeting, the public was invited to send written comments to the Commission. This mechanism provided an opportunity for the public to share their views and insights without attending the meeting.
- Email comments: The public had an opportunity to send written comments to the Commission at OHQ@hhs.gov.
- Formal solicitation of public comment: The Commission sought public comment through Federal Register Notices. Responses were submitted through [regulations.gov](https://www.regulations.gov).

The subcommittees reviewed all the public comments received and addressed them, when appropriate, in their report and recommendations.

Work Process

The subcommittees met regularly and used an iterative process to refine priority focus areas; discuss ideas for recommendations; and review, discuss, and revise draft recommendations. The subcommittees reported their progress, shared their findings, and presented draft recommendations at the Commission's public meetings. Commission members asked questions, provided input, and suggested changes to refine the recommendations.

The subcommittees presented their recommendations at the Commission's public meeting on June 22, 2021. Commission members voted on the recommendations and formed writing groups to write its final report to Congress.

On September 8, 2021, the Commission met to review and vote on their final recommendations and report to Congress and the HHS Secretary. After suggesting minor editorial revisions, Commission members unanimously voted to approve the final report and recommendations.

Chapter 3: Foundational Recommendations to Address Diabetes

Background

The charge to the National Clinical Care Commission is to evaluate and make recommendations regarding improvements to the coordination and leveraging of programs and policies within HHS and other federal agencies to improve the awareness, prevention, and treatment of diabetes and its complications. Historically, the prevention and treatment of diabetes have been considered to be medical problems requiring medical interventions. However, it is clear that social determinants of health, lack of federal trans-agency collaboration, and barriers to accessing care also impact diabetes prevention and treatment. Accordingly, the National Clinical Care Commission formulated recommendations to address social and environmental factors relevant to diabetes, trans-agency collaboration, access to health care, and health equity.

Recommendations

Focus Area 1. Address Social Determinants of Health and Improve Trans-Agency Collaboration

Background

In the U.S., type 2 diabetes is more common and diabetes is more consequential among communities of color; those who live in rural areas; and those with less education, lower incomes, and lower health literacy.² As early as 2012, the American Diabetes Association (ADA), the Endocrine Society, the American College of Physicians, the American Academy of Pediatrics, the Society of General Internal Medicine, and the National Academy of Medicine published statements and issued calls to action to address social determinants of health (SDOH) at the individual, organizational, and policy levels.²¹ In 2021, ADA also published a scientific review describing the associations between SDOH and diabetes risk and outcomes.¹⁵ That review focused on socioeconomic status, health literacy, the food environment and food insecurity, and neighborhood and physical environments, among other topics.

Socioeconomic position

Education, income, and occupation are strong predictors of the onset and progression of type 2 diabetes. In the U.S., the age-adjusted prevalence of diagnosed type 2 diabetes is 75% higher for those with less than a high school education and 33% higher for those with a high school education compared to those with more than a high school education. Having a college education or more is associated with the lowest risk of type 2 diabetes. Compared to those with high incomes, the prevalence of diabetes is 100% higher for those classified as poor, 74% higher for those classified as near poor, and 40% higher for those classified as middle income. Similarly, occupation as assessed by employment status (employed vs. unemployed), job stability, job type, and working conditions shows graded associations with diabetes prevalence and complications. Rural areas have higher age-adjusted prevalences of type 2 diabetes than urban areas, and adults with diabetes in rural areas have had less improvement in cardiovascular risk factors and have less access to preventive services than their urban counterparts.²³ Many of these factors have been associated with a higher risk of progression to type 2 diabetes among individuals with prediabetes.

Health literacy

Health literacy is defined as the degree to which individuals can find, understand, and use services to inform health-related decisions and actions.^{24,25} Nearly half of individuals living with diabetes have limited health literacy. Individuals with type 2 diabetes who are beneficiaries of federally-funded programs, including Medicare and Medicaid, have higher rates of limited health literacy, as do racial and ethnic minority groups disproportionately affected by diabetes, and those with limited educational attainment.^{26,27} Individuals with limited health literacy have less awareness of evidence-based strategies to prevent diabetes and, among those with diabetes, less awareness of and ability to implement evidence-based strategies to manage diabetes and prevent its complications.²⁸ Limited health literacy has been shown to independently contribute to type 2 diabetes incidence. Among individuals with diabetes, it is also associated with worse diabetes control and higher complication rates.

The food environment

Key dimensions of the food environment include food availability, accessibility, affordability, and quality, as well as the marketing and commercial influences that drive consumption. The food environment influences people's food and beverage choices, diet quality, and nutritional status. Marginalized communities are more likely to have poor access to healthy foods but abundant access to energy-dense foods that are low in nutritional quality. They are also more likely to be exposed to the marketing of such foods. Greater access to healthy food outlets, higher availability of grocery stores and full-service restaurants, and lower availability of convenience stores and fast-food restaurants are associated with lower rates of type 2 diabetes.¹⁵

Food insecurity

Food insecurity^{29,30} (the limited or uncertain ability to reliably access safe and nutritious food) is now recognized as a common and potent risk factor for developing type 2 diabetes and its complications and is a contributor to socioeconomic, racial, and ethnic disparities in diabetes outcomes. Food insecurity compels individuals and families to consume low-cost, carbohydrates- and energy-dense (high calorie) foods that increase the risk of type 2 diabetes and make the clinical management of diabetes more challenging. Food insecurity further forces individuals with diabetes to make difficult choices among paying for food, housing, monitoring devices, medicines, and medical care. Finally, populations with food insecurity may be predisposed to transmitting increased risk of type 2 diabetes across generations, in part through abnormal metabolic programming that occurs in the fetus of the pregnant woman with food insecurity before birth.

The built environment

The neighborhoods and physical environments in which people live and work such as buildings, streets, and open spaces have major impacts on their health. Neighborhood walkability and access to green spaces are associated with physical activity and diabetes outcomes.³¹⁻³⁴ Residential segregation by socioeconomic position, race, and ethnicity produces patterns of unequal resource distribution that create and perpetuate health inequities.

Housing instability refers to a spectrum of conditions that range from homelessness, suffering evictions and frequent moves, having trouble paying rent, and living in crowded conditions. Housing instability makes it difficult to attend to preventive services and self-care, leading to worse prevention and control of diabetes and a higher likelihood of complications.³⁵⁻³⁷ In 2020, over 560,000 people in the U.S. were homeless. African Americans accounted for 40% of people experiencing homelessness and Hispanics or Latinos comprised 22% of the homeless population.³⁸ Among individuals with diabetes seen in community health centers, over one-third reported housing instability. In the Veterans Affairs (VA) health care system, veterans with diabetes experiencing homelessness had significantly worse glucose control than those who were housed.³⁷

The ambient environment

Toxic environmental exposures are also associated with diabetes risk. Exposures can be naturally occurring (for example, arsenic in water) or introduced into the environment through human activity (for example, secondhand smoke, air pollution, industrial waste, exposure to endocrine-disrupting chemicals).³⁹⁻⁴¹ Marginalized communities in the U.S. are disproportionately exposed to environmental agents associated with diabetes.⁴²⁻⁴⁴ Explanatory factors include closer proximity of underserved neighborhoods to pollution sources, poor enforcement of regulations, and inadequate responses to community

complaints. Industrial pollution of private wells is an important source of water contamination in Native American Indian communities. Both food packaging from canned foods and the release of chemicals from plastic packaging are important sources of exposure to endocrine-disrupting chemicals linked to diabetes.⁴⁰

Rationale

The role of non-health federal agencies

To prevent and control diabetes, and to reduce health disparities, changes need to take place in the social and environmental contexts in which U.S. residents live, learn, work, and play. The fact that the social and environmental factors fuel the diabetes epidemic make many patients and clinicians feel unsupported in their attempts to prevent and treat diabetes. Implementing changes in federal agencies that are accountable for health care concerns is not sufficient to address diabetes. Federal agencies that are considered to be “non-health”-focused but have a role in shaping the social and environmental contexts must also be involved. These include agencies responsible for domains as varied as food and agriculture, education, housing, transportation, trade and commerce, and food and drugs.

While most developed nations affirmatively address diabetes through trans-sectoral governmental activities, the U.S. has not. The U.S. lacks adequate structures, policies, and practices to coordinate strategic planning across health and non-health agencies. What little work has been done to facilitate trans-agency action around diabetes prevention and treatment has been of a pilot nature and lacks scale. There is an untapped opportunity to better leverage the efforts of federal agencies, and increase coordination among them to achieve the outcomes called for in the National Clinical Care Commission charter.

Policies and programs emanating from non-health-related federal agencies have often been enacted without considering their impact on diabetes. To date, the federal government has not implemented a “Health-in-All Policies” (HiAP) approach to ensure coordination among non-health- and health-related federal agencies whose work is relevant to diabetes. HiAP is an evidence-based collaborative approach that articulates health considerations and integrates them into policies across sectors to improve the health of all people and communities. HiAP can promote diabetes prevention and control by influencing policies and practices of non-health agencies.

Health Impact Assessments (HIAs) are a widely accepted and evidence-based approach to promote HiAP. HIAs use an array of data sources, analytic methods, and input to determine the potential effects of proposed “non-health” policies, plans, programs, or projects on the health of the population and the distribution of health effects across the population. HIAs also provide recommendations on monitoring, managing, and mitigating adverse health

effects. Despite recommendations from the Centers for Disease Control and Prevention (CDC) that state and local governments adopt a HiAP approach, there has been no targeted or sustained effort to advance a HiAP agenda or employ HIAs at the federal level, either within or across federal agencies. There is no mandate that HIAs be considered at the legislative stage or that federal agencies adopt a HiAP process at the rulemaking stage. As a result, many non-health-related federal agencies may implement policies and programs that are antithetical to the missions and objectives of health-related federal agencies. The absence of a HiAP approach and the lack of interagency coordination represent important and costly gaps in federal efforts to delay, prevent, and treat diabetes. The federal government can play a larger role in preventing and controlling diabetes by ensuring that non-health-related federal agencies conduct HIAs and that non-health- and health-related federal agencies establish methodologies for HIAs; receive the resources to generate HIAs; determine the mechanisms to adjudicate and implement HIAs; and support, develop, and train the workforce needed to carry out HIAs.

Currently there is no federal entity that is charged with leading trans-agency efforts to better prevent and control diabetes. Originally mandated by Public Law 93-354⁴⁵ and established in 1975,⁴⁶ the Diabetes Mellitus Interagency Coordinating Committee (DMICC) facilitates communication, collaboration, and coordination on diabetes-related projects among federal agencies and helps to ensure that activities are not duplicated. DMICC is chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and includes select agencies from HHS, but only three non-HHS agencies and departments (the Veterans Health Administration, the U.S. Department of Agriculture [USDA], and the U.S. Department of Defense [DoD]).⁴⁶ While DMICC has fostered diabetes education and biomedical, clinical, and translational research, it lacks the statutory authority to develop or implement a national diabetes strategy or an action plan that leverages and coordinates the work of all relevant health- and non-health-related federal departments and agencies.

Recommendation 3.1: The National Clinical Care Commission recommends the creation of the Office of National Diabetes Policy (ONDP) to develop and implement a national diabetes strategy that leverages and coordinates work across federal agencies and departments to positively change the social and environmental conditions that are promoting the type 2 diabetes epidemic. The National Clinical Care Commission further recommends that the ONDP be established at a level above the U.S. Department of Health and Human Services (HHS) and be provided with funding to facilitate its effectiveness and accountability.

- **3.1a. The ONDP should include, but not be limited to, departments and agencies outlined in the National Clinical Care Commission Report to Congress, including the U.S. Departments of Agriculture, the U.S. Department of Transportation, the U.S. Department of Education, the U.S. Department**

of Justice, the U.S. Department of Defense, the U.S. Department of Labor, the U.S. Department of the Treasury, the Federal Trade Commission, the Federal Communications Commission, the U.S. Department of Housing and Urban Development, the Federal Bureau of Prisons, the U.S. Environmental Protection Agency, the Bureau of Indian Education, the Bureau of Indian Affairs, the U.S. Department of Veterans Affairs, and the U.S. Department of Health and Human Services, among others.

- **3.1b.** ONDP’s responsibilities should include: (1) overseeing the implementation and monitoring of the National Clinical Care Commission’s recommendations; (2) ensuring action, collaboration, and coordination among federal agencies with respect to trans-agency approaches to delaying, preventing, and controlling diabetes; (3) making recommendations to the executive and legislative branches regarding actions they can take to delay, prevent, and better treat diabetes; (4) advancing a health-in-all-policies (HiAP) agenda with respect to diabetes; and (5) providing resources and employing Health Impact Assessments (HIAs) for relevant policies across non-health departments and agencies.
- **3.1c.** HHS should also establish an entity within the Office of the Secretary of HHS to (1) coordinate work across HHS to better prevent and treat diabetes; and (2) serve in the ONDP to foster broad, trans-agency collaborative work between HHS and non-HHS federal agencies aimed at positively changing the social and environmental contexts that are driving the type 2 diabetes epidemic.

Focus Area 2. Ensure Access to Health Care

Background

Access to health care refers to the degree to which individuals and groups can obtain needed services from the health care system. In the U.S., health insurance coverage impacts both individuals’ ability to gain access to care and their health outcomes. In people at risk for or with diabetes, access to health care is critical to reducing the incidence of diabetes, ensuring the early detection of diabetes, reducing the adverse health effects of diabetes, and prolonging life.⁴⁷ As an example, adults with diabetes 65 years of age and older with Medicare insurance have improved survival and fewer health disparities than adults with diabetes less than 65 years of age without Medicare.⁴⁸

In the U.S., health insurance is pluralistic. Historically, its foundation was employer-based coverage for working families. Most working-age adults obtained health insurance coverage for themselves and their dependents as a benefit of employment. After 1965, Medicaid and State Children’s Health Insurance Programs covered the poor, and Medicare covered

virtually all Americans 65 years of age and older and younger people who were medically disabled. This patchwork system left substantial numbers of Americans uninsured, including employed workers whose employers did not provide health insurance coverage, the near poor who earned too much to be eligible for Medicaid, and the poor who did not meet Medicaid coverage requirements. Many, but not all, of these gaps in access to health insurance were addressed by the Affordable Care Act (ACA).

The ACA made its intended impact on health insurance coverage among people with diabetes. From 2009 to 2016, health insurance coverage for U.S. adults 18 to 64 years of age with diabetes improved, with 770,000 more adults gaining health insurance.⁴⁹ Insurance coverage improved for nearly all demographic subgroups with diabetes including men, non-Hispanic whites, non-Hispanic Blacks, and Hispanics; those who were married; those with less than as well as those with more than a high school education; and those with family incomes less than \$35,000. Coverage increased both among people treated with diabetes medications and those with diabetes complications.⁴⁹ Insurance coverage for adults 26 to 64 years of age increased from 85% to 95% for those with diagnosed diabetes, 75% to 92% for those with undiagnosed diabetes. Among those with diabetes and low incomes, insurance coverage leapt from 67% to 94%.⁵⁰ For those 65 years of age and older, coverage remained stable at 99.5%, indicating the ongoing success of the Medicare program.⁴⁹ Analyses of health insurance coverage in the general population eight years after the ACA confirmed that fewer Americans were uninsured and that coverage gaps in health insurance were shorter.⁵¹ Nevertheless, in 2019, 31 million people or 9.5% of the population in the U.S. were uninsured.⁵²

Health insurance coverage affects an individual's ability to achieve optimal health outcomes. Both poor diabetes control (as assessed by HbA1c >9%) and poor blood pressure control (as assessed by blood pressure \geq 140/90 mmHg) are more common among the uninsured than among insured persons with diabetes.⁵³ Compared to insured people, uninsured people with diabetes are more than twice as likely to have HbA1c >9%. Improvements in health outcomes, including survival and reductions in health disparities, have also been demonstrated for older adults with diabetes as a result of entering the Medicare program.⁴⁸

Rationale

Despite gains in insurance, income-related disparities in health care access and outcomes have widened over time.⁵⁴ Compared to adults with higher incomes, U.S. adults with lower incomes have reported having skipped 23% more needed doctor visits, tests, treatments, or prescription medicines because of cost.⁵⁵ Nonadherence due to costs has been reported in 20% to 40% of people with diabetes. For those with self-reported financial insecurity, the nonadherence rate is even higher (60%).⁵⁶

The COVID-19 pandemic has highlighted additional problems with access to care in the U.S. During the early months of the pandemic, 21.9 million Americans lost their jobs or left the workforce and 5.4 million of them became uninsured. Although some people who lost their employer-sponsored health insurance were able to receive insurance through state-based exchanges, the federal government initially declined to open its marketplace to offer special enrollment periods and declined to account for income changes to provide subsidies. These changes resulted in many newly unemployed individuals being unable to purchase health insurance through the marketplace.

The COVID-19 pandemic has also highlighted problems with the Medicaid program.⁵⁷ To date, 12 states have elected not to expand Medicaid, creating a “coverage gap” for adults who have incomes above their states’ eligibility for Medicaid but below the level of income making them eligible for tax credits to purchase health insurance through the marketplace.⁵⁸ In 2019, more than 2.2 million poor adults in the U.S. fell into the insurance coverage gap.⁵⁸ Ninety-seven percent of them lived in the Southern U.S.: 35% in Texas, 19% in Florida, 12% in Georgia, and 10% in North Carolina.⁵⁸ Low-income individuals in the coverage gap are more likely to be Black.^{58, 59}

Taken together, these findings highlight the importance of access to affordable health care for people with or at risk of diabetes. Great strides have been made under ACA, but important gaps remain. To address those gaps, access to employer-sponsored health insurance coverage must be improved; the coverage and the affordability of individual marketplace health insurance plans must be improved; and Medicaid must be expanded to all 50 states.

Preventing and successfully treating diabetes is impossible if individuals do not have access to comprehensive, high-quality, and affordable health care. Access to health care is essential to health equity and is foundational to improving health outcomes for people with or at risk for diabetes.

Recommendation 3.2: The National Clinical Care Commission recommends that federal policies and programs be designed to ensure that all people at risk for and with diabetes have access to comprehensive, high-quality, and affordable health care and that no one at risk for or with diabetes who needs health care cannot get it because of cost.

Focus Area 3. Promote Health Equity in Diabetes

Rationale

Although addressing the social and environmental conditions, improving trans-agency collaboration, and providing access to health care for people at risk for or with diabetes may help prevent and control diabetes, attention must also be paid to the ways in which policies and programs can be leveraged and coordinated to promote diabetes-related health equity. Indeed, some federal policies and programs may inadvertently increase disparities. The National Clinical Care Commission recommends that current and new federal programs and policies affecting people with or at risk for diabetes be carefully reviewed to determine their potential effects on health disparities.

Policies governing Diabetes Self-Management Training (DSMT) for Medicare beneficiaries provide an example of federal policies unintentionally exacerbating health disparities. Diabetes is primarily managed by individuals with diabetes, their families, and caregivers, and exposure to DSMT can help them make better care decisions.⁶⁰ Unfortunately, because federal policies present barriers to the availability and appropriate use of DSMT, disparities based on race (lower for non-whites), health status (lower for those with comorbidities)⁶¹, and in rural residence (limited access to accredited programs) have emerged. Indeed, 62% of rural counties lack any DSMT programs.⁶²

On January 20, 2021, President Joe Biden issued an Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.⁶³ The National Clinical Care Commission supports this Presidential action and recommends additional actions that are consistent with that Executive Order.

Recommendation 3.3: The National Clinical Care Commission recommends that achieving health equity be a component of all federal policies and programs that affect people at risk for or with diabetes. Specifically, the National Clinical Care Commission recommends:

- **3.3a. Federal agencies consider and evaluate the impact on health disparities of all new, all revised, and selected existing policies and programs that affect diabetes prevention, diabetes, and the complications of diabetes.**
- **3.3b. Federal agencies ensure the collection and use of data to assess the impact of those policies and programs on health disparities and modify the policies and/or programs as needed to reduce health disparities.**

Chapter 4: Population-Level Diabetes Prevention and Control

Background

Programs directed by non-healthcare-related federal agencies and departments impact diabetes in the U.S. Transportation, housing, agriculture, commerce, and other domains of government affect diabetes risk and outcomes. This is true for those living with diabetes who are at risk for developing complications; those with prediabetes who are at risk for developing type 2 diabetes; and those in the general public, a proportion of whom are at risk of developing prediabetes or diabetes over their lifetimes. Ensuring that policies and practices of federal agencies and departments, many of which have a broad, population-wide reach, do not contribute to the diabetes epidemic but instead are designed to prevent and control diabetes, is a clinical and public health priority.

Historically, the clinical care of individuals with prediabetes and diabetes has involved a combination of lifestyle counseling, patient self-management education, and therapeutics (medications). However, a majority of Americans with prediabetes and diabetes have inadequate resources and/or live in unsupportive environments with respect to diabetes. This has undermined clinicians' ability to prevent and manage diabetes and prevent its complications.^{15, 64-66} In fact, research has shown that many clinicians report high levels of frustration and clinical "burnout" when working in settings and systems that do not account for the social, material, and psychological needs of patients with diabetes.⁶⁷ As a result, the standard for high-quality, diabetes clinical care has evolved.⁶⁸ Contemporary diabetes care now involves a comprehensive approach that combines the "traditional" model of care (lifestyle counseling and medications) with an "integrated, patient-centered model" of care that includes robust clinic-community linkages. These clinic-community linkages involve referrals to programs, many of which are funded and/or directed by federal agencies, that offer basic goods and services. Examples include programs that provide assistance with nutrition, housing, and transportation, among others. The underlying rationale for this comprehensive, integrated model is that connecting individuals to such resources will help clinicians and patients better prevent and control diabetes and its complications.

Implementing integrated models of diabetes clinical care that extend beyond the walls of the clinic and link patients to effective community resources and programs can improve clinical outcomes of people with diabetes and reduce costs.⁶⁹⁻⁷¹ The American Diabetes Association, the National Academy of Medicine (NAM), NIH, CDC, and the Centers for Medicare & Medicaid Services (CMS) all endorse this integrated model of care, with the

latter—through its Innovation Center—supporting the Accountable Health Communities Program. However, to date, there has been no formal assessment of whether such federal programs help prevent diabetes and/or its complications, or whether they meet the needs of individuals with prediabetes or diabetes. Taken together, such individuals represent nearly half of U.S. adults. Moreover, they represent roughly two-thirds of all U.S. adults eligible to receive any form of public assistance.

The National Clinical Care Commission determined that it is critical to assess how federal programs (including health and non-health-related programs) that influence the social and environmental conditions experienced by individuals at risk for or with diabetes and its complications can be designed, leveraged, and coordinated to enable such an integrated model of care to achieve its objectives. Doing so will not only better support clinicians caring for individuals at risk for or with diabetes, but also will increase the return on investment of federal expenditures, by ensuring that the design of non-health-related federal programs (for example, the Supplemental Nutrition Assistance Program [SNAP], a USDA program) can enhance the efficacy of federal health care programs (for example, Medicare, Medicaid, and HHS programs). Many of the recommendations made by the National Clinical Care Commission Prevention—General Population Subcommittee are intended to ensure that clinicians can provide high-quality, integrated care, and that their patients can successfully prevent or self-manage diabetes.

One of the National Clinical Care Commission’s specific duties is to make recommendations to improve federal education, awareness, and dissemination activities related to the prevention and treatment of diabetes and its complications. Numerous studies have demonstrated that the health literacy of a large segment of U.S. adults is inadequate. In fact, nearly half of individuals living with diabetes have limited health literacy. Individuals with diabetes who are beneficiaries of federally-funded programs such as Medicare and Medicaid have even higher rates of limited health literacy, as do populations disproportionately affected by type 2 diabetes, including certain racial and ethnic minority subgroups and those with limited education.^{26, 27} Individuals with limited health literacy have less awareness of evidence-based strategies to prevent diabetes and, among those with diabetes, less awareness of evidence-based strategies to successfully manage diabetes and prevent its complications. As one example, limited health literacy has been found to be the strongest independent predictor of the consumption of sugar-sweetened beverages, driver of type 2 diabetes risk.²⁸ Comparing those with the lowest to the highest health literacy demonstrates a difference in intake of 240 calories per day from sugar-sweetened beverages—equivalent to one daily 20 oz of a sugar-sweetened soda. In addition, studies have shown that clinicians often struggle when attempting to prevent and manage diabetes for their patients with limited health literacy and report that their patients need additional community-level support to enable effective clinical care.⁷² A number of federal agencies support and direct programs and engage in activities that can influence public

awareness related to diabetes prevention and control. These include CDC, NIH, the Food and Drug Administration (FDA), USDA, and FTC, among others. Many of the Commission's recommendations included in this chapter relate to the coordination and leveraging of the work of these federal agencies and departments to promote education and greater awareness of diabetes prevention and care.

Recommendations

Focus Area 1. Modernize USDA's Supplemental Nutrition Assistance Program

Background and Rationale

Food insecurity and insufficiency increase the risk of developing diabetes, contribute to difficulty^{29, 73, 74} managing diabetes,⁷⁵ and lead to costly and disabling complications.⁷⁵ The relationship between food insecurity³⁰ and diabetes operates through at least four mechanisms: poor dietary quality, cycles of bingeing and fasting, stress pathways, and competing demands leading to poor self-management of diabetes. The USDA SNAP program provides benefits to supplement the food budget of income-eligible individuals and households (approximately 40 million people per year) so they can purchase food and move towards self-sufficiency.^{76, 77} SNAP is a valuable program for reducing food insecurity, but its impacts on diet quality⁷⁸ and diabetes risk have not been optimized. Healthier, nutrient-rich foods often cost more than foods that are energy dense (high calorie) and have lower nutritional value. SNAP has been less successful in providing "nutrition security," a state that encompasses both food security and nutrient content that promotes health.^{79, 80} SNAP benefit recipients often have to stretch their benefit allotments by purchasing lower-cost, less healthy food items,⁸¹ sacrificing nutrition quality and elevating their risk for obesity, diabetes, or diabetes complications, as well as other nutrition-related conditions.

There is substantial overlap between eligibility for SNAP and eligibility for Medicaid and Medicare. In part because of the higher rates of food insecurity among people with lower incomes and in older age groups, diabetes and prediabetes are common in Medicaid and Medicare beneficiaries.⁸²⁻⁸⁴ Efforts to prevent diabetes and diabetes complications in SNAP beneficiaries will provide health benefits for these populations, and yield savings for Medicare and Medicaid.⁸⁵

The National Clinical Care Commission has identified four domains of the SNAP program that need to be addressed to ensure that the vital nutrition assistance that it provides not only does not contribute to diabetes but also prevents diabetes and/or its complications. These include (1) improving dietary quality; (2) expanding individual education efforts for diabetes prevention and catalyzing systems and environmental change to support dietary

behavior change; (3) updating the benefit amount; and (4) expanding awareness and accessibility of the program. The USDA has begun to address some of these domains; enhancing these efforts would help reduce the burden of diabetes and its complications.

Improving dietary quality

SNAP participants currently consume fewer fruits and vegetables and more added sugars than recommended in diets that can prevent and manage diabetes.^{79, 86} Through the Farm Bill, USDA funded a series of healthy food incentive pilot programs, whose intentions are to help SNAP participants purchase healthier foods (often more costly), especially fruits and vegetables. These incentive pilots are currently distributed via small grants administered by USDA.⁸⁷ Rigorous evaluations of these initiatives have consistently shown benefits in improving dietary quality.^{88, 89} The Gus Schumacher Nutrition Incentive Program (GusNIP), formerly known as the Food Insecurity Nutrition Incentives (FINI) Program, is one such promising USDA program that could benefit all SNAP participants and help prevent and control diabetes if implemented program-wide. Additionally, sugar-sweetened beverages are one of the main sources of added sugars in U.S. diets, and especially among SNAP recipients.⁸⁶ Sugar-sweetened beverages contain excess calories, have limited to no nutritional value,⁹⁰ and contribute to type 2 diabetes and diabetes complications. To help ensure that SNAP benefits are used to assist in achieving nutrition security and do not contribute to diabetes or diabetes complications, many experts have recommended removing sugar-sweetened beverages as an allowable SNAP purchase because of the health and economic benefits that would accrue.⁹¹⁻⁹⁴ It has been estimated that, over a ten-year period, eliminating the use of SNAP subsidies to purchase sugar-sweetened beverages would prevent 240,000 cases of type 2 diabetes among SNAP beneficiaries.⁹¹

Expanding educational efforts

To achieve maximum benefit from these healthy incentives and purchase exclusions, greater outreach to and education of SNAP participants would be required. SNAP-Education (SNAP-Ed)⁹⁵ is a promising program that could be amplified to help SNAP participants better achieve food and nutrition security and reduce nutrition-related diabetes risks.

Increasing the benefit

SNAP benefit allotments are determined based on the USDA Thrifty Food Plan (TFP). Many analyses have found that the food procurement and preparation requirements and expectations associated with the TFP are unrealistic and inadequate for providing sufficient funds for most SNAP participants.^{96, 97} In addition, there had been a lag in updating the TFP beyond the required cost-of-living adjustments, making it an even more inadequate basis for calculating SNAP benefit allotments.⁹⁸ In early 2021, the USDA announced that SNAP benefits were inadequate for most participants and began a data-driven reevaluation of the TFP to determine the costs associated with a basic healthy diet and to ensure nutrition

security. On August 16, 2021, USDA released the results of this reevaluation, which determined that the cost of a nutritious, practical, cost-effective diet is 21% higher than the benefit determined based on the current TFP. Based on the findings, in FY 2022 (beginning on October 1, 2021) the average SNAP benefit—excluding additional funds provided as part of the COVID-19 pandemic relief—will increase by \$36.24 per person, per month (an increase of more than 25%).⁹⁹

Expanding awareness and accessibility

Challenges associated with complexity, technology, numeracy, and language proficiency, have kept many SNAP-eligible individuals or families from receiving SNAP benefits and have resulted in disparities in receipt of SNAP benefits.^{100, 101} State-level innovation is needed to overcome these barriers at a local level. These efforts should include but not be limited to streamlining the application process, increasing public awareness of the benefit and how to access SNAP in various languages, increasing the number of sites that accept SNAP, and helping stores in rural areas and “food deserts” meet minimum stocking requirements.

Recommendation 4.1: The National Clinical Care Commission recommends that the USDA SNAP program be enhanced to both reduce food insecurity and improve nutrition sufficiency, both of which will help prevent type 2 diabetes and diabetes complications.

- **4.1a. Implement SNAP-wide fruits and vegetables incentives demonstrated to be effective by the Gus Schumacher Nutrition Incentive Program (GusNIP) for all beneficiaries, by providing at least a 30% incentive on the purchase of fruits and vegetables to improve dietary quality.**
- **4.1b. Eliminate sugar-sweetened beverages from allowable SNAP purchases.**
- **4.1c. Improve and expand SNAP-Education to provide diabetes and nutrition education and awareness programs for beneficiaries to increase fruit and vegetable consumption, reduce added sugars consumption (especially sugar-sweetened beverages), and increase media/marketing literacy, as well as increase its support for policy, systems, and environmental approaches to improve dietary quality.**
- **4.1d. Incentivize testing and implementation of innovative state-level policies, practices, and programs to enhance the access to and receipt of SNAP benefits by eligible individuals and households, and to reduce geographic, racial, ethnic, and linguistic disparities in SNAP enrollment and retention.**

- **4.1e. Sustain efforts to ensure that SNAP benefit allotments are adequate to allow for both food and nutrition security to help prevent and manage diabetes among beneficiaries and implement a process to regularly assess and update the adequacy of SNAP benefits with respect to lowering diabetes risk and managing diabetes.**

Focus Area 2. Improve Nutrition for Children Through USDA non-SNAP Nutrition Assistance Programs and Related Agency Efforts

Background and Rationale

Type 2 diabetes was once considered a disease of older adults. Unfortunately, the incidence of type 2 diabetes is now rapidly increasing in children and adolescents, especially children from low-income families and children of color.¹⁰² Rates of gestational diabetes (diabetes during pregnancy) also are on the rise.¹⁰³ USDA, with its \$146B annual budget, provides nutritional assistance through programs besides SNAP, with a focus on nutrition assistance during pregnancy and early childhood. These programs not only reduce food insecurity but have the potential to prevent and control type 2 diabetes, if redesigned with those objectives in mind.

The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) serves approximately 7 million participants every month. Since revising its food package in 2009 to restrict purchases of unhealthy foods, WIC has been shown to reduce excess weight gain in pregnant and post-partum women,¹⁰⁴ improve birth weight of infants,¹⁰⁵ and reduce childhood obesity.¹⁰⁶ All of these lower the risk of type 2 diabetes. However, this prescriptive food package is at risk of being weakened. Furthermore, inadequate technology infrastructure has limited the efficacy of WIC with respect to diabetes prevention. WIC providers have made technological advances by implementing electronic-benefit transfer (EBT), or e-WIC transactions nationwide. However, the WIC certification process continues to pose challenges for applicants and participants. These challenges could be addressed by allowing remote certification; integrating new projects into WIC sites' computer networks; and enabling innovations such as web-based participant portals, prescreening tools, text-messaging features, and additional transaction models such as online purchasing mobile payments. In addition, as part of its mission to safeguard the health of low-income women, infants, and children, WIC plays a critical role in promoting breastfeeding as the optimal infant feeding choice and has demonstrated effectiveness¹⁰⁷ in increasing breastfeeding rates^{108, 109} among women who utilize WIC services.¹¹⁰⁻¹¹² However, WIC's breastfeeding support services, such as those provided through the WIC Breastfeeding Peer Counselor Program, do not receive adequate funding to offer those services at all WIC sites.

The National School Lunch and Breakfast Programs serve approximately 30 million children each day. Since the inception of the Healthy, Hunger-Free Kids Act (HHFK) in 2010, the incidence of obesity among low-income children in the program declined by 47%.¹¹³ However, some schools face challenges meeting the new nutrition standards, including costs and availability of foods, inadequate staff training, equipment, and infrastructure. As a result, HHFK nutritional standards are continually at risk of being weakened. In addition, many public schools across the country allow or even promote the sale of unhealthy (calorically dense and nutrient-poor) foods, including sugar-sweetened beverages, on campus, in vending machines, cafeterias, and canteens. Given that school meals contribute to more than half of the daily caloric intake of U.S. children who participate in the food programs, these practices increase children's risk of obesity and type 2 diabetes. Notably, those states that have more stringent laws regarding the sale of unhealthy food on school campuses have been shown to have significantly lower rates of obesity among youth.¹¹⁴

The Summer Meal Programs: Summer Food Service Program and Seamless Summer Option

The Summer Food Service Program is a federally-funded, state-administered program that reimburses providers (schools, local government agencies, faith-based and other non-profit community organizations with the ability to manage a food service program) who serve free, healthy meals to children and teens at approved meal sites in low-income areas during the summer when school is not in session. In addition, schools that participate in the National School Lunch or School Breakfast Program are eligible to apply for the Seamless Summer Option, which makes it easier for schools to feed children during traditional summer vacation periods. Once the Seamless Summer Option is approved by the state agency, schools can serve meals free of charge to children, including teenagers through age 18, under the school meal program rules. However, many children who participate in school meal programs (that is, National School Lunch and Breakfast Programs) do not receive healthy meals during the summer. In the summer of 2019, the Summer Food Service Program and the Seamless Summer Option through the National School Lunch and Breakfast Programs reached only 1 in 7 children (13%) who received free or reduced-price lunch during the 2018-2019 school year.¹¹⁵ During the COVID-19 pandemic, USDA expanded the summer meal programs so that program operators could continue serving free meals to all children. The federal government's efforts to expand these programs provided food and nutrition for children when families faced critical food shortages. The role these programs played during the COVID-19 pandemic highlights how important they are for children who will continue to face food insecurity after the pandemic.

The Fresh Fruit and Vegetable Program provides funding to participating schools so that they can provide children with a wide variety of fresh fruits and vegetables that can help prevent type 2 diabetes. The program's budget, however, is only \$183 million (FY 2021 Enacted), or 0.1% of USDA's annual budget. Studies have shown that the program is able

to increase the fresh fruit and vegetable intake of participating children by 1/3 cup per day without increasing calorie intake.¹¹⁶ There is a much greater demand for this program than available funds allow.

Recommendation 4.2: The National Clinical Care Commission recommends that USDA non-SNAP feeding programs be better leveraged to prevent type 2 diabetes in women, children, and adolescents by (1) enhancing Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); (2) further harnessing the National School Lunch and Breakfast Programs to improve dietary quality; and (3) expanding the Summer Nutrition Programs and the Fresh Fruit and Vegetable Program.

- 4.2a. Further strengthen the WIC program by sustaining the evidence-based, prescriptive WIC food package; expand funding for breastfeeding peer counseling services (see also Recommendation 4.7); invest in improvements to information systems and technology to enable greater access and service for WIC participants.
- 4.2b. Maintain the nutrition standards found to be salutary in the Healthy Hunger-Free Kids Act (HHFKA) and provide adequate funding for schools to (a) purchase, prepare, and serve healthy, quality foods and beverages for school meals and snacks to meet the HHFKA nutrition standards and (b) deliver training and technical assistance to support maintenance and attainment of HHFKA nutrition standards, and skills to run a program to effectively prevent type 2 diabetes.
- 4.2c. In collaboration with the U.S. Department of Education, the U.S. Department of the Interior, the U.S. Environmental Protection Agency, USDA should ensure that all students in public and tribal schools have reliable access to safe, appealing, and free drinking water. This could be accomplished through a combination of federal incentives and possibly tying receipt of funding for school-based food programs in the future.
- 4.2d. Prohibit the sale of calorically dense and nutrient-poor foods, including sugar-sweetened beverages, on public school campuses; and employ an incentive program to enable schools to cover essential costs such as those for physical activity/athletic programs previously underwritten by the sale of such unhealthy foods and beverages. Receipt of federal funds for school-based food programs should be tied to implementation of such restrictions.
- 4.2e. Strengthen, increase funding for, and improve access to and participation in summer feeding programs, including partnerships and collaboration between public and private sectors, to promote innovation in rural areas and other high-risk areas where participation has been low. Funding for these programs should be increased to enable scaling to meet population needs.

Patient Testimonial

-- Joseph Angelo, a 58-year-old man with type 2 diabetes since 2014 who currently manages his condition using oral medications and an injectable diabetes medication. Mr. Angelo lost his job and was part of a pilot program that provided incentives to purchase fresh fruits and vegetables.



"IT'S LIKE THE DAY AFTER CHRISTMAS

Having diabetes myself, I've been taught by my doctors and nurses about the things I should and shouldn't eat to help me manage my diabetes. This education has been great. But when I actually try to follow their advice, I'm hit with the sticker shock of reality. A lot of folks on a fixed income struggle with how to make decisions about what foods to buy and eat with the limited resources we have. Mostly, we're trying to think of what we can get the most meals out of. Fresh fruits and vegetables have a higher mark-up compared to processed foods or junk food or soda, so a lot of people have little choice but to eat healthier foods.

For me this SNAP incentive will absolutely help me buy and eat healthier foods, as opposed to the cheaper, processed foods that have empty calories and are more immediately filling. Having such a program can make the sticker shock of reality go away, motivating me to buy and eat the kinds of food that can keep me healthy. It makes making the right choice become the easier choice for me.

Stretching out SNAP dollars this way means that buying nectarines, peaches, broccoli or carrots is a decision more of us will make, because it has better value both financially and health-wise. The SNAP fruits and vegetable incentive will stretch my dollar further. Without it, the high cost of fruits and vegetables has made it hard for me to even look at them; now I really can consider buying them.

It feels like the day after [Christmas], when the prices go down. All those fruits and vegetables that I had wanted to buy the day before but couldn't because they were so expensive, now (all of a sudden) they're attainable!"

Focus Area 3. Modify USDA Programs That Support Farmers to Make the U.S. Food Supply Healthier

Background and Rationale

The Farm Bill (\$86 billion) provides a great opportunity to link the aims of supporting farmers and achieving food security with public health and health care goals related to diabetes. The Farm Bill is a powerful, underutilized tool to potentially prevent and control diabetes, curb health care spending, and reduce disparities. Below are three USDA programs that could be substantially enhanced to help reduce the risk for diabetes and diabetes complications in the U.S. population.

The **Specialty Crop Block Grant Program** aims to enhance the competitiveness of specialty crops, which are defined as “fruits, vegetables, tree nuts, dried fruits, horticulture, and nursery crops.”¹¹⁷ The associated budget was \$85 million, or 0.1% of the Farm Bill budget.

The **Specialty Crop Research Initiative** works to address the critical needs of sustaining the specialty crop industry including conventional and organic food production systems. This includes efforts to improve production efficiency, handling and processing, productivity, and profitability of specialty crops over the long term. The associated budget was also \$85 million, or 0.1% of the Farm Bill budget.

The **Healthy Food Financing Initiative (HFFI)** provides grants and loans to improve access to fresh and healthy foods by financing grocery stores, farmers’ markets, food hubs, and co-ops in urban and rural areas. The grants and loans provided through the initiative help food retailers overcome the higher costs and initial barriers associated with providing fresh and healthy food options for individuals and families who live in low-access areas. Evidence¹¹⁸ shows that HFFI-financed programs increase food security and reduce intake of added sugars and decrease the percentage of daily calories from solid fats, alcoholic beverages, and added sugars. The associated budget was ~\$25 million, or 0.03% of the Farm Bill budget.

Recommendation 4.3: The National Clinical Care Commission recommends that resources be provided to USDA to create an environmentally friendly and sustainable U.S. food system promoting the production, supply, and accessibility of foods such as “specialty crops” (fresh fruits, dried fruits, vegetables, tree nuts) that will attenuate the risk for type 2 diabetes and the complications of diabetes.

- 4.3a. Significantly expand and increase funding for the USDA Specialty Crop Block Grants to support the safe production and distribution of food and drive demand through education for specialty crops to increase dietary diversity as an aid to help people prevent and/or control diabetes.

- **4.3b. Significantly increase funding for the USDA Specialty Crop Research Initiative grants to improve specialty crop production efficiency, handling and processing, productivity, and profitability (including specialty crop policy and marketing) over the long term in a sustainable manner.**
- **4.3c. Significantly expand and increase funding for the USDA evidence-based Healthy Food Financing Initiative, a federal effort to improve food access and health in low-income, underserved communities and communities of color in urban and rural areas that supports farmers and healthy food retailers to improve access to nutritious, affordable, and fresh food.**
- **4.3d. Funding and expansion should be implemented by 2030 to achieve population-wide benefits.**

Focus Area 4. Encourage the Consumption of Water Over Sugar-Sweetened Beverages

Background and Rationale

When water replaces caloric beverages, consuming water is associated with improved glycemic (blood sugar) control.¹¹⁹ Tap water is the preferred source of drinking water, but in areas where tap water is known to be contaminated, filtered or bottled water is acceptable. Many regions of the U.S. face persistent challenges in providing clean tap water to their populations because of contamination of water sources or the systems that deliver water to homes, schools, and workplaces (see Focus Area 4.8).¹²⁰

Replacing sugar-sweetened beverages with water in institutions such as schools and delivering clean water to homes to replace sugar-sweetened beverages have been shown to be particularly promising^{121, 122} in reducing obesity and type 2 diabetes risk. Modelling studies have shown that consuming water instead of sugar-sweetened beverages could significantly reduce the national prevalence of obesity and diabetes, by lowering caloric intake and preventing metabolic side effects of consuming liquid sugar.¹²³ To enhance diabetes prevention and control, strategies to increase clean water availability and consumption should be coupled with strategies that reduce sugar-sweetened beverage availability, with the overall goal of promoting water consumption and reducing consumption of added sugars.

Sugar-sweetened beverages represent the largest single source of added sugar in average U.S. diets (30-40%) and comprise between 50% and 90% of the recommended daily limit of added sugars.¹²⁴ However, many Americans consume well above the average amount, placing them at especially high risk for type 2 diabetes. Nearly two-thirds of U.S. children and youth consume at least one sugar-sweetened beverage per day, one in five consume

two sugar-sweetened beverages per day, and one in ten consume three or more sugar-sweetened beverages per day. Highest intake levels of sugar-sweetened beverages are observed among adolescents, groups with lower socioeconomic status, and non-Hispanic Blacks and Hispanics.^{125, 126} Among those who drink one or more sugar-sweetened beverages, calories from sugar-sweetened beverages alone exceed the recommended daily limit for added sugars, and often exceed 25% of total daily calories. Sugar-sweetened beverage consumption is associated with type 2 diabetes, cardiovascular disease, and all-cause mortality.¹²⁷ Diabetes risk resulting from sugar-sweetened beverage consumption is a consequence not only of excess caloric intake but of unique effects of added sugars on metabolism. Consuming one sugar-sweetened beverage per day increases the risk of type 2 diabetes by about 20%. There is an even greater risk among those who consume more than one sugar-sweetened beverage per day.¹²⁸ In the U.S., sugar-sweetened beverage consumption alone is projected to account for 1.8 million new cases of type 2 diabetes over the next 10 years. The percentage of cases attributable to sugar-sweetened beverages is much higher in low-income populations and communities of color, and sugar-sweetened beverage consumption is a significant contributor to race/ethnicity-, education-, and income-related disparities in diabetes.¹²⁹

While numerous public health associations and specialty medical entities have concluded that consuming sugar-sweetened beverages contributes to type 2 diabetes, the beverage industry has funded research and campaigns to dispute these conclusions.¹³⁰⁻¹³² Although scientific reports have addressed the prevalence and health hazards of sugar-sweetened beverage consumption,¹³³ the U.S. government has not issued official guidance to the public about sugar-sweetened beverage consumption and diabetes risk. This has limited the ability of clinicians to effectively guide their patients in the prevention and treatment of diabetes and policy makers to address advertising, marketing, and sales of sugar-sweetened beverages. Recommendations to reduce or eliminate sugar-sweetened beverages from the daily diet have largely been absent from the CDC's National DPP curriculum in the past.¹³⁴ It came to the Commission's attention that by the time this report is released, CDC is expected to have updated the National DPP program around the language related to sugar sweetened beverages.

Meanwhile, many non-governmental health organizations have recommended limiting the intake of sugar-sweetened beverages through communication campaigns, implementing warning labels (see Background and Rationale for Recommendation 4.5a), restricting access to sugar-sweetened beverages in schools, and/or raising the price of sugar-sweetened beverages.¹³⁵ However, less attention has been paid to worksite sales bans. A study of a workplace sugar-sweetened beverage sales ban by a large employer found that, among employees who were daily sugar-sweetened beverage consumers (≥ 12 oz/day), mean daily intake of sugar-sweetened beverages decreased by approximately 50% 10 months after the ban; reductions in sugar-sweetened beverage intake correlated with improvements in

waistline circumference and insulin sensitivity.¹³⁶ The intervention was also found to be cost saving to the employer.¹³⁷ Based on the evidence, health systems around the country are beginning to restrict sugar-sweetened beverage sales.

Additionally, increasing the price of sugar-sweetened beverages with excise taxes of as little as one cent per ounce (about 10% of the price) has been shown to reduce sugar-sweetened beverage consumption by 10% to 20% and raise significant revenue to fund health promotion activities.^{138, 139} Modelling studies demonstrate that such reductions will reduce the incidence of type 2 diabetes, especially among children, low-income individuals, and people of color.¹²⁹ Furthermore, reductions in sugar-sweetened beverage consumption can delay or prevent the development of diabetes complications and is cost saving to society. Despite the health benefits of reductions in sugar-sweetened beverage consumption, the beverage industry has consistently opposed taxation and has lobbied for state laws to make sugar-sweetened beverage taxation unlawful at county and municipality levels.¹⁴⁰ It has been estimated that a federal sugar-sweetened beverage tax of only one penny per ounce would generate ~\$7 billion per year.¹⁴¹ Over time, such a tax would generate at least \$80 billion and save \$55 billion in direct health care costs.¹⁴²

Recommendation 4.4: The National Clinical Care Commission recommends that all relevant federal agencies promote the consumption of water and reduce the consumption of sugar-sweetened beverages in the U.S. population, and that they employ all the necessary tools to achieve these goals, including education, communication, accessibility, water infrastructure, and sugar-sweetened beverage taxation.

- **4.4a. USDA should add a symbol for drinking water to the MyPlate graphic and increase water promotion messaging in all consumer-facing materials issued by its Center for Nutrition Policy Promotion. Water is not currently depicted on the USDA MyPlate.**
- **4.4b. Child nutrition programs should be a conduit for education to promote consumption of water and reduce consumption of sugar-sweetened beverages. USDA should encourage hydrating with water instead of sugar-sweetened beverages and provide safe water education in WIC nutrition education and in childcare settings. Congress should harness the Child Nutrition Reauthorization Act to strengthen existing water provisions for school nutrition programs.**
- **4.4c. HHS should commission a scientific report under the joint auspices of the U.S. Surgeon General and include other relevant federal health agencies to summarize and present a synthesis of the evidence regarding the causal relationship between sugar-sweetened beverage consumption and obesity and type 2 diabetes. The report should be authored by experts in diabetes**

and clinical medicine, nutrition and metabolism, epidemiology and public health, and health disparities; authors should be free of any conflicts of interest related to the food and beverage industry.

- 4.4d. With additional funding, CDC, NIH, and USDA should develop and implement a national campaign and associated materials to both promote consumption of water and reduce consumption of sugar-sweetened beverages as a strategy to promote overall health, including the prevention of obesity, type 2 diabetes, and cardiovascular disease. CDC should also include such messages across all its relevant programs.
- 4.4e. Similar to the federal tobacco tax, the U.S. Department of the Treasury should impose an excise (not sales) tax on sugar-sweetened beverages to cause at least a 10% to 20% increase in their shelf price. The revenues generated should be reinvested to promote the health of those communities that bear a disproportionate burden of type 2 diabetes (for example, promote child nutrition and improve access to clean water in low-income communities and communities of color). This federal sugar-sweetened beverage tax should not pre-empt state or local authorities from levying their own additional excise tax on sugar-sweetened beverages.
- 4.4f. All federal agencies should promote drinking water and reduce sugar-sweetened beverage consumption within their own organizations and through the grants and programs they fund or administer. All agencies should increase access to free, clean, and appealing sources of drinking water for their employees and visitors and develop procurement and other policies that curb the availability and sale of sugar-sweetened beverages to their employees and visitors.
- 4.4g. HHS should serve as a federal model by (a) ensuring onsite access to safe, clean, and appealing drinking water; (b) restricting the sale of sugar-sweetened beverages in HHS-owned or HHS-leased offices, workplaces, and health care facilities; and (c) measuring the impact of these interventions on employee behavior and diabetes-related outcomes through voluntary participation in an evaluation of the model.
- 4.4h. The Office of the U.S. Trade Representative should ensure that all international trade agreements allow for the taxation of sugar-sweetened beverages and front-of-package health advisory labels and icons (see also Recommendation 4.5).

Patient Testimonial

--Carmen George MS, Community Outreach and Patient Empowerment, Navajo Nation

"Working in Navajo communities in the public health field with COPE (Community Outreach and Patient Empowerment), our vision and hope is to enable people to live healthier lives. This often begins with increasing access and availability of healthy foods and healthy beverages. As we know, diabetes rates in many indigenous communities are sky high. Several Navajo Nation communities have shared with us that the water quality and water access on the reservation is a major concern and barrier to leading a healthier lifestyle. There is a history of uranium mining here that has contaminated many water sources. We are working hard to turn this around and promote the consumption of water instead of sugary drinks. By addressing this underlying issue, Navajo people will have access to choose healthy food and clean, safe water to reduce the burden of diabetes."



Focus Area 5. Enhance FDA's Role in Preventing and Controlling Diabetes Through New Labeling and Claim Requirements

Background and Rationale

The general public, especially those of lower educational and income status who are at greater risk for type 2 diabetes and diabetes complications, is frequently misinformed about the nutritional value and health risk of foods and beverages,¹⁴³ especially processed and packaged foods. Current labeling regulations are inadequate to identify risk and allow individuals to reduce their consumption of foods and beverages that can lead to a higher burden of diabetes and other cardiometabolic diseases. Inaccurate marketing claims about the health benefits of products, combined with a federal nutrition label that requires high levels of scientific numeracy and health literacy to be understood, poses challenges for many consumers when it comes to protecting their own and their families' health.¹⁴⁴ The fact that many Americans are uncertain as to which foods increase diabetes risk has contributed to the disease burden, making the work of other federal health agencies (for example, CDC, CMS, and Health Resources and Services Administration [HRSA]) more challenging and more costly.

Evidence from around the globe suggests that food and beverage labeling that is clearer, more direct, and more compelling than that required by FDA can improve dietary quality at individual and population levels.¹⁴⁵⁻¹⁴⁷ This is due to both changes in consumer purchase patterns and product reformulations by industry. In addition, to fulfill FDA's goal of supporting informed consumer decision making, the agency should ensure that food labels are truthful, not misleading, and provide clarity for consumers seeking a healthy diet. For example, FDA should enhance regulations to ensure that objective, science-based standards are used when products use the term "whole grain."¹⁴⁸ New standards of identity, nutrition labeling, and claim allowances for so-called toddler drinks ("toddler milks" and "transition formulas") are needed to prohibit the use of misleading terms such as "milk" and "formula" and "recommended" or "necessary" for these products. FDA should also mandate scientific evidence for all health claims and require disclaimers that such products are not intended for children younger than 12 months or as a substitute for breastmilk or infant formula.^{149, 150} Additionally, a new requirement around the inclusion of "added sugars" is needed; specifically, "added sugars" should be added to the existing regulation that disqualifies the use of health claims or qualified health claims if a product contains excess levels of total fat, saturated fat, cholesterol, or sodium. This rule should also apply to nutrient content claims.¹⁴⁴

Recommendation 4.5: The National Clinical Care Commission recommends that the U.S. Food and Drug Administration (FDA) improve its food and beverage labeling regulations that influence both food and beverage industry practices and consumer behavior to better prevent and control diabetes.

- **4.5a.** Congress should authorize FDA to implement a new national, compulsory, uniform, simple, easily recognizable and understandable front-of-package icon system that alerts consumers to the health attributes and health risks of food and beverage products based on their ingredients. The front-of-package icon/warning system should be informed by evidence accrued from existing epidemiological, clinical, and nutritional sciences, and its design should be informed by health communication science.
- **4.5b.** In communicating added sugar content contained in products in the revised Nutrition Facts Label (and in the Recommended Daily Allowance), FDA should use teaspoon units in addition to grams to enable consumers to estimate their added sugar intake relative to daily limits.
- **4.5c.** FDA should implement a robust, multilingual communication campaign to improve awareness of the new labeling on added sugar and the rationale for the labeling (highlighting the potential harms of consuming excess added sugars).
- **4.5d.** FDA should update its policies and regulations to prevent industry claims on food and beverage products that mislead U.S. consumers to believe that unhealthy foods are healthy.

Focus Area 6. Restrict Commercial Advertising and Marketing of Unhealthy Foods and Beverages to Children Younger Than 13 Years of Age

Background and Rationale

Over the last decade, rates of type 2 diabetes have been exploding among U.S. youth of color, with rates tripling among certain Native American tribal youth, doubling among Black youth, and increasing up to 50% among Latinx and Asian/Pacific Islander youth.¹⁰² The expansion of the type 2 diabetes epidemic into children and adolescents in large part is a result of a food environment that increasingly promotes unhealthy dietary patterns. The unfettered advertising and marketing of what is commonly described as “junk food” (high-calorie, high-sugar, high-sodium, nutrient-poor foods) and beverages to children through television, film, social media, and other internet platforms, including marketing campaigns targeting children of color, have been shown to be significant drivers of the consumption of unhealthy foods and beverages among children.¹⁵¹ Children under the age of 13 are especially vulnerable to marketing and advertising and lack the critical skills to detect if and when they are being deceived.¹⁵²

A number of countries have instituted regulations and/or bans related to the marketing of unhealthy food to children in their efforts to prevent type 2 diabetes in younger people. These strategies have been shown to significantly reduce children's exposure to unhealthy food advertisements and consumption of sugar-sweetened beverages.¹⁴⁶

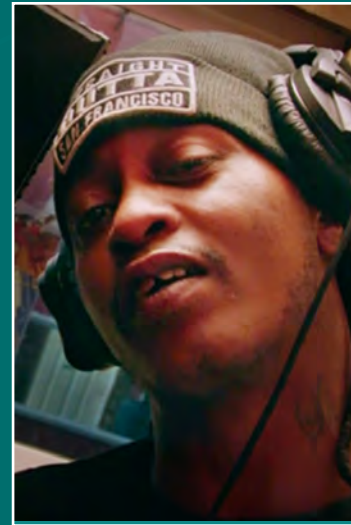
Extensive work by FTC over a decade ago, in collaboration with other agencies, examined the industry practices that were contributing to the obesity and type 2 diabetes epidemics in children and adolescents. FTC was subsequently not empowered to regulate the practices of advertisers or their communication platforms to protect children.¹⁵² Specifically, FTC was not allowed to create guidelines or promulgate regulations through notice-and-comment rulemaking regarding food and beverage advertising to children; restrict commercial advertising and marketing to children by advertisers, communication networks, and online platforms of those foods and beverages that contribute to unhealthy dietary patterns (calorie-dense and nutrient-poor foods and beverages, as defined by U.S. Dietary Guidelines); or monitor the practices of food and beverage advertisers, and any associated communication networks and online platforms, by routinely accessing marketing and advertising information. The food and beverage industry's commitment to self-regulate what and how it markets to children is widely acknowledged to have failed to reverse or change these marketing practices or children's diets.¹⁵³

Recommendation 4.6: The National Clinical Care Commission recommends that the Federal Trade Commission—in order to prevent children's exposure to, and consumption of, calorie-dense and nutrient-poor foods and beverages that can lead to obesity and type 2 diabetes—be provided the authority, mandate, and requisite resources to (a) create guidelines and rules regarding the marketing and advertising practices of the food and beverage industry and associated communication networks and platforms targeted to children younger than 13 years old, (b) restrict industry practices based on these rules, (c) fully monitor these practices, and (d) enforce such rules.

Patient Testimonial

-- Monteil Lee, aka Telly Mac, a 39-year-old rap artist with diabetes and a history of an amputation

"When I was younger, the beverage companies and their ads made me want to chase sugar. That big glass jug with a big smile made from the sugary drink mix -- it kind of inspired me as a kid. They tricked me into thinking that if I drank it, I'd be happy too. I just had to have it. But that's not right. They shouldn't be tricking kids to drink stuff that can make them sick later on. I suffered an amputation from diabetes when I was 37 years old, so I know how this goes down.



Anything that can make these sugary drinks less accessible to people is a good thing in my book. Right now, they're cheap, they market them like crazy, and they're everywhere in my neighborhood. No doubt a tax would make folks less likely to buy them. That would not only keep people healthy but would leave them more money in their pockets to spend on the good things in life, instead of having to spend it on diabetes medications or syringes."

Focus Area 7. Further Promote and Support Breastfeeding to Reduce the Risk of Diabetes Among Mothers and Their Children

Background and Rationale

Breastfeeding has long been recognized as providing short-term health benefits for babies and mothers. Growing evidence supports breastfeeding as having long-term benefits. Maternal breastfeeding is independently associated with lower odds of type 1 diabetes and lower odds of obesity in the offspring, an important risk factor for type 2 diabetes. Breastfeeding also generates health benefits for the mother that may persist for decades. Women who breastfeed enjoy a 30% reduction in the risk of developing diabetes and a lower risk of cardiovascular disease, hypertension, and breast and ovarian cancer.¹⁵⁴ These benefits are associated with greater breastfeeding intensity (proportion of infant feedings from breast milk) and duration of breastfeeding with an apparent threshold at six months' duration.

Over the past 10 years, effective breastfeeding promotion policies and programs at federal, state, and community levels have been guided by strategies outlined in the 2011 Surgeon General's Call to Action to support breastfeeding. These policies and programs have helped improve overall breastfeeding rates. One example is the federal Special Supplemental Nutrition Program for WIC, which serves more than half of the infants born in the U.S. WIC works to ensure that mothers and families who utilize its services understand the benefits of breastfeeding and receive the support they need to achieve their breastfeeding goals. WIC provides several different types of breastfeeding support, including access to trained breastfeeding staff, the WIC Peer Counseling Program, free classes on newborn behavior and breastfeeding, and the provision of breast pumps for mothers returning to school or work.

Currently, four of five U.S. mothers begin breastfeeding at the birth of their infant; however, the proportion who breastfeed quickly declines such that fewer than half of infants are exclusively breastfed at three months of age.^{155, 156} Moreover, there are marked racial and ethnic, socioeconomic, geographic, and occupation-related disparities in breastfeeding initiation and duration.¹⁵⁷ These factors must be addressed to ensure that all mothers and families have the opportunity to reach their breastfeeding goals and experience the potential long-term health benefits, including reduced risk of diabetes.

A leading reason for mothers, and particularly low-income mothers, to stop breastfeeding is the need to return to work. While the work environment has improved for lactating mothers, a recent CDC study found that only about half of worksites offer lactation support for breastfeeding mothers.^{155, 158} Research has demonstrated that paid maternity leave for

at least three months is positively associated with breastfeeding duration, with women who return to work at or after 13 weeks have two to three times higher odds of breastfeeding beyond three months¹⁵⁹ and nearly two-fold greater odds of breastfeeding for at least six months.

Recommendation 4.7: The National Clinical Care Commission recommends that federal agencies promote and support breastfeeding to (a) increase breastfeeding rates, (b) enhance the intensity and duration of breastfeeding among mothers who breastfeed, and (c) reduce disparities in breastfeeding rates, duration, and intensity. Additional funding should be provided for federal programs that promote and support breastfeeding to overcome persistent societal and employment-based obstacles to breastfeeding.

- **4.7a:** Provide additional funding for successful programs that promote and support breastfeeding, including USDA’s Food Nutrition Service (FNS) WIC Peer Counselor programs; HRSA Maternal and Child Health Bureau’s Healthy Start program and the Maternal, Infant, and Early Childhood Home Visiting Program; and CDC’s Maternity Practices in Infant Nutrition and Care and Breastfeeding Report Card.
- **4.7b:** The Department of Labor should
 - ◊ Expand existing federal protections for mothers in the workplace including mothers covered under the Fair Labor Standards Act (non-salaried employees) as well as those who are not covered under the Fair Labor Standards Act (salaried employees).
 - ◊ Develop and disseminate resources to help employers comply with federal law requiring them to provide the time and a place for nursing mothers to express breast milk.
 - ◊ Implement a monitoring system to ensure that employers are complying with federal law requiring that they implement lactation support programs.
- **4.7c:** NIH, the Agency for Healthcare Research and Quality, the Center for Medicare and Medicaid Innovation, USDA, and other federal agencies should support community-based and community-informed demonstration projects and research to (1) identify and evaluate the impact of effective, evidence-based breastfeeding support interventions among minority women and women with lower socioeconomic status; and (2) inform implementation and scaling efforts.

- 4.7d: HHS should update the 2011 Surgeon General’s Call to Action to Support Breastfeeding to reflect the current landscape of breastfeeding research and provide updated breastfeeding policy and program guidance for the new generation of health care providers, public health officials, women, and families.
- 4.7e: CMS should enact and adequately fund a Medicaid incentive payment mechanism to incentivize hospitals and facilities providing maternal and newborn services to implement and demonstrate adherence to evidence-based policies, practices, and procedures proven effective in both initiating and increasing the duration of breastfeeding (for example, the Ten Steps to Successful Breastfeeding framework developed by the World Health Organization and the United Nations Children’s Emergency Fund [UNICEF]).
- 4.7f: Enact national maternity leave legislation to provide mothers with up to three months of paid leave, which has been shown to both increase rates of breastfeeding initiation and enhance the duration of breastfeeding. The paid leave provided under this legislation would be distinct from unpaid leave available to employees through the Family and Medical Leave Act.

Patient Testimonial

--*Darian Torrez, school teacher*

"[I did not have a good breastfeeding experience with my first child], solely because I had lack of knowledge. I didn't know that I could reach out to a lactation consultant. My doctors at the time didn't inform me or help me in any way, like say you can reach out to a lactation consultant to help you, to get you help. So I kind of felt like that was the main reason why.

When I had my daughter five years later, it was completely different. I mean, I knew that those resources were available. And so, at the hospital, I made sure to have the lactation consultant in my room whenever I needed her. And I got the help I needed if something was wrong. I asked questions. And so I think it's really important for those resources to be available for women.

[About my pumping experience at work], my only option that was given was, 'Well, I guess you could use your lunchtime and there's a room in the lounge that you can use to do that.' [The room] was pretty small. It fit a chair and a little table and that was it. I told my husband over and over, 'It feels so weird because all of the teachers are sitting in the lounge and ... they know that I'm going to hide in this closet to pump and it just makes for a very awkward encounter.'

That 30 minutes was just so stressful, and I think I started producing less and less milk because I was so stressed."



Focus Area 8. Improve the Ambient and Built Environments to Prevent Type 2 Diabetes and Diabetes Complications

Background and Rationale

Attributes of the ambient and built environments are influenced by federal policies and have substantial population-level impacts on the risk of developing type 2 diabetes and diabetes complications. To date, however, the federal agencies and departments whose work affects the ambient and built environments have not evaluated how their work may influence diabetes in the U.S. and have not coordinated their efforts with other agencies working on diabetes prevention and control.

Accumulating evidence links diabetes to ambient environmental factors such as air pollution, water contamination, and chemicals associated with metabolic and endocrine (hormonal) dysfunction.¹⁶⁰ Relevant pollutants and contaminants present in the air, land, water, and/or manufactured and household products include (a) particulate matter and nitrogen oxides in the air; (b) heavy metals (arsenic, lead, uranium) in water; (c) and endocrine-disrupting chemicals including polychlorinated biphenyls; organochlorine pesticides; bisphenol A, phthalates, and possibly per- and polyfluoroalkyl substances present in plastics.³⁹⁻⁴¹ Disproportionate exposure to such environmental toxins is an underappreciated contributor to racial, ethnic, and geographic disparities in diabetes.⁴²⁻⁴⁴

With respect to the built environment, area-level attributes such as walkability, green space, urban sprawl, physical activity resources, and active transport opportunities have also been shown to be determinants of type 2 diabetes and diabetes complications.³¹⁻³⁴ In addition, the built environments of areas and neighborhoods with higher concentrations of Latinos, African Americans, American Indians, and low-income individuals have been shown to be less health promoting than those with lower concentrations, a phenomenon that contributes to disparities in diabetes and its complications. Enhancing the built environment will also improve the ambient environment by reducing air pollution.

Recommendation 4.8: The National Clinical Care Commission recommends that all federal agencies whose work influences the ambient (air, water, land, and chemical) and built environments modify their policies, practices, regulations, and funding decisions so as to lead to environmental changes to prevent and control diabetes.

- **4.8a.** All federal agencies should limit the extent to which their work contributes to individual-level and population-level exposure to environmental pollutants and contaminants associated with diabetes and/or diabetes complications. The Environmental Protection Agency should ensure that environmental protections are in place to limit individual-level and population-level exposure and implement abatement measures, prioritizing those exposures that contribute to diabetes-related disparities.

- **4.8b. All federal agencies (in particular, the U.S. Department of Transportation and the U.S. Department of Housing and Urban Development [HUD]) should modify their policies, practices, regulations, and funding decisions related to the built environment to prevent diabetes and diabetes complications by enhancing walkability, green space, physical activity resources, and active transport opportunities. Priority should be given to those regions and projects that could mitigate the effects of unhealthy built environments on diabetes-related disparities.**

Focus Area 9. Improve Housing Policy and Expand Smoke-Free Policies to HUD's Subsidized Housing

Background and Rationale

Homelessness, housing instability, and poor-quality housing pose a risk for diabetes,³⁵ and significantly impair diabetes management among those with diabetes.^{36,37} The federal government currently influences housing through two of its agencies: HUD and the Internal Revenue Service (IRS). HUD subsidizes housing through public authority-owned housing (more than two million people), and the housing voucher program (approximately five million people) for privately owned subsidized housing (commonly known as "Section 8 Housing"). However, fewer than one in five families (17%) eligible for public or subsidized housing ever receive these services.¹⁶¹

IRS manages the Low-Income Housing Tax Credit Program, which gives tax credits to developers who build low-income, subsidized, or mixed housing. States use a process called a Qualified Allocation Plan (QAP)¹⁶² to choose which projects receive the low-income tax credits. This process scores a project based on a set of mandatory criteria set up by IRS, and any supplemental criteria that individual states choose to add. Currently, the mandatory IRS criteria address the location of the property, characteristics of the population that will move into the housing, types of properties existing on the site, and energy efficiency. However, there are no health-related attributes in the IRS criteria.

Data suggest that housing plays an important role in clinical outcomes, and families that need to spend more than 30% of their incomes on housing have difficulty affording food, medications, and medical care (see Recommendation 4.1). A large, randomized trial sponsored by HUD (*Moving to Opportunity*) demonstrated that moving families from public housing in a high poverty zone to subsidized housing in a low poverty zone is associated with lower diabetes incidence.¹⁶³

Exposure to tobacco smoke elevates the risk of type 2 diabetes and amplifies the risk of diabetes complications (especially macrovascular complications) and death among people with diabetes.¹⁶⁴ Diabetes prevalence is nearly twice as high among people living in public housing (17.6%) compared to the general population (9.4%).¹⁶⁵ Smoking rates and rates of exposure to secondhand smoke are higher among people with diabetes and prediabetes,

especially among those who are poor, have limited education, and are Black, which more than double the odds of smoke exposure.¹⁶⁶⁻¹⁶⁸ Socioeconomic and racial/ethnic disparities in diabetes incidence, complications, and death, arise in part due to inequitable access to tobacco control interventions. In July 2018 HUD implemented a mandatory smoke-free policy¹⁶⁹ that required all public housing authority-owned housing to prohibit combustible tobacco use in indoor dwelling, indoor shared areas, and outdoor areas within 25 feet of exits and windows. The policy includes the provision of smoking cessation services to residents who smoke. However, this policy does not apply to multi-unit housing including Section 8 federally subsidized housing, leaving these sites unprotected from secondhand smoke unless residents voluntarily make their apartments smoke-free. Expanding HUD's smoke-free policy to federally subsidized housing units could have population-level benefits by reducing diabetes incidence, diabetes-related complications, and diabetes-related deaths.

Recommendation 4.9: The National Clinical Care Commission recommends that, to reduce type 2 diabetes incidence and diabetes complications, housing opportunities for low-income individuals and families be expanded, and that such individuals and families be housed in health-promoting environments.

- 4.9a. The U.S. Department of Housing and Urban Development (HUD) should expand its federal housing assistance programs to allow access for more qualifying families, such that over a 20-year period, all that qualify can access subsidized or public housing.
- 4.9b. The Internal Revenue Service (IRS) should further incentivize developers to place new housing units in areas of low poverty, as data show that moving people from areas of high poverty to low poverty favorably affects the incidence of obesity and diabetes.
- 4.9c. The IRS should mandate that states include neighborhood health parameters (such as availability of health care services, transportation, employment opportunities, education opportunities, food availability, and physical activity resources) in the required IRS Qualified Allocation Plan criteria.
- 4.9d. IRS should establish a means to fund or subsidize the cost of embedding health services (if needed) in housing developments to incentivize committing space or employing unused space for such services in their plans.
- 4.9e. HUD should broaden implementation of indoor smoke-free policies to include subsidized multi-unit housing, require multi-unit housing adopting smoke-free policies to provide access to cessation resources (that is, referrals to cessation resources), and in collaboration with the CDC Office on Smoking and Health, work to align these policies with its related policies in public housing so as to ensure that loss of housing is not an unintended consequence.

Patient Testimonial

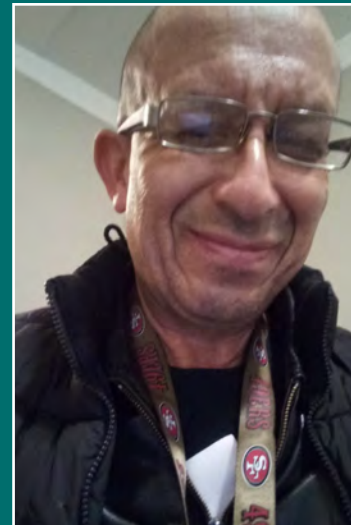
--Ricardo Guillory, a veteran and former residential construction worker

"I've had diabetes for 11 years, and for four of them I was homeless. When I was homeless, my diabetes got so out of control that I had to be hospitalized. My blood sugar was over 600 and the doctor said I was one step away from a coma.

There were so many challenges to taking care of my diabetes when I was homeless and living in a shelter. For one, I had no place to store my medications and no place to keep my insulin cold. So I missed a ton of doses. I had a really bad diet because I had no place to cook. For breakfast and dinner, I relied on the unhealthy food in the shelter and spent all day on street trying to find lunch. It was hard to have regular meals, which made it tricky knowing when to take my insulin. I had to be on my feet all day, which was really hard with my neuropathy. I couldn't even keep a regular doctor. Not having a home base made it hard to stay organized and I couldn't keep appointments, plus I had so many more urgent demands. So I just got my care in the ER.

I was on the list for low income housing for 3-4 years and finally got a place. The place is not much to write home about, but it is right near Lake Merritt [Oakland] and there are great walking paths there. Having my own place means that I can rest, sleep well, exercise, and cook my own food—healthy food. I have a place to safely store my medications. I can get mail, I can schedule and make my doctor appointments, and I now have a regular doctor. My mental health is better; I'm not so worried anymore and I am more motivated to care [for] myself. Now I can really focus on my diabetes care. During this time my HbA1c went from 13% [very poor diabetes control] to 7% now [excellent diabetes control].

I think my story tells it all in terms of how important it is to have your own roof over your head, your own bed to sleep in, and your own kitchen to cook in when you have diabetes."



Focus Area 10. Align Federal Research Priorities to Enable Population-Wide Discoveries Related to Diabetes Prevention and Control

Background and Rationale

It has been nearly 50 years since Congress passed the National Diabetes Research and Education Act,¹⁷⁰ the first legislation directed at coordinating and expanding the government's research and prevention efforts related to diabetes. This law mandated that the National Institutes of Health establish a National Commission on Diabetes to develop a long-range plan to combat diabetes,¹⁷¹ with an emphasis on creating a coordinated, interdisciplinary research program. The plan and subsequent action led to a world-class research program that has resulted in a deeper understanding of the epidemiology of diabetes, discoveries into diabetes causes and its complications, and significant advances in clinical prevention and treatment. This research has focused on understanding the basic biology of diabetes and its complications and intervening at the individual patient level in clinical settings. More recently, NIH, through the Diabetes Mellitus Interagency Coordinating Committee, updated its strategic plan to guide diabetes-related research and nutrition research.¹⁷² These investments have helped advance the field even further and have informed and improved the clinical prevention and care for individuals at risk for or with in the U.S. and globally.

However, since the National Commission on Diabetes issued its report in 1975, our understanding of the diabetes epidemic has evolved, and there now is a greater appreciation of the interactions between social and environmental conditions, stress, health behaviors, and diabetes incidence, diabetes complications, and related disparities. The population-level burden of type 2 diabetes, in large part, is a consequence of the unhealthy social and environmental conditions prevalent in U.S. society (see Figure 2. The National Clinical Care Commission Framework for Diabetes Prevention and Control, Chapter 3). There is an urgent need to leverage and coordinate research across a range of federal "non-health" departments and agencies to answer critical questions related to the social and environmental drivers of diabetes. Especially needed is research to evaluate the effects of social and environmental policy changes and related programs on diabetes outcomes. Resultant discoveries have the potential to benefit not only the general public but also those at risk for diabetes (that is, preventing or delaying type 2 diabetes among those with prediabetes) and those with established diabetes (that is, preventing or delaying complications in those with diabetes). Such research will also help ensure that clinicians can provide high-quality, integrated clinical care and that patients can successfully self-manage diabetes.

Recommendation 4.10: The National Clinical Care Commission recommends federal investments in research that will yield discoveries that generate population-level benefits in the prevention and control of type 2 diabetes, with a particular focus on elucidating and changing the social and environmental conditions associated with greater risk of diabetes and its complications.

- 4.10a. The U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), the U.S. Department of Transportation (DoT), the Federal Trade Commission (FTC), the Federal Communications Commission (FCC), the Food and Drug Administration (FDA), and others should fund research into how their policies and practices affect diabetes risk and management and could be changed or (if/when beneficial) amplified to better prevent and control diabetes.
- 4.10b. The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) should support large-scale natural experiments research—including cost-effectiveness analysis—to inform the evidence base related to social and environmental policies that prevent and control type 2 diabetes. Special focus should be paid to “health in all policies” types of interventions relevant to non-health agencies’ activities and other public health (non-clinical) interventions. The Centers for Medicare & Medicaid Innovation (CMMI) or alternative federal entities should support demonstration projects in collaboration with non-health agencies related to influencing social determinants of health, reducing diabetes risk, improving diabetes control, and preventing complications (for example, USDA’s SNAP interventions, the U.S. Department of Housing and Urban Development’s housing interventions, EPA and freshwater interventions, DoT and walkability interventions).
- 4.10c. Investments in research training need to be made by NIH, CDC, and non-health agencies to enhance the workforce skilled in the competencies needed to carry out health impact assessments and related simulation work.
- 4.10d. NIH should expand its initiative on Precision Nutrition to (1) include clinical trials that can inform critical population health questions related to which foods, beverages, ingredients, and additives promote/prevent the development of type 2 diabetes; (2) include studies of communication interventions and (counter) marketing practices to inform which practices work best for which sub-populations with respect to changing dietary patterns to prevent type 2 diabetes, and which practices elevate diabetes risk; (3) expand the definition of “precision” to go beyond targeting the individual to include targeting cultural and geographic entities (neighborhoods).

- 4.10e. NIH should encourage that nutrition and metabolic research accurately quantify water intake and use this information to better study the associations between water consumption and health across the lifespan. USDA should develop methods to incorporate water consumption into USDA Food Patterns (water is a beverage that currently is not a contributor to USDA food groups or subgroups).
- 4.10f. NIH should support research (in collaboration with other federal agencies) to better understand the role of (1) exposures related to environmental pollutants, toxins, contaminants, unclean water, and endocrine disrupting chemicals on metabolic function and diabetes risk; and (2) life course trauma (including interpersonal violence, discrimination, racism, and disability) on metabolic function and diabetes risk, and associated interventions to reduce exposure to such trauma and/or mitigate the effects of trauma on diabetes outcomes.

Chapter 5: Diabetes Prevention in Targeted Populations

Background

In this chapter the National Clinical Care Commission addresses diabetes prevention in persons at high risk of developing diabetes, especially those with prediabetes, a state associated with an increased risk of type 2 diabetes and cardiovascular disease. We also address research needs for preventing type 1 and type 2 diabetes. Recommendations included in this chapter were built upon those of the previous chapters. Implementing recommendations presented in previous chapters such as improving access to health care, making positive changes in food and agricultural policies, enhancing nutritional assistance programs, and improving the built environment (see Chapters 3 and 4) will benefit all people in the U.S. including those with prediabetes.

Prediabetes

Prediabetes is a metabolic state in which blood glucose levels are higher than normal but not high enough to be classified as diabetes. The American Diabetes Association criteria define prediabetes as either a fasting plasma glucose of 100-125 mg/ dL (impaired fasting glucose [IFG]), a 2-hour post challenge glucose level of 140-199 mg/dL (impaired glucose tolerance [IGT]), or an HbA1c value of 5.7% to 6.4%.¹⁷³

Prediabetes is prevalent in the U.S. CDC estimates that 88 million adults (about 34.5% of the U.S. population over the age of 18) and 18% of teenagers have prediabetes.^{2, 8} Most persons with prediabetes are unaware that they have this condition; only about 15% of persons with prediabetes reported being told by a health professional that they had prediabetes.² Overweight and obesity are strong risk factors for developing prediabetes. The prevalence of prediabetes also increases with age.

Persons with prediabetes are at higher risk of developing type 2 diabetes. Around 5% to 10% of people with prediabetes develop type 2 diabetes every year, and progression rates vary depending on population characteristics and prediabetes definitions.^{174, 175} The rate of progression is higher in those with both IFG and IGT compared to persons with only IFG or IGT.¹⁷⁶⁻¹⁷⁹ A study of over 77,000 persons with prediabetes found that the risk of developing type 2 diabetes increased with higher HbA1c levels and with higher body mass index (BMI).¹⁸⁰

Diabetes Prevention in People With Prediabetes

There are effective ways of delaying or preventing the progression from prediabetes to type 2 diabetes. The Diabetes Prevention Program (DPP) study, published in 2002, showed that a lifestyle intervention focused on a healthy diet, physical activity, and approximately 7% weight loss reduced the incidence of type 2 diabetes in persons with prediabetes by 58%; and metformin (a diabetes medication) reduced the incidence of type 2 diabetes by 31%.¹⁴ This translated to about six cases of type 2 diabetes prevented per 100 person-years for the lifestyle intervention, and about three cases of type 2 diabetes prevented per 100 person-years for metformin.¹⁴

Subsequent analysis of the DPP study determined that the lifestyle intervention was effective in all persons with prediabetes, regardless of age, BMI, or baseline risk of progression to type 2 diabetes.^{14, 181} In contrast, metformin was effective in younger persons, individuals with a higher BMI, persons with a history of gestational diabetes, and persons at higher baseline risk of progression to type 2 diabetes.^{14, 181, 182} The effectiveness of lifestyle interventions and metformin has been confirmed by several other studies with prediabetes defined by different criteria (persons with IFG or IGT).¹⁸³⁻¹⁸⁶

Evidence also suggests that both the DPP lifestyle intervention and metformin are cost-effective in preventing or delaying the onset of type 2 diabetes. In the U.S., interventions that cost less than \$50,000 to \$100,000 per quality-adjusted life-year (QALY) gained are generally considered to be cost-effective. The DPP lifestyle intervention, when implemented in a small group format (with 10 participants per class), cost \$13,200 per case of type 2 diabetes delayed or prevented and \$27,100 per QALY gained, and metformin costs \$14,300 per case of type 2 diabetes delayed or prevented and \$35,000 per QALY gained, over three years (the length of the DPP study).^{187, 188} If the effects of the DPP lifestyle intervention extend beyond the timeframe of when the intervention is delivered, and studies suggest they do,¹⁸⁹ cost per QALY gained would further decrease. It has thus been estimated that over 10 years, the DPP lifestyle intervention implemented in a group format would cost \$8,412 per QALY gained and metformin is slightly cost-saving (it had slightly lower costs than not providing an intervention).¹⁸⁸ For comparison, intensive glycemic control for patients with newly diagnosed type 2 diabetes costs approximately \$41,000 per QALY gained over a lifetime.

There are other compelling reasons for people with prediabetes to participate in a DPP lifestyle program focused on diet, physical activity, and weight loss, aside from prevention of type 2 diabetes. People with prediabetes are at increased risk of cardiovascular disease (CVD), chronic kidney disease, and death from any cause.¹⁹⁰⁻¹⁹² Preventing CVD and other adverse health outcomes therefore is an important goal of diabetes prevention interventions. In the DPP study, the lifestyle intervention improved CVD risk factors (lower blood pressure, lower triglycerides, higher HDL cholesterol) compared with placebo and

metformin therapy.¹⁹³ Both lifestyle intervention and metformin were associated with reductions in weight.¹⁴

The DPP and subsequent translation studies served as the model for the National DPP, the CDC-supported national partnership of public and private organizations that provides a high-quality lifestyle change program to persons with prediabetes to reduce their risk of type 2 diabetes and improve their overall health. To date, the National DPP has supported almost 2,000 CDC-recognized program delivery organizations across all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and several U.S. territories. These organizations are offering the lifestyle change program in-person, online, via distance learning platforms, or through a combination of these delivery modes to reach high-risk populations. The National DPP has enrolled 561,509 adults at high risk for type 2 diabetes in its lifestyle change program and supported numerous partner organizations in securing health benefit coverage for the program.

Gaps and Opportunities

In 2018, an estimated 1.5 million new cases of diabetes were diagnosed among people aged 18 and older in the U.S., and many of these new cases were preventable.² However, the vast majority of persons with prediabetes have not enrolled in or participated in a lifestyle change program or have not been prescribed metformin, despite the proven efficacy and cost-effectiveness of the interventions in preventing type 2 diabetes.¹⁹⁴ Enrollment in lifestyle interventions has been limited due to individuals' lack of awareness of prediabetes, low referral rates by providers, insufficient availability of classes, including online classes, and lack of insurance coverage.¹⁹⁵ Prescribing of metformin for type 2 diabetes prevention has been limited by the failure of the FDA to approve this medication for diabetes prevention, lack of patient awareness of the potential role for metformin and clinician awareness of the benefits of metformin, and clinicians' assumptions that patients would prefer not to take a medication for type 2 diabetes prevention.¹⁹⁵ This represents a missed opportunity to (1) prevent type 2 diabetes, (2) help address racial and ethnic disparities in the prevalence of diabetes, and (3) improve the health outcomes of Americans.

Reducing the incidence and prevalence of diabetes in the U.S. is a public health priority, and ensuring that type 2 diabetes prevention interventions are available to all persons with prediabetes and are equitably implemented in all populations at risk should be a crucial component to addressing this priority. Achieving these goals will require a sustained focus on enhancing federal policies and programs related to diabetes prevention, including improving the awareness and diagnosis of prediabetes, and ensuring the availability of, access to, utilization of, and sustainability of evidence-based diabetes prevention interventions.

Organizational Success: Federal Programs Can Successfully Prevent Type 2 Diabetes

By maintaining a focus on type 2 diabetes prevention, the Indian Health Service was able to consistently lower the prevalence of diabetes in American Indian and Alaska Native adults, the population with the highest prevalence of type 2 diabetes in the U.S., for four years, dropping from 15.4% in 2013 to 14.6% in 2017.^{196, 197}

Recommendations

Focus Area 1. Raise Public Awareness About Prediabetes and the National DPP

Background and Rationale

Since 2016 CDC has collaborated with the Ad Council on a national public service campaign to raise awareness about prediabetes. The campaign website has links to a brief self-administered test for risk of prediabetes and locations where the National DPP lifestyle change program is offered. As of June 30, 2021, 4.1 million unique individuals visited the Prediabetes Awareness Campaign website and 3.7 million completed the risk test.¹⁹⁸ Nevertheless, among people with prediabetes, gaps in awareness of the condition and familiarity with the National DPP remain substantial. The CDC 2020 National Diabetes Statistics Report showed that only 15.3% of adults with prediabetes (based on level of fasting blood glucose or HbA1c) reported having been told they had prediabetes by a health professional.² The National Health and Nutrition Examination Survey revealed that levels of awareness were especially low for young and early middle-aged adults, men, and individuals of Asian or Hispanic ancestry. Analyses of another nationally representative study, the National Health Interview Survey, found that only 4.9% of adults diagnosed with prediabetes by a physician were advised to participate in a diabetes prevention program. These results underscore the need to improve awareness of prediabetes and the National DPP among both patients and clinicians.¹⁹⁹

Recommendation 5.1: The National Clinical Care Commission recommends increasing support to CDC for its campaign to raise awareness of prediabetes and promote enrollment in the National DPP lifestyle change program.

- **To more effectively reach populations disproportionately affected by type 2 diabetes risk, CDC should use multiple methods including social media to increase awareness of prediabetes and the opportunity to delay or prevent type 2 diabetes.**

- CDC should continue tracking visits to the Do I Have Prediabetes campaign page and completions of the prediabetes risk test, with an expanded focus on the degree to which populations at increased risk are being reached in order to reduce disparities in awareness and engagement in interventions.

Organizational Success: National Alliance for Hispanic Health Incorporates Cultural Adaptations to Support Type 2 Diabetes Prevention Success

The National Alliance for Hispanic Health (NAHH), a CDC grantee, works with several affiliate sites to engage and enroll persons of Hispanic or Latinx descent who are at high risk for type 2 diabetes in the National DPP lifestyle change program. One of NAHH's affiliates, the Hispanic Federation, worked to create culturally relevant materials for their community members in central Florida, representing groups from Puerto Rico, Mexico, and several Central and South American countries.

Acknowledging the cultural differences across these diverse groups and incorporating them into the program curriculum has enabled participants to better understand and embrace the lifestyle change program. The Hispanic Federation built on the foundation of the Spanish version of the CDC's *PreventT2* curriculum and adapted it for their participants in interactive ways, incorporating local foods. They offered healthy potlucks and invited participants to bring dishes from their countries so that everyone could learn new recipes and share a piece of their culture. As a result, many participants also formed friendships and found exercise partners, which further supported their lifestyle change goals. These cultural adaptations helped improve participant retention and overall satisfaction with the program, resulting in a combined weight loss of over 500 pounds across 170 program participants.

Focus Area 2. Expand Coverage for Screening/Diagnostic Testing Used to Identify Individuals With Prediabetes

Background and Rationale

Currently there are three widely accepted tests with established criteria for diagnosing prediabetes: fasting blood glucose, the oral glucose tolerance test, and HbA1c. Furthermore, the 2021 U.S. Preventive Services Task Force (USPSTF, an independent panel of scientific experts) recommendations²⁰⁰ and the 2021 American Diabetes Association Standards of Medical Care in Diabetes²⁰¹ both recommend fasting blood glucose, oral

glucose tolerance tests, and HbA1c as appropriate for clinicians to consider in screening for and diagnosing prediabetes and diabetes. However, Medicare does not cover the cost of HbA1c testing for prediabetes screening, contributing to low rates of screening. The two tests that are covered (fasting blood glucose and oral glucose tolerance tests) present logistical barriers (that is, they require fasting by the patient and an extended visit) to identifying patients with prediabetes. These logistical issues do not apply to HbA1c testing.

Recommendation 5.2: The National Clinical Care Commission recommends that the Centers for Medicare & Medicaid Services provide coverage for hemoglobin A1c testing when used to screen for prediabetes.

Focus Area 3. Adopt and Promote Clinical Quality Measures for Screening and Follow-Up of Abnormal Blood Glucose

Background and Rationale

In 2019 a technical expert panel convened by the American Medical Association proposed three electronic clinical quality measures for review by the National Quality Forum to monitor and improve quality of care for patients with prediabetes. The proposed measures are:

- Screening patients aged 40 and older with a BMI ≥ 25 kg/m² for abnormal blood glucose at least once in the previous three years.*
- Providing one of the following interventions for patients with prediabetes during the 12 months following determination of abnormal blood glucose.
 - ◊ Referral to a CDC-recognized diabetes prevention program
 - ◊ Referral to Medical Nutrition Therapy with a registered dietitian
 - ◊ Prescription of metformin
- Retesting patients' blood glucose in the year after they were identified with prediabetes.

Recent surveys conducted among clinicians indicate significant gaps in awareness of CDC-recognized lifestyle change programs and referrals to such programs for management of prediabetes.²⁰²⁻²⁰⁴ Studies of electronic medical records conducted after publication of the 2015 USPSTF guidelines on screening for type 2 diabetes prevention found marked

* The USPSTF now recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. (<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes>)

variation by clinic in levels of screening, frequent failure to document a diagnosis of prediabetes when the diagnostic criteria had been met, and low levels of referral for individual or group behavioral intervention.^{202, 205} These findings underscore the salience of the proposed quality measures to monitor and improve the timely diagnosis of prediabetes and implementation of preventive measures.

The opportunity to identify and counsel patients at risk for type 2 diabetes may be missed during an acute or routine visit because of competing priorities or incomplete information available at the time. Nevertheless, as testing for abnormal blood glucose or HbA1c has become more common, opportunities exist to leverage retrieval of testing results so that appropriate referrals can be made. To facilitate better adherence to the proposed guidelines, administrative and clinical data can be queried to create a registry of patients at higher risk or already meeting the criteria for prediabetes (that is, on the basis of BMI and history of hypertension, abnormal blood glucose, or HbA1c results). Clinic staff could contact patients in the registry to discuss prediabetes, offer definitive diagnostic testing, and provide opportunities to enroll in the National DPP lifestyle change program. The patient's medical record could be flagged for reinforcement of these messages at future visits. Projects that have retrieved results from the medical record to systematically identify and report patients with prediabetes have shown improvement in referrals to the National DPP lifestyle change program.^{206, 207}

Recommendation 5.3: The National Clinical Care Commission recommends that all federal agencies that directly deliver or influence the delivery of medical care should implement the 2019 American Medical Association-proposed prediabetes quality measures related to screening for abnormal blood glucose, intervention for prediabetes, and retesting of abnormal blood glucose in patients with prediabetes.*

- **These agencies should implement a process for systematically using administrative and clinical data to identify patients at risk for or already meeting criteria for prediabetes and to ensure appropriate referral and follow-up.**
- **To support implementation of these measures, quality-improvement programs should be introduced to improve performance and reduce disparities.**

* The USPSTF now recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. (<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes>)

Focus Area 4. Support Metformin Use for Type 2 Diabetes Prevention

Background and Rationale

Metformin has been approved by FDA for the treatment of type 2 diabetes mellitus since 1995.²⁰⁸ Accumulating clinical evidence supports the use of metformin for delaying the onset of type 2 diabetes in individuals with prediabetes who are at high risk.²⁰⁸ However, metformin does not have an FDA-approved indication for prediabetes. Prescribing metformin for prediabetes currently is considered an “off label” use and, hence, the use of metformin in patients with prediabetes is infrequent.

Because of the availability of multiple generic versions of metformin, pharmaceutical companies have little financial incentive to pursue an FDA approval for metformin to be used in patients with prediabetes. While data could be submitted to FDA for review through other means without participation of a pharmaceutical company (for example, a Citizen’s Petition), as outlined in 21CFR 10.30, organizations interested in pursuing an FDA indication for metformin to be used for prediabetes are hesitant to take on the responsibilities because of the costs and amount of work involved with filing a Citizen’s Petition.²⁰⁹ Pursuing an approval from FDA would require the applicant to collect, analyze, and organize data to show the safety and effectiveness of metformin in patients with prediabetes. A comprehensive synthesis of available data currently is not available.

Recommendation 5.4: The National Clinical Care Commission recommends that funding be provided to NIH to collect, analyze, and summarize the available data from the Diabetes Prevention Program study describing the effectiveness and safety of metformin for type 2 diabetes delay or prevention in patients with prediabetes, including subpopulations most likely to benefit. Such a summary (with safety and efficacy data) should then be used to inform an appropriate submitter’s request for FDA to review and consider an indication for the use of metformin in high-risk patients with prediabetes.

Focus Area 5. Ensure Insurance Coverage for Diabetes Prevention Interventions

Background and Rationale

The National DPP lifestyle change program is effective at preventing or delaying the progression from prediabetes to diabetes; however, participant referrals and enrollment remain low compared to the need, and most persons with prediabetes are not referred to or enrolled in the program.¹⁹⁴ Section 2713 of the Affordable Care Act requires private health plans to cover certain evidence-based preventive services and to eliminate cost-sharing for preventive care. These services include evidence-based preventive services recommended by USPSTF based on the strength of the scientific evidence.²¹⁰ The current

USPSTF recommendation on screening for type 2 diabetes includes the following as part of its recommendation: “Clinicians should offer or refer patients with prediabetes to effective preventive interventions.” The recommendation notes that “lifestyle interventions that focus on diet, physical activity, or both and metformin have demonstrated efficacy in preventing or delaying progression to diabetes in persons with prediabetes.”²⁰⁰ Private insurers are not consistently providing coverage for the National DPP lifestyle change program, a proven effective diabetes prevention intervention. This contributes to its under-implementation and underutilization and results in greater numbers of preventable cases of type 2 diabetes.

Recommendation 5.5: The National Clinical Care Commission recommends, consistent with provisions of the Patient Protection and Affordable Care Act, that all insurers be required to provide coverage for participation in and completion of a CDC-recognized diabetes prevention program for those who are eligible.

Focus Area 6. Support All Proven-Effective Delivery Modes for Evidence-Based Diabetes Prevention Interventions

Background and Rationale

Federal agencies use a variety of modes (for example, in-person, online, and distance learning [telehealth]) to deliver evidenced-based interventions to delay or prevent type 2 diabetes.²¹¹ Other diabetes-related interventions, such as the Department of Defense Diabetes Center of Excellence Virtual Diabetes Self-Management Education, have also been successfully implemented in a fully virtual platform. Despite efforts within federally-funded health care programs, access to evidence-based type 2 diabetes prevention interventions needs to be further improved. Additionally, coverage of proven-effective delivery modes varies across private and public payers. Promoting and improving coverage for evidence-based type 2 diabetes prevention interventions through a variety of delivery modes would help improve access.

Recommendation 5.6: The National Clinical Care Commission recommends that Congress promote coverage for all proven-effective modes of delivery (for example, in-person, online, and distance learning [telehealth]) for evidence-based interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards.

Focus Area 7. Improve Medicare Diabetes Prevention Program Coverage

Background and Rationale

Section 1115A of the Social Security Act²¹² established the Center for Medicare and Medicaid Innovation (CMMI) to test innovative payment techniques and service delivery models. The Medicare Diabetes Prevention Program (MDPP) was one of the models tested. Based on the positive results, MDPP was officially expanded in scope and duration in 2016. This expansion was implemented into practice in 2018. The MDPP expanded model is currently being evaluated,²¹³ based on factors such as quality of care delivered, patient outcomes, and costs. MDPP services are covered services under the model expansion, pending results of the evaluation.²¹⁴ However, based on findings from the original DPP study, subsequent translation studies demonstrating the program's effectiveness in non-clinical settings, and the results of the 15-year DPP Outcomes Study, the DPP lifestyle intervention has already been studied extensively and has substantial evidence supporting its effectiveness across settings and populations.

Additionally, full virtual delivery of the MDPP is not currently included under the expanded model. This may limit CMS's ability to enroll a sufficient number of Medicare beneficiaries to evaluate the expanded model. It is also inconsistent with the National DPP, which allows virtual delivery and requires virtual delivery organizations to meet the same CDC national quality standards and achieve the same participant outcomes as in-person delivery organizations. During the COVID-19 pandemic, CMS issued flexibilities allowing for virtual delivery of MDPP services; however, it is unclear whether the flexibilities will remain after the pandemic.

Finally, there is a once-in-a-lifetime limit on the MDPP service.²¹⁵ However, various factors may affect participants' ability to fully engage in or complete the program, which may warrant an individual's need to repeat the program or re-enroll at a future date.

Recommendation 5.7: The National Clinical Care Commission recommends that the Medicare Diabetes Prevention Program (MDPP) be approved as a permanent covered benefit (not only a model expansion service) and that coverage of MDPP be expanded to include virtual delivery. Furthermore, the "once in a lifetime" limit on participation in the MDPP should be removed.

Focus Area 8. Streamline and Harmonize the National DPP and MDPP

Background and Rationale

In response to the growing rate of type 2 diabetes in the U.S., Congress authorized CDC to establish the National DPP in 2010.²¹⁶ The National DPP provides a framework for type 2 diabetes prevention efforts based on (1) a trained workforce of lifestyle coaches; (2) national quality standards supported by the CDC Diabetes Prevention Recognition Program; (3) a national network of program delivery organizations sustained through public/private payer coverage; and (4) participant referral and engagement. The CY 2017 Physician Fee Schedule (PFS) final rule enables National DPP program delivery organizations with full or preliminary CDC recognition to enroll as MDPP suppliers.²¹⁴ However, some organizations in rural and underserved areas experience challenges achieving preliminary or full CDC recognition and applying to become MDPP suppliers because of administrative burdens associated with the CDC recognition process and the CMS payment requirements. There are minor differences between MDPP and the National DPP program structure, including blood glucose eligibility criteria, allowable service delivery modalities, and requirements for ongoing maintenance sessions, making it difficult for a provider organization to deliver both the National DPP and MDPP.

Recommendation 5.8: The National Clinical Care Commission recommends that CDC continue its efforts to streamline the National DPP recognition process while maintaining quality, and that CMS streamline its payment process for the MDPP. Differences in program eligibility, delivery modalities, and duration between the National DPP (led by CDC) and the MDPP (led by CMS) should also be eliminated or, at a minimum, reduced.*

Focus Area 9. Update the MDPP Payment Model

Background and Rationale

The CY 2017 and 2018 Physician Fee Schedule (PFS) final rules^{214, 217} established the benefit structure and payment rates for the MDPP based on a diabetes prevention program model test conducted by the YMCA of the USA (Y-USA) from 2013 to 2015. The payments are adjusted annually by the 12-month percent change in the Consumer Price Index U.S. city

* The National Clinical Care Commission notes that the CMS CY 2022 Physician Fee Schedule Proposed Rule, which if adopted, may better align the duration of the MDPP and National DPP, and would increase MDPP payment for participants who attend at least 9 sessions, was recently posted for public comment. (<https://www.govinfo.gov/content/pkg/FR-2021-07-23/pdf/2021-14973.pdf>)

average (CPI-U) for the period ending June 30th of the year preceding the update year. The current MDPP payment model offers reimbursement only when participants reach certain attendance and weight loss benchmarks.

Under this model, program delivery organizations assume a level of risk and may be under-resourced to cover the upfront costs associated with program certification, marketing, and participant engagement and enrollment. While large, primarily virtual program delivery organizations have been able to negotiate different payment schedules and/or rates with other insurers and employers that address some of the barriers in the current MDPP reimbursement model, smaller organizations have not been able to do so. Current reimbursement rates may not fully incentivize program delivery organizations to apply to become MDPP suppliers as only a limited number of eligible organizations with CDC preliminary or full recognition have applied to become MDPP suppliers. This limits the availability of programs for people with prediabetes. The reimbursement rates may also have a disproportionate impact on smaller and rural programs.

Recommendation 5.9: The National Clinical Care Commission recommends that funding be provided to support the testing of new payment models that allow for greater upfront payments and more equitable risk-sharing between CMS and MDPP program delivery organizations. In addition, there should be an increase in payment levels to MDPP program delivery organizations to make MDPP programs financially sustainable.*

*The National Clinical Care Commission notes that the CMS CY 2022 Physician Fee Schedule Proposed Rule, which if adopted, may better align the duration of the MDPP and National DPP, and would increase MDPP payment for participants who attend at least 9 sessions, was recently posted for public comment. (<https://www.govinfo.gov/content/pkg/FR-2021-07-23/pdf/2021-14973.pdf>)

Focus Area 10. Enhance Medicaid Coverage of the National DPP

Background and Rationale

Medicaid coverage for the National DPP lifestyle change program is a state-level decision. Since 2012, only 16 states have enacted varying levels of Medicaid coverage of the National DPP through Medicaid State Plans, 1115 waivers, pilots with Medicaid managed care organizations (MCOs), and additional mechanisms.²¹⁸ State Medicaid Agencies, or MCOs in the case of voluntary coverage, determine the types of delivery modes (for example, in-person, online, distance learning/telehealth) that will be covered.

However, there are variations across states in terms of (1) whether the National DPP lifestyle change program will be made a covered benefit under that state's Medicaid program, (2) delivery modes covered, and (3) the level of reimbursement authorized. Additionally, risk factors for type 2 diabetes are higher in Medicaid beneficiaries, a population that is vulnerable to the limitations in services available to them.

Recommendation 5.10: The National Clinical Care Commission recommends that financial incentives be provided for state Medicaid programs to cover the National DPP lifestyle change program and other evidence-based type 2 diabetes prevention interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards. This should include coverage of all proven modes of delivery (that is, in-person, online, and distance learning or telehealth) that produce successful participant outcomes.

Focus Area 11. Support Federal Programs Focusing on Diabetes Prevention

Background and Rationale

An estimated 34.2 million Americans (about one in 10 Americans of all ages including one in seven adults) have diabetes, and 88 million people aged 18 years or older (more than one in three adults) have prediabetes. American Indians and Alaska Natives have the highest prevalence of diabetes of any racial and ethnic group.² The Special Diabetes Program for Indians (SDPI) was established by Congress in 1997 in response to the type 2 diabetes epidemic among American Indians and Alaska Natives. The SDPI is coordinated by the Indian Health Service (IHS) Division of Diabetes with guidance from the Tribal Leaders Diabetes Committee, and it provides funds for diabetes treatment and prevention to IHS, Tribal, and urban Indian health programs across the U.S.²¹⁹ The SDPI supports diabetes prevention and treatment among American Indians and Alaska Natives with great success. By maintaining a focus on diabetes prevention and through funds from the SDPI, the IHS

was able to lower the prevalence of diabetes in American Indian and Alaska Native adults consistently for four years, dropping from 15.4 percent in 2013 to 14.6 percent in 2017.¹⁹⁶ ¹⁹⁷ However, funding for this program has not increased since 2004.

There are also geographic disparities in diabetes prevalence. Alabama has the highest prevalence of diabetes (13.2%) among all U.S. states; the U.S. regions with the highest diabetes prevalence are in the Southeast and Appalachia.²²⁰ Rural areas of the U.S. also have a higher prevalence of diabetes and generally have less medical infrastructure compared to urban areas.^{221, 222} HRSA's Delta States Rural Development Network Grant Program provides network development grants to the eight states in the Mississippi Delta for network and rural health infrastructure development.²²³ The program requires grantees to focus on diabetes, cardiovascular disease, and obesity, but not specifically on type 2 diabetes prevention. Given the higher burden of diabetes in the Southern U.S. and the proven effectiveness of diabetes prevention interventions, providing additional resources to HRSA's Delta States Rural Development Network Grant Program would allow the program to include type 2 diabetes prevention as a focus, while not detracting from the program's, or HRSA's, other important aims.

Recommendation 5.11: The National Clinical Care Commission recommends

- **Funding for the Special Diabetes Program for Indians (SDPI) in five-year increments so that evidenced-based tribal diabetes prevention programs have the resources to (1) sustain the effort to combat diabetes and its complications; (2) develop additional culturally appropriate, high-impact type 2 diabetes prevention interventions; and (3) evaluate outcomes.**
- **An increase in SDPI funding to address inflation costs, which have consumed more than 34% of the program's resources since 2004, the last year Congress increased funding for the Special Diabetes Program. In the future, annual increases in funding should, at a minimum, address the costs of inflation.**
- **An increase in funding to HRSA's Delta States Network Grant Program to allow the program to include type 2 diabetes prevention as a focus.**

Organizational Success: A Special Diabetes Program for Indians (SDPI) Grantee Provides Diabetes Prevention Services to a Rural, Underserved Community

The Lake County Tribal Health Consortium is an SDPI grantee providing the National DPP lifestyle change program in rural Northern California. Lake County is a medically underserved area that ranks at the bottom of California's 58 counties for poorest health as assessed by death from all causes. By percentage, the county has one of the largest Native American populations in the state, with members from over 100 recognized tribes, creating a uniquely diverse tribal community. The Consortium feels honored to provide diabetes prevention services to its community, helping them prevent diabetes and its complications and feel and live better. Several recent participants in Lake County Tribal Health Consortium's diabetes prevention program shared the following thoughts:

"The teacher and other people in class we all help each other and learn new things to help each other and learn new things to help each other in our journeys."

"I liked having an instructor that was in our level of understanding in the struggles of weight loss."

"The instructor was awesome! I learned a lot from [him/her]! I love how the group came together. I was not embarrassed about my weight. I would recommend the program to everybody. I do plan on staying in the group to further my education about weight, diabetes, and fitness."

Focus Area 12. Diabetes Prevention Research Recommendations

Recommendations for Type 2 Diabetes Prevention Research

Background and Rationale

The National DPP was authorized by Congress in 2010 with an evidence-based lifestyle change program as its foundation.²¹¹ The National DPP lifestyle change program was developed based on the DPP study, a large NIH- and CDC-funded national research project that included adults of all ages and racial/ethnic groups in whom type 2 diabetes is more common. The DPP study demonstrated that for people with prediabetes who are at high risk of developing type 2 diabetes, an intensive lifestyle intervention of healthy diet, physical activity, and approximately 7% weight loss can significantly reduce the risk of developing type 2 diabetes by 58% over a 2.8-year period. The study also demonstrated that metformin can reduce the risk of developing type 2 diabetes by 31% over 2.8 years.¹⁴

In spite of these remarkable outcomes, the majority of people with prediabetes have not participated in a diabetes prevention program such as the National DPP lifestyle change program, and are not taking metformin.¹⁹⁴ Without intervention, the risk of persons with prediabetes developing type 2 diabetes persists and even increases over time. For example, in the DPP study, 29% of the participants in the placebo group progressed to type 2 diabetes over a 3-year period, and 62% progressed to type 2 diabetes over 15 years.^{14, 189}

While the best way to prevent the progression from prediabetes to type 2 diabetes in the long term is currently uncertain, the DPP study showed that weight loss was highly correlated with diabetes prevention. However, many people in the lifestyle intervention group who lost weight ultimately regained the weight after completing the clinical trial.²²⁴

The majority of people with prediabetes who would benefit from metformin are not taking the medication.¹⁹⁴ The reasons for not using metformin for prediabetes likely include (1) physicians not wanting to use medication to treat people with prediabetes, (2) physicians' and patients' lack of awareness of the benefit of using metformin, (3) concerns about possible side effects of metformin, (4) concerns about lack of FDA approval for use in prediabetes, or (5) a combination of these reasons. Further studies on metformin uptake and alternative medication choices are needed for people with prediabetes. There are also disparities in implementation and uptake of diabetes prevention programs, which may be a result of social, geographic, financial, or cultural barriers, or other reasons.

Additionally, people with prediabetes are a heterogeneous group. Individuals have different physiologic abnormalities that contribute to dysglycemia (abnormal blood glucose levels). As a result, some people with prediabetes may develop type 2 diabetes and other complications (such as cardiovascular disease and kidney failure) more quickly than others.²²⁵ More research is needed to better identify people with prediabetes who are at high risk of developing type 2 diabetes and diabetes complications so that screening and interventions can be tailored to maximize effectiveness. Research to assess the performance of screening tests and efficacy of interventions across racial and ethnicity populations is also needed.²²⁶

Recommendation 5.12: The National Clinical Care Commission recommends funding type 2 diabetes prevention research to discover how to ensure that all individuals at high risk of developing type 2 diabetes are able to lower their risk for diabetes and its complications. Examples of areas for further research include:

- **What impediments prevent participation in effective diabetes prevention programs for communities with the greatest needs?**
- **Are programs that combine both lifestyle intervention and metformin to prevent diabetes more effective than programs with either lifestyle change or metformin alone?**

- **What is the best number, frequency, duration, and content of lifestyle intervention sessions to successfully prevent diabetes in the long term?**
- **What are the barriers to long-term maintenance of weight loss for those people who successfully completed a diabetes prevention program?**

Finally, dissemination and implementation research is needed to determine how best to promote the use of effective in-person and virtual diabetes prevention programs. Such efforts should aim to understand and address barriers at multiple levels, including system policies, health care provider referrals, and patient uptake.

Recommendations for Type 1 Diabetes Prevention Research

Background and Rationale

It is not well understood why people develop type 1 diabetes. Approximately 30% of patients with new onset type 1 diabetes present with diabetic ketoacidosis (DKA).^{227, 228} DKA is a serious yet avoidable acute metabolic complication that can lead to coma and even death. Evidence suggests that some interventions (such as immune modulators and monoclonal antibodies) may be able to delay or prevent type 1 diabetes.²²⁹ Better understanding of the causes of type 1 diabetes can help identify those at high risk before they develop type 1 diabetes complications such as DKA.

In 1998 Congress passed the Special Statutory Funding Program for Type 1 Diabetes Research, also known as the Special Diabetes Program (SDP). This program has resulted in substantial progress in type 1 diabetes research and development of innovative collaborative research consortia and clinical trials networks. SDP funded research studies such as the Environmental Determinants of Diabetes in the Young (TEDDY) and the Type 1 Diabetes TrialNet have improved our understanding of the basic biology of type 1 diabetes and are making strides to discover new treatment and prevention modalities.^{229, 230} Additional research is needed to leverage emerging data from TEDDY and TrialNet to (1) develop precise and effective screening programs that can be used to identify people at high risk for type 1 diabetes who might benefit from interventions, and (2) advance research to prevent type 1 diabetes. Further study is also needed on efficient and cost-effective methods for screening the general population for risk of developing type 1 diabetes.

The SDP was originally funded at five-year intervals but the program has most recently been funded for shorter intervals, sometimes on an annual basis. Short-term funding inhibits the opportunities for significant research progress because it limits the ability to plan and initiate long-term research projects. Sustained multiyear funding is needed to use federal dollars most effectively; maximize research opportunities for long-term studies such as TEDDY and TrialNet; and pursue new promising treatment and prevention studies and trials. Additionally, the SDP funding for type 1 diabetes research has been level at \$150M since 2004.

Recommendation 5.13: The National Clinical Care Commission recommends

- Funding the Special Diabetes Program (SDP) in five-year increments so that new, innovative research can effectively be developed.
- An increase in SDP program funding to address inflation costs. Inflation costs have consumed more than 34% of the program's resources since 2004, the last year Congress increased funding for SDP. In the future, annual increases in funding should, at a minimum, address the costs of inflation.

Chapter 6: Treatment and Complications

Background

Diabetes is a complex metabolic condition that impacts personal choices, affects quality of life and life expectancy, and requires substantial health system resources.

There are several types of diabetes that have different causes, but all result in elevated blood glucose levels (that is, hyperglycemia). Severe hyperglycemia itself can be life threatening (for example, diabetic ketoacidosis), and when present over longer periods of time, chronic hyperglycemia can damage the heart and blood vessels, eyes (diabetic retinopathy), kidneys (diabetic nephropathy), and nerves (diabetic neuropathy). These may result in heart attack, stroke, vision loss, kidney failure, and amputations. Diabetes complications can be prevented or delayed by comprehensive diabetes care that includes optimal control of blood glucose, blood pressure, and cholesterol levels. Lifestyle modifications and medications are cornerstones of diabetes treatment, and both must be coupled to ongoing self-management.

Standards of medical care for diabetes are regularly updated and disseminated to provide evidence-based guidance on diabetes treatment. Despite these guidelines, only about one in three people with diabetes achieve guideline-recommended levels of care.²³¹ This is especially true among those who are younger, socioeconomically disadvantaged, and have inadequate health insurance. The Commission has focused on the gap between available resources and the use of those resources by people with diabetes. The Commission's priority areas related to diabetes treatment and complications and specific recommendations have been designed to narrow this gap.

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.

Consensus Statement on U.S. Health Care Reform for People with Diabetes, November 2020

Achieving and maintaining optimal health and wellbeing while living with diabetes requires that patients and their caregivers

- Have access to and understand information about diabetes, its management, and its potential complications;
- Participate collaboratively with health care providers in selecting treatments that are consistent with their unique characteristics and goals of care; and
- Have the skills, confidence, psychosocial and material support to perform the necessary self-management tasks.

In addition, health systems must proactively deliver high-quality individualized diabetes care and community resources must support the self-management needs of individuals with diabetes.

Given the complexity of treating diabetes and its complications, the Commission has elected to focus on several factors at the levels of persons with diabetes, clinical practices, health care systems, and government policies that have the greatest likelihood of improving the delivery of high-quality care to all Americans with diabetes.

Recommendations

Focus Area 1. Diabetes Self-Management Training

Reduce Administrative Barriers to Diabetes Self-Management Training

Background

Substantial knowledge and skills are required by people with diabetes to manage their disease. Diabetes affects all aspects of an individual's life. People with diabetes are expected to make healthy dietary choices; engage in regular physical activity; perform frequent monitoring; take medications consistently; deal with psychological and financial stresses of having a chronic, life-threatening disease; and proactively seek and obtain ongoing medical care. Diabetes self-management education and support (DSMES) facilitate the knowledge and the skills necessary to manage diabetes on a daily basis. DSMES is designed to help people with diabetes learn, integrate, and maintain these vital behaviors as part of their overall treatment program. Diabetes self-management training (DSMT) is the Medicare benefit that covers DSMES services to Medicare beneficiaries.

DSMT improves confidence and quality of life for people with diabetes, and is cost-effective²³² in reducing hospital admissions, readmissions, and the risk of complications.²³³ ²³⁴ Standard DSMT curricular content is delivered by diabetes care and education specialists and addresses the causes of diabetes, common treatments, and strategies to incorporate healthy eating, taking medications appropriately, monitoring blood glucose levels, and preventing complications. DSMT also imparts healthy coping and problem-solving skills. DSMT uses a person-centered approach based on individual needs and cultural characteristics and is provided by accredited programs that meet and maintain established standards.

Despite robust evidence demonstrating the effectiveness of DSMT, fewer than five percent of Medicare beneficiaries with a new diagnosis of diabetes receive DSMT. There is strong evidence that increased participation in DSMT significantly reduces spending through prevention of emergency room visits and inpatient hospitalizations due to diabetes complications. Disparities in access to DSMT by age, sex, race, language, and availability of DSMT providers contribute to inequities.⁶¹

Underutilization of DSMT is multifactorial. Contributing factors may include outdated standards, burdensome administrative requirements, and inconsistent auditing processes. These factors contribute to a shortage of diabetes care and education specialists and a lack of programs in some geographic areas that have a high prevalence of diabetes.²³⁵

Rationale

Medicare coverage for DSMT was first established in 2000. CMS quality standards for DSMT²³⁶ were established then but have not been updated since. According to CMS regulations, either the CMS quality standards for DSMT or the National Standards for Diabetes Self-Management Education and Support (NSDSMES) govern the development, delivery, and maintenance of accredited and recognized DSMT programs. Even though the NSDSMES quality standards have regularly been revised, each iteration must align with the CMS quality standards, which themselves need to be updated as they no longer align with evidence-based best practices. For example, DSMT services do not allow use of HbA1c as a criterion for diagnosis of diabetes, even though this is the most commonly used test to diagnose and monitor diabetes. Additionally, coverage for DSMT is limited to a maximum of 10 hours within the first year after a diagnosis of diabetes and a maximum of two hours per year in subsequent years. Given the evolving nature of diabetes over the life of an individual, these limited hours do not allow for individualized education and support and limit the impact of DSMT. Other diabetes-related, CMS-covered benefits, such as Medical Nutrition Therapy (MNT), allow for additional hours based on a person's individualized educational needs.²³² However, this flexibility is not available for DSMT. These reimbursement restrictions for DSMT also prevent MNT and DSMT from being provided on

the same day. Additionally, the requirements for copays and deductibles for these services are a barrier to access to DSMT and increase disparities in diabetes care.

Recommendation 6.1: The National Clinical Care Commission recommends that CMS update the 2000 Medicare Quality Standards that govern diabetes self-management training (DSMT) and establish a process for ongoing review, updating, and revision, with broad input from persons and parties affected by these standards. CMS should ensure that eligibility, documentation, and reimbursement requirements are clearly defined and that they are consistently applied across all parties involved in accreditation, billing, and reimbursement, including Medicare Administrative Contractors and auditors. Updates should include a reduction in administrative burden regarding standards, documentation, and reimbursement requirements for DSMT programs.

The administrative burden associated with meeting the NSDSMES and low reimbursement rates from CMS make it difficult for DSMT programs to remain financially viable. Medicare Administrative Contractors have at times misinterpreted the DSMT reimbursement requirements and auditors have requested documentation that exceeds the accrediting organization requirements. These requirements should be reevaluated to align with current evidence-based care.

The Commission recommends the following changes in CMS regulations related to DSMT to improve access and engage more people with diabetes:

- Allow the initial 10 hours of DSMT to remain available beyond the first 12 months from diagnosis until fully utilized.^{237, 238}
- Allow for six additional hours (instead of two hours) of DSMT, if necessary.^{232, 239}
- Allow MNT and DSMT to be delivered on the same day.
- Eliminate copays and deductibles (cost sharing) for DSMT.²⁴⁰
- Expand the types of providers who can refer for DSMT (for example, podiatrists, specialists treating diabetes-related complications, and emergency medicine physicians).²⁴¹⁻²⁴³
- Allow community-based sites to provide DSMT.
- Standardize the data collection required to simplify the process and ensure consistency across DSMT programs. CMS should ensure that all relevant partners including claims adjudicators follow a consistent approach throughout the audit and oversight processes to ensure better alignment with the purpose and scope of high-quality DSMT programs of all types and sizes.

Benefits of Community-Based Diabetes Education Programs

Rationale

Community-based diabetes education programs modify the formal approach used by DSMT. They are commonly offered in group settings and in diverse locations including schools, work sites, community centers, or places of worship. These programs generally are led by trained public health workers who come from the communities they serve and self-identify as community health workers, promotores de salud (the Spanish term for community health workers), community health representatives, community health advisors, or other related titles.²⁴⁴ Classes are generally tailored to meet the unique scheduling, cultural, educational, and language preferences of the communities being served. These programs are not intended to replace formal DSMT but can serve as an avenue to increase access to DSMT and other health care resources.

Evidence supports the effectiveness of community-based diabetes education programs for diverse groups of participants, including minority Medicare beneficiaries.²⁴⁵⁻²⁴⁸ However, these programs are often supported by grant funding,^{246, 249} and do not have a sustainable, direct source of reimbursement. Innovative collaborations between community-based diabetes education programs and accredited DSMT²⁵⁰ programs can be complementary and help organizations meet quality standards.²⁵¹

Recommendation 6.2: The National Clinical Care Commission recommends that CMS develop reimbursement mechanisms for community-based diabetes education programs, as a complement to existing accredited/recognized DSMT programs, when evidence shows that these programs improve diabetes outcomes.

Focus Area 2. Improve Access to Effective Diabetes Devices

Background

Management of diabetes involves maintaining blood glucose at near-normal levels, especially in young and otherwise healthy patients in whom early intensive control has long-term beneficial effects. To achieve this goal, some patients may need to monitor their blood glucose levels by pricking their fingers and inject insulin several times a day. However, these finger prick glucose levels do not fully capture the dynamic changes in blood glucose levels that occur throughout the day; and the finger pricking is uncomfortable. People with diabetes also face the specter of severe hypoglycemia (dangerous low blood glucose levels resulting from some diabetes treatments), which can lead to altered mental status, unconsciousness, seizures, or even death.

Many technologic advances have emerged to facilitate self-management and improve the quality of life for patients with diabetes. These include insulin pumps and continuous

glucose monitors (CGM). Insulin pumps continuously deliver small amounts of insulin into the tissue under the skin in a way that mimics how the pancreas normally works. They also allow for frequent adjustments to the amount of insulin being administered. CGM devices collect glucose information through frequent and painless sampling of the fluid in the tissue under the skin. These devices measure glucose levels and display trends throughout the day and night. This information allows patients to modify lifestyle choices and diabetes medications (sometimes in real-time), and some devices alert patients to blood glucose trends that suggest impending hypoglycemia. Newer pumps, when combined with CGM devices, automatically adjust insulin delivery without direct patient input (that is, they function as an “artificial pancreas”).

Growing evidence suggests that these devices can provide a wide range of benefits to patients with diabetes, including improved glucose control and reduced glucose variability. Patient-reported outcomes suggest that use of these devices can lead to a better understanding of and control over blood glucose changes and reduce patients’ fear of hypoglycemia. Additionally, using these advanced technologies can help reduce the burden of diabetes-related care, diabetes distress, and acute diabetes complications.²⁵²⁻²⁵⁴

Rationale

Diabetes devices are underutilized by patients with diabetes who could benefit from their use. There are many reasons for this underutilization. Administrative burdens exist for both patients and clinicians in obtaining and maintaining insurance coverage for these devices. Additionally, CMS eligibility requirements are not interpreted or applied uniformly across parties involved with eligibility review and approval. Furthermore, CMS coverage of blood glucose testing supplies is not aligned with eligibility requirements for diabetes technologies. Of great concern, eligibility requirements and coverage are lagging behind the evolving evidence of their effectiveness.^{255, 256}

Recommendation 6.3: The National Clinical Care Commission recommends that CMS use existing processes to update and regularly reevaluate (at least every three years) eligibility requirements for various diabetes devices leading to appropriate coverage determinations when there is sufficient evidence to support such national determinations. CMS should ensure that, to the extent there are national requirements established, eligibility, documentation, and reimbursement requirements are clearly defined, and that they are consistently applied across all parties involved, including Medicare Administrative Contractors and auditors. In evaluating the data to revise eligibility requirements, CMS should evaluate the current evidence, including published, peer-reviewed evidence, and consider both glycemic benefits and non-glycemic benefits (including patient-reported outcomes, which may include quality-of-life and diabetes distress).

There is currently a National Coverage Determination (NCD)²⁵⁷ for infusion pumps and a Local Coverage Determination (LCD)²⁵⁸ for CGM. Stakeholders report that the eligibility criteria for NCD and LCD are outdated and do not reflect the current evidence on who would benefit from access to diabetes technologies.²⁵⁹⁻²⁶¹ CMS eligibility requirements for diabetes technologies need to be updated to better reflect the patient population for whom these technologies are “medically reasonable and necessary.”

Given that evidence continues to evolve, CMS should regularly reevaluate and revise its coverage criteria. CMS currently has a process to review and revise NCDs. The process can be initiated internally or by external requests. From the perspectives of patients and providers, this process is not optimally utilized to keep CMS coverage criteria current with the evolving data. By using existing processes to regularly evaluate new data, CMS can ensure that appropriate patients are able to use the reasonable and necessary diabetes technologies to manage their diabetes in a timely manner. The National Clinical Care Commission believes that regularly revisiting the evidence at intervals of no more than every three years is a reasonable timeframe to allow for meaningful new evidence to accrue while still being frequent enough so that patients’ access to diabetes technologies are not unreasonably delayed.

Examples of existing requirements that may pose barriers to patients and providers and suggestions to address these barriers are described below.

1. Glucose and C-peptide* and auto-antibody levels should be removed as eligibility criteria for insulin pumps.
2. Frequent blood glucose testing (that is, four times per day) should be removed as an eligibility criterion for insulin pumps.
3. Multiple daily injections of insulin should be removed as an eligibility criterion for CGM.
4. For durable medical equipment suppliers, Medicare Administrative Contractors and auditors should better align their interpretation and application of eligibility and reimbursement requirements. Coverage determinations should be written clearly so that the interpretation is consistent.
5. In-person follow-up visits should not be required to maintain eligibility for diabetes devices. Virtual care (for example, telephone or video visits) may be sufficient to accomplish the same monitoring goals.

* C-peptide (or connecting peptide) is produced by the pancreas in equal amounts to insulin. A low or absent C-peptide level in the setting of an elevated blood glucose level reflects low or absent insulin production, and thus may indicate type 1 diabetes or patients with diabetes whose pancreases can no longer produce insulin.

6. The approval process for continued access to diabetes devices should be streamlined when patients transition to Medicare from other insurance coverage.

In addition, hypoglycemia avoidance and patient quality of life should be considered in establishing and revising coverage determinations for diabetes devices.

While growing evidence supports the short-term benefits of insulin pumps, CGMs, and artificial pancreas systems, data on longer-term clinical benefits and cost-effectiveness are needed to support CMS as the agency considers whether to establish new or modify existing NCDs. Given that the available data are insufficient to support using these devices among all patients with diabetes, identifying the gaps in evidence is important to inform future research. To enhance transparency regarding where those gaps exist, CMS should include a summary (as part of the NCD) of the additional information needed for the agency to determine if a technology is “medically reasonable and necessary.” This information could help facilitate research to fill those gaps.

Patient Testimonial:

A 65-year-old man has had type 1 diabetes since he was 2 years old and recently transitioned to Medicare. He has used an insulin pump and CGM for years with good blood glucose control. Upon transitioning to Medicare, he was told by his clinician that Medicare regulations require him to prove that he has type 1 diabetes to continue receiving supplies for his insulin pump and CGM. Specifically, he was told he needs fasting blood work to measure C-peptide, which is usually very low in type 1 diabetes. He lives in a rural community and must drive two hours to get his blood work done. Because of his diabetes and the long travel time, he was unable to fast, and as a result, the results of his blood work were deemed invalid despite the C-peptide level being undetectable. He had to repeat the test but developed hypoglycemia during fasting for the test. To treat the hypoglycemia, he had to take supplemental glucose, which elevated his blood glucose but unfortunately invalidated the C-peptide results. On his third attempt, he lied about fasting so that his C-peptide results could be deemed valid. During this time, he ran out of supplies for his pump and CGM, which have been integral to the management of his diabetes.

Patient Testimonial:

A 68-year-old man had his pancreas removed as a treatment for pancreatic cancer. As a result, he does not make insulin. His physician determined that an insulin pump with advanced features would allow for better blood sugar control and minimize treatment complexity while maximizing quality of life. However, the patient does not meet CMS criteria for an insulin pump because he does not have autoantibodies and his C-peptide level is detectable. As an advocate for the patient, the doctor has to work with the device manufacturer to obtain a loaner pump as a compassionate measure without any guarantee that the device will continue to be available if the manufacturer chooses to no longer provide it.

Health Care Provider Experiences:

- A physician is required to document in the medical record that an older adult with diabetes has more than one year of life expectancy before the patient is allowed to receive the prescribed device and supplies.
- A physician documents that a patient is performing blood glucose testing four times per day, as required by CMS criteria to obtain a CGM device. However, the request for the device was denied when the patient's glucose meter data download shows an average of 3.9 blood glucose tests per day.
- A supplier of durable medical equipment requires the treating physician to change phrases and addend the medical record to meet supplier requests, even when the same language was previously accepted by the same supplier.
- A physician is required to document in the medical record that a patient who is already using a CGM device is also performing blood glucose testing four times per day using a blood glucose meter. However, meter-based testing is impossible for the patient because Medicare no longer covers blood glucose meters and supplies when a patient begins to use a CGM device. The patient's only option is to purchase these supplies on their own.

Focus Area 3. Team-Based Care

Increasing the Health Care Workforce

Background

Person-centered, team-based care is critical to improving the lives of people with diabetes. The National Academy of Medicine defined team-based care as “The provision of health services to individuals, families, and/or their communities by at least two health providers who work collaboratively with patients and their caregivers—to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality care”.^{262, 263} Team-based care is one of the most effective ways to ensure that people with diabetes have their care needs met and attain improved overall health and wellbeing.²⁶⁴⁻²⁶⁸

Person-centered, team-based care facilitates access to care and delivery of essential health care services. A recent AHRQ report entitled “*Creating Patient-centered Team-based Primary Care*”²⁶⁵ described person-centered care as relationship-based, making the person feel known, respected, engaged, and knowledgeable. Fundamental to this approach is the belief that, when clinical practices draw on the expertise of a variety of team members, people are more likely to get the care and support they need.^{265, 269} Competing demands such as coexisting medical and behavioral health conditions, multiple medications, general preventive care, social factors, and/or stressors often impede the ability of people with diabetes to manage diabetes effectively.^{270, 271} These complexities also interfere with a single health care provider’s ability to offer high-quality, guideline-recommended care. One of the most effective approaches to address these gaps in care and improve outcomes is to empower non-physician providers to work as part of an inter-professional care team and assist patients with diabetes.²⁶⁴⁻²⁶⁸

People with diabetes are most likely to seek care at primary care practices, and this setting is optimal to develop sustained relationships, coordinate care among specialists, and address family, social, and mental health needs. Thus, integrating inter-professional team-based care into primary care is critical.^{265, 269} The composition of person-centered care teams can vary but should reflect the diversity of the communities served by the primary care practice. Working in conjunction with a physician, team members often include (1) nurses, (2) dietitians, (3) social workers, (4) integrated behavioral health specialists, (5) clinical pharmacists, (6) care coordinators, (7) medical assistants, and/or (8) community health workers (CHWs).

For this report, the Commission focuses on key aspects of person-centered, team-based care that have the greatest potential to (1) improve diabetes outcomes, patient experience, and provider experience, and (2) reduce health care cost; and that may be addressed by federal agencies.

Rationale

For practices to implement team-based care, they need access to an appropriately trained workforce, adequate reimbursement to support the team, and assistance and support in incorporating the team into their practice.

Team-based care requires a trained health care workforce that reflects the needs of communities

The numbers of primary care clinicians, behavioral health specialists, dentists, and other team members are insufficient to meet the needs of people with diabetes, especially in rural and underserved settings.²⁷² Since a large proportion of trainees stay in the area where they train, location of training programs has important implications.^{272, 273} Several deficiencies and barriers in federal efforts impeded the development of an adequate workforce for team-based care:

- Lack of a global assessment of primary health care workforce needs.
- Lack of standardized data collection to demonstrate the impact of training on health care workforce needs.
- Agencies that support training programs are not required to address health care workforce needs identified by HRSA.
- Limits are placed on the types of health care professional trainees that are allowed in certain HRSA training programs, making it challenging to provide interprofessional training.

Health care professional training is primarily supported by CMS with graduate medical education payments to teaching hospitals (about \$11 billion annually). Each teaching hospital is allowed to determine the specialty training it provides. This flexibility helps individual health care systems meet their immediate hospital workforce needs; however, those needs often do not align with local or national health care workforce needs.²⁷² This flexibility also has the potential unintended consequence of training more specialists and fewer primary care providers.

HRSA provides a health workforce assessment that describes the supply, demand, distribution, and education of the U.S. health care workforce.²⁷⁴ HRSA also manages more than 70 HHS workforce programs and aligns its programs to meet workforce needs. Despite a recent increase in funding for the HRSA National Health Services Corp, the number of trainee positions funded by HRSA is still inadequate to meet the workforce needs of underserved communities.

Adequate reimbursement is required for practices to implement and sustain team-based care

The lack of reliable reimbursement for team members limits practices' ability to develop and implement such practices. This is especially problematic for CHWs, clinical pharmacists, and behavioral health specialists, all of whom can help improve outcomes for people with diabetes, if they are included as part of team-based care. Value-based payment models have the potential to support the inclusion of additional team members. There are a variety of innovative ways in which these value-based payment models might incentivize and support the inclusion of additional team members. Centers for Medicare and Medicaid Services/Center for Medicare and Medicaid Innovation (CMS/CMMI) are currently testing value-based payment models and initiatives.

Technical assistance is needed by primary care practices to implement team-based care

Implementing team-based care requires a change in the approach to and design of care delivery. Primary care practices, especially small and medium-sized practices, do not have the expertise and/or resources for this transformation. Technical assistance (or practice consultation and coaching) can facilitate practice transformation and the adoption of evidence-based practices, quality improvement, and system changes.²⁷⁵⁻²⁷⁹ The Primary Care Extension Program (PCEP) was established by the Accountable Care Act to provide this type of technical assistance but lacks funding. AHRQ has used limited funds to support PCEPs in a small number of states. These demonstration projects have shown improvements in implementing disease prevention strategies and integrating elements of team-based care by participating primary care practices.²⁸⁰⁻²⁸² Additional funding would allow the extension of this model to all states, accelerating the uptake of team-based care.

Recommendation 6.4: The National Clinical Care Commission recommends that steps be taken to ensure an adequate workforce and to enhance and sustain team-based care to improve outcomes for people with diabetes.

- Establish a process within HHS to routinely assess and identify all health care workforce needs and ensure that training program funding across agencies is directed to meet those needs.
- Ensure the Health Resources and Services Administration (HRSA) training programs are designed to meet unmet needs in the team-based health care workforce.
 - ◊ Evaluate and address regulatory or statutory limitations on HRSA training programs that affect the agency's ability to meet the needs of team-based care and new care models.

- ◆ Increase funding for exemplary HRSA programs that support training health care professionals in team-based care in medical shortage areas, such as the HRSA National Health Services Corp.
- Identify and implement mechanisms for involvement of community health workers, clinical pharmacists, and integrated (or collaborative) behavioral health services in existing and future value-based models of care (alternative payment models)
- Enhance funding to AHRQ through Primary Care Extension Programs and other mechanisms to provide technical assistance to medical practices to implement team-based care.

Patient Testimonial

Stephanie is a 37-year-old woman who has had type 2 diabetes for seven years. In 2017, her blood glucose was consistently in the 300s and her physician referred her to work with the clinical pharmacist to optimize her medication regimen. She subsequently had eight visits during which the pharmacist helped her adjust her insulin doses. After 14 months, her blood glucose improved to values consistently in the lower 100s, significantly reducing her risk for many life-altering complications associated with diabetes.

Stephanie was ecstatic to see her hard work pay off and wanted to continue improving her health only to be met with a significant financial barrier. When she went to pick up her insulin at the pharmacy, her copay was over \$900 for a one-month supply. Stephanie was overwhelmed, frustrated, and confused. It turns out her new job had different insurance coverage, which led to the surprising high cost. Stephanie was then faced with the decision to resign from her job and apply for Medicaid to be able to afford her insulin or keep her job and not be able to afford the insulin. She reached out to the clinical pharmacist who connected Stephanie to a manufacturer insulin savings program, which could provide her with an affordable monthly co-pay for the insulin. Through the help of the clinical pharmacist, Stephanie reached her goal blood glucose levels, has avoided significant complications, and has maintained affordable access to insulin.

Community Health Workers

Background

Many of the barriers to improving health outcomes for people with diabetes are economic, social, and/or environmental. Overcoming these social determinants of health (SDOH) requires connections between providers and community resources. Enhancing trust and cultural competence is particularly relevant given the health disparities in communities of color. CHWs serve as a liaison between health services and social services and the community. CHWs are frontline public health workers who are trusted members of or have a particularly good understanding of the community. To be most successful, CHW “natural helper” skills take precedence over clinical skills.²⁸³ Community health worker interventions have been shown to be cost effective in improving diabetes knowledge, lifestyle behaviors, and diabetes health outcomes, especially in disadvantaged populations.^{284, 285} Given the significant health disparities for people with diabetes, implementing effective strategies for communities that are disadvantaged is particularly important.

Rationale

Despite CHWs’ contributions to the improved health outcomes of people with diabetes,^{284, 285} uptake of CHWs by care teams has been low because of limited reimbursement and barriers to implementation. CMS has recognized the role of CHWs. The CMS Final Rule issued July 15, 2013 allowed Medicaid agencies to reimburse community-based preventive services, including those provided by CHWs.²⁸⁶ However, most states have narrowly interpreted this rule concluding that it only applies to medical preventive services and not social, economic, and behavioral services. In addition, on January 7, 2021, CMS issued a “roadmap” with guidance to state health officials. The roadmap was designed to drive the adoption of strategies that address SDOH in Medicaid and the Children’s Health Insurance Program.²⁸⁷ However, CHWs were not specifically mentioned in the roadmap.

In addition to reimbursement issues, organizations need assistance to integrate CHWs into team-based care. The CDC has grants, toolkits, and online resources to assist health care organizations, community organizations, and states in implementing and sustaining a CHW workforce. Increased funding to CDC would accelerate the implementation and sustainability of CHWs by addressing system and policy level barriers to integration at the state level.

Recommendation 6.5: The National Clinical Care Commission recommends that steps be taken to enhance implementation and sustainability of community health workers (CHWs) as critical members of diabetes care teams.

- CMS should clarify and build on the 2013 final rule, expanding the scope of Medicaid-reimbursable services by CHWs to include social, behavioral, and economic supports as part of covered services.
 - ◊ Clarify that Medicaid funding is available for CHWs to address social determinants of health (SDOH), building on the January 7, 2021 - CMS SDOH Roadmap.
 - ◊ Clarify that CHW qualifications should focus on life experience, interpersonal skills as natural helpers, community membership, as well as formal education or clinical training.
 - ◊ Develop policies that require CHW services be delivered in accordance with evidence-informed standards for CHW programs such as those developed by the National Committee for Quality Assurance, the CDC CHW Core Consensus (C3) Project, the Community Guide, and the National Association of Community Health Workers (NACHW).
- Increase funding to CDC to expand programs to assist all states in infrastructure development and processes to integrate CHW services in a comprehensive, whole-person approach that includes economic, behavioral, and social supports, as well as clinical and preventive services.

Focus Area 4. Expand Virtual Care

Background and Rationale

Diabetes prevalence is higher in rural and underserved communities than in urban areas. People with diabetes living in rural and/or underserved communities have limited access to health care facilities and specialty care and often endure long and difficult commutes or lack the transportation needed to access guideline-recommended care. Travel and time constraints keep many individuals from receiving diabetes education services, adequate primary care, and specialty care. Additionally, Medicare beneficiaries using diabetes devices (for example, insulin pumps and continuous glucose monitors) are required to have regular interim medical visits to be approved for their ongoing use. The required in-person visits pose additional challenges to individuals with work or family demands or disabilities.

During the COVID-19 Public Health Emergency, CMS issued waivers to allow the use of telemedicine to facilitate data sharing, receipt of ongoing diabetes care and education, and continued use of diabetes devices without in-person visits. The waivers are well received by the medical community and patients and are helping patients receive needed care without in-person visits.

Virtual care, a broader term than telemedicine, generally encompasses (1) use of web-based portals for communication between patients and their care teams; (2) electronic consultations between primary care and specialty clinicians; (3) telehealth clinic visits; (4) data (from diabetes device) sharing between patients and their care teams; (5) diabetes education classes for patients using technology-based platforms; and (6) real-time, peer-to-peer consultations and mentoring for clinicians and care teams.

Virtual care, including telemedicine, can help care teams and patients access additional resources and services,^{288, 289} and reduce the gaps in receipt of high-quality diabetes care. Continuing access to and reimbursement for virtual care such as telemedicine visits will allow clinicians to provide best-practice diabetes care to rural and underserved communities.

Opportunities

To benefit from virtual care, patients with diabetes must have access to and subsequently adopt digital connectivity and services. The federal government is working to expand broadband access for those who lack digital connectivity and help them overcome barriers to adoption.

The Commission identified additional federal programs and policies that have shown great potential in helping deliver virtual care to a wide range of patients.

- **The VA/DoD Virtual Medical Center (VA-VMC).** The VA-VMC is a novel program developed jointly by the Department of Veterans Affairs and Department of Defense.²⁹⁰ This virtual approach to diabetes self-management education and support (DSMES) helps patients overcome travel and schedule barriers by providing access to real-time DSMES and peer support groups and a wealth of educational materials. This program became the first *nationally* certified DSMES program recognized by the American Diabetes Association. If used across federal agencies (for example, through collaborative agreements), this program can deliver virtual DSMES to patients who otherwise do not have access to DSMES services or have travel and time constraints.

- **E-consults.** CMS has implemented reimbursement codes for interprofessional consultations conducted through electronic communication (known as “e-consults”). E-consults are formal, synchronous or asynchronous, clinician-to-clinician consultations without patient presence and occur within a shared electronic health record or web-based portal. E-consults have been shown to improve access to specialty care, avoid delays in care, reduce costs to patients and the health care system, enhance clinician knowledge of how to better evaluate and/or manage many conditions, and improve communication and collaboration between clinicians. As an example, VA’s e-consults reduced response time for specialty consults from an average of 34.4 to 2.4 days across several specialties.²⁹¹⁻²⁹³

Recommendation 6.6: The National Clinical Care Commission recommends that Congress support use of virtual care modalities in the following ways:

- **Remove geographic and originating site restrictions so that CMS can provide access to telehealth services as appropriate.**
- **Make permanent the ability for Federally Qualified Health Centers and Rural Health Centers to provide services by telehealth.**
- **Make permanent the telehealth waiver for Diabetes Self-management Education and Support (DSMES)/Diabetes Self-Management Training (DSMT); and**
- **Maintain coverage for audio-only visits to comply with the Executive Order on *Advancing Racial Equity and Support for Underserved Communities*.**

Telehealth is safe and effective when compared to in-person visits for diabetes education and clinical care.²⁹⁴⁻²⁹⁸ For those with limited digital literacy or access, telephone visits have shown equivalent benefits to video visits.²⁹⁹ Telehealth serves as an important option for patients to receive individualized and optimized diabetes care. It can help improve clinical outcomes and lower costs.

Telementoring to Improve Access to High-Value Care for People With Diabetes

Background

Practices affiliated with the Indian Health Service (IHS) and with HRSA serve patient populations with a prevalence of diabetes that exceeds the national average.^{300, 301} Patients served in such settings may also find it more difficult to receive specialty care.³⁰²⁻³⁰⁴ Front line primary care clinicians serving these patients are often responsible for delivering ongoing care but may not have all the tools and specialty expertise needed. Virtual care such as technology-enabled collaborative learning and capacity building or telementoring programs can help the clinicians access specialty care expertise effectively and more cost-efficiently. Several federal departments and agencies such as VA, CMS, IHS, AHRQ,³⁰⁵ and HRSA have already begun using telementoring to help meet the needs of the patients they serve, though to a limited extent.

The Extension for Community Healthcare Outcomes (Project ECHO) based at the University of New Mexico is an example of successful telementoring programs. Its hub-and-spoke model enables capacity building through ongoing, knowledge-sharing between geographically isolated care teams and a faculty of specialty care experts.

Rationale

IHS and HRSA both face challenges to maximize the benefits of telementoring for people with diabetes. Despite having conducted pilot projects, each agency has limited capacity to continue or expand these programs. Funding for technology-enabled collaborative learning and capacity building was offered to IHS and HRSA through legislation,³⁰⁶ but competing demands for managing other health issues have reduced the funding available for addressing diabetes care. In addition, neither IHS nor HRSA has the internal administrative capacity to administer large demonstration projects of hubs (specialty experts) and spokes (primary care teams) and collect data to monitor effectiveness. Collaboration between CMMI, which has administrative expertise, and an entity experienced in diabetes care telementoring will enhance the effectiveness of demonstration projects within both IHS and HRSA.

Recommendation 6.7: The National Clinical Care Commission recommends that the Centers for Medicare & Medicaid Innovation (CMMI) fund a demonstration project with the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS) that utilizes a technology-enabled collaborative learning and capacity building model (for example, Project ECHO-type model) to support uptake and

implementation of diabetes care best practices among primary care providers and care teams. The project should include training of community health workers, payment for both hub and spoke participants' time, collection and analysis of interim data, and utilization of a shared-services approach for training on the telementoring model, infrastructure, and data collection to inform broader implementation.

- In collaboration with HRSA, provide diabetes-related telementoring to small or rural health clinics (spokes) to include focus on social determinants of health and behavioral health issues that impact diabetes outcomes and leverage existing academic center hubs to support uptake and implementation of diabetes care best practices.
- In collaboration with IHS and tribal and urban Indian clinics, create supportive learning and mentorship relationships to assist in implementing diabetes care best practice and leverage the existing Tribal Epidemiology Centers and academic center hubs.

The demonstration projects should include reimbursement for clinicians and members of the care team to attend mentoring sessions because this is an extension of patient care. Data collection should be designed to assess impacts on patient outcomes, clinician and care team satisfaction, and associated health care costs. If successful, expansion of this model may improve the receipt of high-quality, individualized diabetes care and optimize health outcomes for a large segment of the population that is largely underserved.

This recommendation is specific for HRSA and IHS to develop demonstration projects of clinician-to-clinician mentoring using a virtual platform to help improve access to diabetes specialty care for the patients they serve.

Focus Area 5. Hypoglycemia Safety and Quality Measure

Background

Quality of care is often tracked with quality measures to ensure favorable outcomes across populations. Such quality measures are often used by health systems and payers to drive performance and quality improvement. Quality measures for diabetes primarily focus on improving glucose control because the degree and duration of hyperglycemia are directly related to the risk of long-term diabetes complications (for example, blindness, end-stage kidney disease, and amputations). However, for many older adults with advanced complications and comorbidities and for people with limited life expectancy, such treatment goals have modest benefits and carry increased risk.

Rationale

Severe hypoglycemia (dangerously low blood glucose levels) is not uncommon among people treated with some diabetes medications including insulin. The risk of attendant harms (for example, falls, fractures, hospitalizations, and death) from severe hypoglycemia are increased in older adults. Therefore, less intensive glucose targets should be applied to older adults with diabetes who are taking medications that increase risks of hypoglycemia, but who are unable to recognize and/or appropriately treat hypoglycemia (for example, patients with dementia), and to individuals across the life span with clinical conditions that limit life expectancy (for example, patients with metastatic cancer). In such persons, the risks from hypoglycemia, treatment burden, and costs may outweigh any potential benefits. Such potential overtreatment lies at the intersection of low-value practices and patient safety and should be discouraged.

Current federal quality measures focus solely on avoiding high blood glucose levels. However, treatment approaches that relax glucose control in some older adults or those with limited life expectancy are widely considered high-quality diabetes care. Nonetheless, clinicians often treat such patients to achieve lower blood glucose levels, which is an unintended consequence of current quality measures. In doing so they may minimize or overlook the potential risks of hypoglycemia to the individual. Therefore, a quality measure that focuses on avoiding hypoglycemia needs to be developed and applied to patients with diabetes in whom hypoglycemia poses short-term risks for major complications.

Recommendation 6.8: The National Clinical Care Commission recommends that CMS develop and implement a quality measure to assess potential overtreatment, inappropriate treatment, or risk of harm among Medicare beneficiaries with diabetes and life-limiting conditions to reduce the incidence of severe hypoglycemia and improve patient safety.

Focus Area 6. Insulin Affordability

Background

Insulin is essential for life and for the survival of patients with type 1 diabetes. In type 1 diabetes, the pancreas makes so little insulin that without insulin treatment the person will develop dangerously high blood glucose levels, a condition termed diabetic ketoacidosis. Diabetic ketoacidosis is a medical emergency that almost always requires hospitalization and can be fatal. For other people with diabetes, their bodies make enough insulin to avoid ketoacidosis but not enough to control their blood glucose levels. These individuals require insulin to control glucose levels over time to avoid the chronic complications of diabetes. At least 7 million people in the U.S. require insulin to manage their diabetes and for many of these people, insulin is life-sustaining. Having access to insulin day in and day out is critical for managing diabetes and essential to achieving a long and healthy life.

Rationale

Diabetes treatment with insulin became available in the 1920s. Over time, major advances in the way insulin is formulated have enhanced its effectiveness. Many of these changes have long since moved from being proprietary and patent-protected. Despite this, the cost of insulin has increased dramatically at a rate that far exceeds the rate of inflation, making it unaffordable for many patients with diabetes. In 1999 a vial of insulin lispro (Humalog®) cost \$21 and in 2019 it cost \$332.³⁰⁷ A person with diabetes can require several vials of insulin each month, and the monthly cost for insulin can exceed \$1,000. This does not include the costs for the supplies needed to administer insulin and to monitor blood glucose levels. The high cost of insulin poses a tremendous barrier to optimal diabetes treatment. At least one in four individuals treated with insulin report rationing³⁰⁸ their insulin while even more make significant trade-offs in other aspects of their lives (for example, food, housing, transportation, etc.) to purchase the insulin they need.

Opportunities

Part D Senior Savings Model

In January 2021, CMMI launched a new approach for pharmacy payment called the Part D Senior Savings Model.³⁰⁹ The model is testing the impact of offering Medicare beneficiaries a choice of enhanced Part D plan options that have lower out-of-pocket costs for insulin. The program is available to beneficiaries who receive Part D coverage through stand-alone prescription drug plans or Medicare Advantage Prescription Drug plans. Beneficiaries have broad access to multiple types of insulin at a maximum copay of \$35 per insulin per month in the deductible, initial coverage, and coverage gap phases of the Part D benefit. Participating pharmaceutical manufacturers pay the 70% discount in the Part D coverage gap for the insulins they market. Part D sponsors are also required to encourage healthy behaviors and medication adherence through rewards and incentive programs. The Medicare Part D Senior Savings model has the potential to reduce out-of-pocket costs and provide stable, predictable copays for the insulins. This offers an opportunity for CMMI to conduct widespread testing and rigorous evaluation of the Part D Senior Savings Model, and if effective, encourage its broad implementation by CMS.

The above program serves as a promising, intermediary step. However, this does not apply to all Medicare beneficiaries with diabetes. For example, those who are using insulin pumps have their insulin covered by Medicare Part B and cannot take advantage of the Part D Senior Savings Model, nor can people with other forms of insurance or no insurance. Much more needs to be done to reduce the cost of insulin, a life-sustaining medication.

Recommendation 6.9: The National Clinical Care Commission recommends that federal policies and programs remove cost barriers to ensure that insulin is affordable for all people with diabetes and that no one with diabetes who needs insulin cannot get it because of cost.

Curbing major price escalations for insulin and making it more accessible will involve policies and programs of several federal agencies. The Commission's recommendation is based on what needs to be done, with recognition that how to accomplish this will be a complex task with many steps and components.

Possible interventions to make insulin accessible and affordable for people with diabetes:^{307, 310-312}

"The adverse outcomes associated with diabetes, and the resulting costs of care, can be reduced with effective treatments, preventive strategies, and diabetes self-management education and support."

American Diabetes Association

- Cap maximum price increases for insulin at no more than the rate of inflation.
- Limit out-of-pocket costs without increasing premiums or deductibles through one or more of the following policies:
 - ◊ Limit cost sharing to a copay of no more than \$35.
 - ◊ Provide first-dollar coverage.
 - ◊ Cap costs at no more than \$100 per month.
- Develop a payment model for Medicare Part B beneficiaries in addition to Part D that lowers out-of-pocket costs for insulin.
- Provide "safety net" measures and laws providing immediate access to insulin in emergency circumstances, especially for people with type 1 diabetes who are unable to afford insulin.
- Allow government negotiation of drug prices.
- Eliminate rebates or ensure that rebates that are paid by a manufacturer to Pharmacy Benefit Managers are transparent and passed on to patients without increasing premiums or deductibles.
- Reform the regulatory and legal processes to facilitate introducing biosimilar insulins to create marketplace competition.
- Eliminate anticompetitive arrangements including pay-for-delay, shadow pricing, "evergreening" of patents (that is, patent extensions for minor changes in the formulation or mode of delivery) and limit re-labeling brand drugs as "authorized generics" of the parent pharmaceutical company.

Patient Testimonial

--Andrew (Drew) Wickman

" I was diagnosed with 'sugar diabetes' at the age of 3 in 1949. I've seen a lot of changes over the last 72 years. I've gone from urine testing with a test tube and Clinitest tablets to finger sticks and then continuous glucose monitors. Insulin has gone from NPH U40 beef/pork insulin to genetically modified Humalog. Delivery has gone from a glass syringe and a needle as big as a pipe, which came with cleaning wires and a sharpening stone, to an insulin pump/CGM loop system. I remember buying a vial of insulin for \$1.40 and not having or needing insurance. Now without Medicare and insurance through my employer I couldn't afford to have type 1 diabetes. I've been fortunate to have suffered from only one complication in all these years. My Diabetic Retinopathy was treated with laser surgery and has been stable since around 1980 with only minimal loss of peripheral vision. I'm happy, healthy and active at the age of 74 and now my concerns involve Medicare regulations which are apparently made for people who live in cities and not for rural residents."



Focus Area 7. Coverage for Secondary Prevention

Background

Once diabetes is diagnosed, treatment goals are directed to maintaining health and preventing damage to the heart, eyes, kidneys, and nerves. Diabetes complications are the greatest cause of morbidity and mortality and the largest contributor to the cost of diabetes.³¹³ If complications are present, the cost of diabetes care is three times higher than when there are no complications.³¹⁴

Prevention strategies fall into three categories: primary prevention aimed at preventing a disease before it occurs, secondary prevention aimed at reducing the impact of a disease once it has occurred, and tertiary prevention aimed at reducing disability and restoring function in someone with a complication of the disease. Much can be done to avert (primary prevention), delay (secondary prevention), or mitigate (tertiary prevention) the complications of diabetes, particularly by adhering to evidence-based guidelines. Unfortunately, nearly two-thirds of people with diabetes are not receiving secondary or tertiary prevention care, putting them at risk for avoidable health care utilization and costs.²³¹

As a provision of the Affordable Care Act, health insurers are required to cover, at no cost to the patient, primary prevention services that the U.S. Preventive Services Task Force recommends as Grade A or Grade B. However, secondary prevention strategies (for example, diabetes self-management education and support) and tertiary prevention strategies (for example, eye exams to identify diabetic retinopathy in its earlier stages and allow treatment to prevent blindness) are not treated similarly, even if they are highly cost-effective.

Rationale

Providing pre-deductible coverage (that is, coverage at no cost to the patient) for some of the most critical secondary and tertiary prevention services for diabetes offers an opportunity to help close existing care gaps and the associated human and financial costs of diabetes complications. This is especially true for those with health disparities and the uninsured or under-insured. The causes for these treatment gaps are multifactorial and include patient-, clinician-, and health system-related factors. Lack of affordability, however, is a major patient-related factor that prevents optimized care and better outcomes. For most patients, including Medicare beneficiaries, secondary and tertiary prevention services require cost sharing (that is, copays) as part of the coverage. For people with diabetes, and especially those with lower incomes, cost sharing reduces treatment adherence. Removing cost sharing enhances adherence to prevention services and therapies.³¹⁵ A consequence of reduced adherence resulting from medication cost sharing is increases in health care utilization and costs from emergency department visits and hospital stays.³¹⁶ There are many

high-value secondary and tertiary prevention treatments and services that can delay the onset and progression of and disability associated with diabetes complications, but their use is often limited by cost.

Recommendation 6.10: The National Clinical Care Commission recommends that HHS establish a process to determine and regularly reevaluate high-value diabetes services and treatments to be fully covered (pre-deductible) by health insurance based on their ability to prevent development or progression of diabetes complications.

Some examples of services and treatments to consider for pre-deductible coverage:

- Equipment and supplies for self-monitoring blood glucose and continuous glucose monitoring
- Diabetes Self-Management Training (DSMT) (Medicare) / Diabetes Self-Management Education and Support (DSMES) (other than Medicare)
- Retinal exams (“diabetes eye exam”)
- Shoes and foot orthotics for people with diabetes who have lost sensation in their feet because of nerve damage from diabetes
- Certain high-value medications shown to reduce heart disease and kidney failure in patients with diabetes. These medications include sodium-glucose co-transporter-2 inhibitors, glucagon-like peptide-1 receptor agonists, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, and mineralocorticoid receptor antagonists

Focus Area 8. Research Needs

Evaluation of Barriers to Diabetes Self-Management Education and Support

The underutilization of DSMES is multifactorial, with barriers at the health system, clinician, and patient levels. Some of the barriers have been identified, but research is needed to uncover and understand additional barriers.²³² In addition, research is needed to test approaches to address these barriers and improve referral to and uptake of DSMES. Critical to the research process is stakeholder engagement, to understand the perspectives of payers, providers, referring clinicians, and people with diabetes, with the goal of developing and disseminating effective approaches to increase utilization of and continued engagement with DSMES. Research should test and identify innovations that are able to increase DSMES utilization, are feasible and acceptable to diverse patient populations and relevant stakeholders, and have the potential to be sustained.

Recommendation 6.11: The National Clinical Care Commission recommends that the National Institutes of Health prioritize funding for research to identify and address factors that affect referrals to and patient uptake of DSMES such as patient-, clinician-, and systemic-level barriers, quality measures and incentives, and patient-reported outcomes and perspectives.

Examples of research approaches to be tested include:

- Address social determinants of health and racial and systemic inequities that prevent populations disproportionately burdened with diabetes from engagement in DSMES.
- Use novel care delivery paradigms that may involve integration and collaboration of community and clinic systems to broaden referral and uptake of DSMES.
- Enhance health care system processes to ensure provider understanding of the need for DSMES and provide support for making and increasing referrals.
- Improve provider communication with people with diabetes and foster shared decision making to encourage uptake and engagement in DSMES.
- Leverage and engage key family members and peer support to enhance engagement of people with diabetes in the DSMES process.

Implementation Research for Team-based Care

There is a need to study implementation strategies to accelerate adoption of team-based care to improve diabetes outcomes. Such implementation research attempts to close the gap between knowing and doing (documented as a 17-year gap by the Institute of Medicine) by identifying and addressing barriers to the uptake of new, proven health interventions.^{317, 318} Historically, funding for dissemination and implementation research has not been prioritized by federal agencies. Research should be supported by federal agencies to study new models of care delivery and ways to enhance uptake of team-based care.

Recommendation 6.12: The National Clinical Care Commission recommends increased funding for implementation research across federal agencies (for example, AHRQ, NIH, CMS, HRSA, IHS, CDC, VA, and DoD) to better translate team-based care into practice and test new team-based care models and payment systems to improve diabetes care and outcomes.

Research is needed to identify the best ways to implement team-based care and eliminate delays in implementation. As an example of an implementation research project, an HHS Office of Minority Health grantee initiated a project to train staff at 20 federally qualified

health centers in the MidWest Clinicians' Network, a member organization of health centers across 10 Midwestern states, to offer group visits for patients with diabetes. While diabetes group visits have been shown to be effective in improving health outcomes (such as blood sugar and blood pressure control, and quality of life), there is limited research on how to integrate diabetes group visits into community health centers serving disadvantaged populations and their cost-effectiveness. If successful, these study results could be scaled to the 140 community health centers in the MidWest Clinicians Network and to other community health centers across the U.S.³¹⁹ Research projects such as this can provide important new information on barriers and facilitators to implementation and dissemination of team-based care.

Impact of Digital Connectivity as a Social Determinant of Health

Diabetes is more prevalent in communities with low internet connectivity, lower incomes, lower achieved education levels, and older age. Indeed, there is an inverse relationship between the prevalence of diabetes and the degree of broadband connectivity. Digital connectivity, or lack of it, is associated with not only access to health care but also education and distance learning, employment such as remote work, job searches, online applications, training, and much more. This suggests that digital connectivity is a “super” social determinant of health because it amplifies the impact of other social factors.³²⁰⁻³²³ There is an urgent need to both accelerate broadband access and understand the barriers to adoption of digital resources to improve health and health outcomes and reduce disparities for those at risk for or living with diabetes. Further, investigation of the mechanisms of how digital connectivity is associated with health is critical to improving health outcomes.

Recommendation 6.13: The National Clinical Care Commission recommends that digital connectivity be investigated as a social determinant of health affecting the development and progression of diabetes.

- The Federal Communications Commission (FCC), the U.S. Department of Agriculture (USDA), and the U.S. Department of Health and Human Services (HHS) should expand the scope of an inter-agency memorandum of understanding (MOU) beyond the Rural Telehealth Initiative or establish another mechanism to bring together the appropriate federal agencies to share information on and investigate (1) the relationship between digital connectivity and health; and (2) the types of digital services and the level of adoption of digital services needed to make a positive impact on health.
- FCC should conduct research to better understand the associations of digital connectivity, diabetes prevalence, and improved diabetes health outcomes.

Chapter 7: Looking Forward

Diabetes is a serious clinical and public health problem. The disease and its complications affect tens of millions of Americans of all ages, lead to preventable suffering and death, impact families, pose an enormous financial burden on our nation's health care system and on society, and contribute to health inequities. Despite clinical, public health, and government efforts, the number of Americans with diabetes and its complications has grown each year, and diabetes costs continue to rise. To reverse these trends and to protect the health and wellbeing of Americans, the National Clinical Care Commission believes that our nation needs (1) a National Diabetes Strategy informed by this report to leverage the work of federal programs and (2) an Office of National Diabetes Policy to further develop the National Diabetes Strategy, monitor its implementation, and report progress to Congress and to the American people.

Develop and Implement a National Diabetes Strategy

The National Clinical Care Commission 2021 Report to Congress and the Secretary of Health and Human Services provides a framework for a comprehensive National Diabetes Strategy and includes specific recommendations for both health- and non-health-related agencies to better address the diabetes epidemic.

The National Clinical Care Commission recommends that the National Diabetes Strategy prioritize the following:

- Enhance collaboration and coordination across all federal agencies on matters that impact diabetes prevention and treatment.
- Influence social and environmental conditions by improving dietary quality, marketing oversight, food labeling, and the ambient and built environments.
- Ensure that achieving health equity is a goal of all federal policies and programs that impact people at risk for and with diabetes.
- Improve access to comprehensive, high-quality, and affordable health care for people at risk for and with diabetes.
- Make medications accessible and affordable for people with diabetes.
- Prevent diabetes in those at high risk by increasing awareness of prediabetes and ensuring that those with prediabetes have access to lifestyle intervention programs.

- Reduce regulatory barriers for key diabetes treatments, expand the health care workforce, and implement policies that facilitate safe and effective care for people at risk for or with diabetes.

The Commission also urges Congress to promptly implement the Commission's recommendations to prevent and control diabetes, to improve the health outcomes of millions of Americans with diabetes, and to protect the health and wellbeing of current and future generations of Americans at risk for developing diabetes.

Establish an Office of National Diabetes Policy

Over the past decades, the federal government has invested substantial health care resources to combat the diabetes epidemic in the U.S. As highlighted in the report, some of the federal programs have made great strides in helping control diabetes and improve patients' health outcomes. However, the Commission finds that the federal agencies' and departments' policies and programs that impact both health care and non-health functions should be further leveraged to improve efficiency and to maximize the impact of federal resources, and that a national office focusing on policies and programs to address the diabetes epidemic is needed to ensure coordination across all agencies and departments.

To develop, implement, and monitor the National Diabetes Strategy built upon the National Clinical Care Commission's recommendations, the Commission recommends Congress create an Office of National Diabetes Policy (as described in Chapter 3). The Office of the National Diabetes Policy should coordinate federal policies and programs that have an impact on diabetes across agencies and departments and evaluate, monitor, and report progress on the implementation of the National Clinical Care Commission's recommendations and the development and implementation of the National Diabetes Strategy to Congress and the public on an annual basis.

The National Clinical Care Commission urges Congress and the Secretary of Health and Human Services to promptly enact these recommendations and implement a long-term strategy to combat this growing health crisis and help the more than 100 million Americans with or at risk for diabetes.

Appendices

Appendix A. National Clinical Care Commission

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Appendix B. National Clinical Care Commission Subcommittees

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Appendix C. Summary of the National Clinical Care Commission's Recommendations

Foundational Recommendations (Chapter 3)

Recommendation 3.1: The National Clinical Care Commission recommends the creation of the Office of National Diabetes Policy (ONDP) to develop and implement a national diabetes strategy that leverages and coordinates work across federal agencies and departments to positively change the social and environmental conditions that are promoting the type 2 diabetes epidemic. The National Clinical Care Commission further recommends that the ONDP be established at a level above the U.S. Department of Health and Human Services (HHS) and be provided with funding to facilitate its effectiveness and accountability.

- 3.1a. The ONDP should include, but not be limited to, departments and agencies outlined in the National Clinical Care Commission Report to Congress, including the U.S. Department of Agriculture, the U.S. Department of Transportation, the U.S. Department of Education, the U.S. Department of Justice, the U.S. Department of Defense, the U.S. Department of Labor, the U.S. Department of the Treasury, the Federal Trade Commission, the Federal Communications Commission, the U.S. Department of Housing and Urban Development, the Federal Bureau of Prisons, the U.S. Environmental Protection Agency, the Bureau of Indian Education, the Bureau of Indian Affairs, the U.S. Department of Veterans Affairs, and the U.S. Department of Health and Human Services, among others.
- 3.1b. ONDP's responsibilities should include: (1) overseeing the implementation and monitoring of the NCCC recommendations; (2) ensuring action, collaboration, and coordination among federal agencies with respect to trans-agency approaches to delaying, preventing, and controlling type 2 diabetes; (3) making recommendations to the executive and legislative branches regarding actions they can take to delay, prevent, and better treat type 2 diabetes; (4) advancing a health-in-all-policies (HiAP) agenda with respect to diabetes; and (5) providing resources and employing Health Impact Assessments (HIAs) for relevant policies across non-health departments and agencies.
- 3.1c. HHS should also establish an entity within the Office of the Secretary of HHS to (1) coordinate work across HHS to better prevent and treat diabetes; and (2) serve in the ONDP to foster broad, trans-agency collaborative work between HHS and non-HHS federal agencies aimed at positively changing the social and environmental contexts that are driving the type 2 diabetes epidemic.

Recommendation 3.2: The National Clinical Care Commission recommends that federal policies and programs be designed to ensure that all people at risk for and with diabetes have access to comprehensive, high-quality, and affordable health care and that no one at risk for or with diabetes who needs health care cannot get it because of cost.

Recommendation 3.3: The National Clinical Care Commission recommends that achieving health equity be a component of all federal policies and programs that affect people at risk for and with diabetes. Specifically, the National Clinical Care Commission recommends:

- Federal agencies consider and evaluate the impact on health disparities of all new, all revised, and selected existing policies and programs that affect diabetes prevention, diabetes, and the complications of diabetes.
- Federal agencies ensure the collection and use of data to assess the impact of those policies and programs on health disparities and modify the policies and/or programs as needed to reduce health disparities.

Recommendations for Population-Level Diabetes Prevention and Control (Chapter 4)

Recommendation 4.1: The National Clinical Care Commission recommends that the USDA SNAP program be enhanced to both reduce food insecurity and improve nutrition sufficiency, both of which will help prevent type 2 diabetes and diabetes complications.

- 4.1a. Implement SNAP-wide fruits and vegetables incentives demonstrated to be effective by the Gus Schumacher Nutrition Incentive Program (GusNIP) for all beneficiaries, by providing at least a 30% incentive on the purchase of fruits and vegetables to improve dietary quality.
- 4.1b. Eliminate sugar-sweetened beverages from allowable SNAP purchases.
- 4.1c. Improve and expand SNAP-Education to provide diabetes and nutrition education and awareness programs for beneficiaries to increase fruit and vegetable consumption, reduce added sugars consumption (especially sugar-sweetened beverages), and increase media/marketing literacy, as well as increase its support for policy, systems, and environmental approaches to improve dietary quality.
- 4.1d. Incentivize testing and implementation of innovative state-level policies, practices, and programs to enhance the access to and receipt of SNAP benefits by eligible individuals and households, and to reduce geographic, racial, ethnic, and linguistic disparities in SNAP enrollment and retention.

- 4.1e. Sustain efforts to ensure that SNAP benefit allotments are adequate to allow for both food and nutrition security to help prevent and manage diabetes among beneficiaries and implement a process to regularly assess and update the adequacy of SNAP benefits with respect to lowering diabetes risk and managing diabetes.

Recommendation 4.2: The National Clinical Care Commission recommends that USDA non-SNAP feeding programs be better leveraged to prevent diabetes in women, children, and adolescents by (1) enhancing Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); (2) further harnessing the National School Lunch and Breakfast Programs to improve dietary quality; and (3) expanding the Summer Nutrition Programs and the Fresh Fruit and Vegetable Program.

- 4.2a. Further strengthen the WIC program by sustaining the evidence-based, prescriptive WIC food package; expand funding for breastfeeding peer counseling services (see also Recommendation 4.7); invest in improvements to information systems and technology to enable greater access and service for WIC participants.
- 4.2b. Maintain the nutrition standards found to be salutary in the Healthy Hunger-Free Kids Act (HHFKA) and provide adequate funding for schools to (a) purchase, prepare, and serve healthy, quality foods and beverages for school meals and snacks to meet the HHFKA nutrition standards and (b) deliver training and technical assistance to support maintenance and attainment of HHFKA nutrition standards, and skills to run a program to effectively prevent diabetes.
- 4.2c. In collaboration with the U.S. Department of Education, the US Department of the Interior, the U.S. Environmental Protection Agency, USDA should ensure that all students in public and tribal schools have reliable access to safe, appealing, and free drinking water. This could be accomplished through a combination of federal incentives and possibly tying receipt of funding for school-based food programs in the future.
- 4.2d. Prohibit the sale of calorically dense and nutrient-poor foods, including sugar-sweetened beverages, on public school campuses; and employ an incentive program to enable schools to cover essential costs such as those for physical activity/athletic programs previously underwritten by the sale of such unhealthy foods and beverages. Receipt of federal funds for school-based food programs should be tied to implementation of such restrictions.
- 4.2e. Strengthen, increase funding for, and improve access to and participation in summer feeding programs, including partnerships and collaboration between public and private sectors, to promote innovation in rural areas and other high-risk areas where participation has been low. Funding for these programs should be increased to enable scaling to meet population needs.

Recommendation 4.3: The National Clinical Care Commission recommends that resources be provided to the USDA to create an environmentally friendly and sustainable U.S. food system promoting the production, supply, and accessibility of foods such as “specialty crops” (fresh fruits, dried fruits, vegetables, tree nuts) that will attenuate the risk for type 2 diabetes and the complications of diabetes.

- 4.3a. Significantly expand and increase funding for the USDA Specialty Crop Block Grants to support the safe production and distribution of food and drive demand through education for specialty crops to increase dietary diversity as an aid to help people prevent and/or control diabetes.
- 4.3b. Significantly increase funding for the USDA Specialty Crop Research Initiative grants to improve specialty crop production efficiency, handling and processing, productivity, and profitability (including specialty crop policy and marketing) over the long term in a sustainable manner.
- 4.3c. Significantly expand and increase funding for the USDA evidence-based Healthy Food Financing Initiative, a federal effort to improve food access and health in low-income, underserved communities and communities of color in urban and rural areas that supports farmers and healthy food retailers to improve access to nutritious, affordable, and fresh food.
- 4.3d. Funding and expansion should be implemented by 2030 to achieve population-wide benefits.

Recommendation 4.4: The National Clinical Care Commission recommends that all relevant federal agencies promote the consumption of water and reduce the consumption of sugar-sweetened beverages in the U.S. population, and that they employ all the necessary tools to achieve these goals, including education, communication, accessibility, water infrastructure, and sugar-sweetened beverage taxation.

- 4.4a. USDA should add a symbol for drinking water to the MyPlate graphic and increase water promotion messaging in all consumer-facing materials issued by its Center for Nutrition Policy Promotion. Water is not currently depicted on the USDA MyPlate.
- 4.4b. Child nutrition programs should be a conduit for education to promote consumption of water and reduce consumption of sugar-sweetened beverages. USDA should encourage hydrating with water instead of sugar-sweetened beverages and provide safe water education in WIC nutrition education and in childcare settings. Congress should harness the Child Nutrition Reauthorization Act to strengthen existing water provisions for school nutrition programs.

- 4.4c. HHS should commission a scientific report under the joint auspices of the U.S. Surgeon General and include other relevant federal health agencies to summarize and present a synthesis of the evidence regarding the causal relationship between sugar-sweetened beverage consumption and obesity and type 2 diabetes. The report should be authored by experts in diabetes and clinical medicine, nutrition and metabolism, epidemiology and public health, and health disparities; authors should be free of any conflicts of interest related to the food and beverage industry.
- 4.4d. With additional funding, CDC, NIH, and USDA should develop and implement a national campaign and associated materials to both promote consumption of water and reduce consumption of sugar-sweetened beverages as a strategy to promote overall health, including the prevention of obesity, type 2 diabetes, and cardiovascular disease. CDC should also include such messages across all its relevant programs.
- 4.4e. Similar to the federal tobacco tax, the U.S. Department of the Treasury should impose an excise (not sales) tax on sugar-sweetened beverages to cause at least a 10% to 20% increase in their shelf price. The revenues generated should be reinvested to promote the health of those communities that bear a disproportionate burden of type 2 diabetes (for example, promote child nutrition and improve access to clean water in low-income communities and communities of color). This federal sugar-sweetened beverage tax should not pre-empt state or local authorities from levying their own additional excise tax on sugar-sweetened beverages.
- 4.4f. All federal agencies should promote drinking water and reduce sugar-sweetened beverage consumption within their own organizations and through the grants and programs they fund or administer. All agencies should increase access to free, clean, and appealing sources of drinking water for their employees and visitors and develop procurement and other policies that curb the availability and sale of sugar-sweetened beverages to their employees and visitors.
- 4.4g. HHS should serve as a federal model by (a) ensuring onsite access to safe, clean, and appealing drinking water; (b) restricting the sale of sugar-sweetened beverages in HHS-owned or HHS-leased offices, workplaces, and healthcare facilities; and (c) measuring the impact of these interventions on employee behavior and diabetes-related outcomes through voluntary participation in an evaluation of the model.
- 4.4h. The Office of the U.S. Trade Representative should ensure that all international trade agreements allow for the taxation of sugar-sweetened beverages and front-of-package health advisory labels and icons (see also Recommendation 4.5).

Recommendation 4.5: The National Clinical Care Commission recommends that the U.S. Food and Drug Administration (FDA) improve its food and beverage labeling regulations that influence both food and beverage industry practices and consumer behavior to better prevent and control diabetes.

- 4.5a. Congress should authorize FDA to implement a new national, compulsory, uniform, simple, easily recognizable and understandable front-of-package icon system that alerts consumers to the health attributes and health risks of food and beverage products based on their ingredients. The front-of-package icon/warning system should be informed by evidence accrued from existing epidemiological, clinical, and nutritional sciences, and its design should be informed by health communication science.
- 4.5b. In communicating added sugar content contained in products in the revised Nutrition Facts Label (and in the Recommended Daily Allowance), FDA should use teaspoon units in addition to grams to enable consumers to estimate their added sugar intake relative to daily limits.
- 4.5c. FDA should implement a robust, multilingual communication campaign to improve awareness of the new labeling on added sugar and the rationale for the labeling (highlighting the potential harms of consuming excess added sugars).
- 4.5d. FDA should update its policies and regulations to prevent industry claims on food and beverage products that mislead U.S. consumers to believe that unhealthy foods are healthy.

Recommendation 4.6: The National Clinical Care Commission recommends that the Federal Trade Commission – in order to prevent children’s exposure to, and consumption of, calorie-dense and nutrient-poor foods and beverages that can lead to obesity and type 2 diabetes -- be provided the authority, mandate, and requisite resources to (a) create guidelines and rules regarding the marketing and advertising practices of the food and beverage industry and associated communication networks and platforms targeted to children younger than 13 years old, (b) restrict industry practices based on these rules, (c) fully monitor these practices, and (d) enforce such rules.

Recommendation 4.7: The National Clinical Care Commission recommends that federal agencies promote and support breastfeeding to (a) increase breastfeeding rates, (b) enhance the intensity and duration of breastfeeding among mothers who breastfeed, and (c) reduce disparities in breastfeeding rates, duration, and intensity. Additional funding should be provided for federal programs that promote and support breastfeeding to overcome persistent societal and employment-based obstacles to breastfeeding.

- 4.7a: Provide additional funding for successful programs that promote and support breastfeeding, including USDA’s Food Nutrition Service (FNS) WIC Peer Counselor programs; HRSA Maternal and Child Health Bureau’s Healthy Start program, the Maternal, Infant, and Early Childhood Home Visiting Program; CDC’s Maternity Practices in Infant Nutrition and Care and Breastfeeding Report Card.
- 4.7b: The Department of Labor should
 - ◊ Expand existing federal protections for mothers in the workplace including mothers covered under the Fair Labor Standards Act (non-salaried employees) as well as those who are not covered under the Fair Labor Standards Act (salaried employees).
 - ◊ Develop and disseminate resources to help employers comply with federal law requiring them to provide the time and a place for nursing mothers to express breast milk.
 - ◊ Implement a monitoring system to ensure that employers are complying with federal law requiring that they implement lactation support programs.
- 4.7c: NIH, the Agency for Healthcare Research and Quality, the Center for Medicare and Medicaid Innovation, USDA, and other federal agencies should support community-based and community-informed demonstration projects and research to (1) identify and evaluate the impact of effective, evidence-based breastfeeding support interventions among minority women and women with lower socioeconomic status; and (2) inform implementation and scaling efforts.
- 4.7d: HHS should update the 2011 Surgeon General’s Call to Action to Support Breastfeeding to reflect the current landscape of breastfeeding research and provide updated breastfeeding policy and program guidance for the new generation of health care providers, public health officials, women, and families.
- 4.7e: CMS should enact and adequately fund a Medicaid incentive payment mechanism to incentivize hospitals and facilities providing maternal and newborn services to implement and demonstrate adherence to evidence-based policies, practices, and procedures proven effective in both initiating and increasing the duration of breastfeeding (for example, the Ten Steps to Successful Breastfeeding framework developed by the World Health Organization and the United Nations Children’s Emergency Fund [UNICEF]).
- 4.7f: Enact national maternity leave legislation to provide mothers with up to three months of paid leave, which has been shown to both increase rates of breastfeeding initiation and enhance the duration of breastfeeding. The paid leave provided under this legislation would be distinct from unpaid leave available to employees through the Family and Medical Leave Act.

Recommendation 4.8: The National Clinical Care Commission recommends that all federal agencies whose work influences the ambient (air, water, land, and chemical) and built environments modify their policies, practices, regulations, and funding decisions so as to lead to environmental changes to prevent and control diabetes.

- 4.8a. All federal agencies should limit the extent to which their work contributes to individual-level and population-level exposure to environmental pollutants and contaminants associated with diabetes and/or diabetes complications. The Environmental Protection Agency should ensure that environmental protections are in place to limit individual-level and population-level exposure and implement abatement measures, prioritizing those exposures that contribute to diabetes-related disparities.
- 4.8b. All federal agencies (in particular, the U.S. Department of Transportation and the U.S. Department of Housing and Urban Development [HUD]) should modify their policies, practices, regulations, and funding decisions related to the built environment to prevent diabetes and diabetes complications by enhancing increasing walkability, green space, physical activity resources, and active transport opportunities. Priority should be given to those regions and projects that could mitigate the effects of unhealthy built environments on diabetes-related disparities.

Recommendation 4.9: The National Clinical Care Commission recommends that, to reduce type 2 diabetes incidence and diabetes complications, housing opportunities for low-income individuals and families be expanded, and that such individuals and families be housed in health-promoting environments.

- 4.9a. The U.S. Department of Housing and Urban Development (HUD) should expand its federal housing assistance programs to allow access for more qualifying families, such that over a 20-year period, all that qualify can access subsidized or public housing.
- 4.9b. The Internal Revenue Service (IRS) should further incentivize developers to place new housing units in areas of low poverty, as data show that moving people from areas of high poverty to low poverty favorably affects the incidence of obesity and diabetes.
- 4.9c. The IRS should mandate that states include neighborhood health parameters (such as availability of health care services, transportation, employment opportunities, education opportunities, food availability, and physical activity resources) in the required IRS Qualified Allocation Plan criteria.
- 4.9d. IRS should establish a means to fund or subsidize cost of embedding health services (if needed) in housing developments to incentivize committing space or employing unused space for such services in their plans.

- 4.9e. HUD should broaden implementation of indoor smoke-free policies to include subsidized multi-unit housing, require multi-unit housing adopting smoke-free policies to provide access to cessation resources (that is, referrals to cessation resources), and in collaboration with the CDC Office on Smoking and Health, work to align these policies with its related policies in public housing so as to ensure that loss of housing is not an unintended consequence.

Recommendation 4.10: The National Clinical Care Commission recommends federal investments in research that will yield discoveries that generate population-level benefits in the prevention and control of type 2 diabetes, with a particular focus on elucidating and changing the social and environmental conditions associated with greater risk of diabetes and its complications.

- 4.10a. The U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), the U.S. Department of Transportation (DoT), the Federal Trade Commission (FTC), the Federal Communications Commission (FCC), the Food and Drug Administration (FDA), etc. should fund research into how their policies and practices affect diabetes risk and management and could be changed or (if/when beneficial) amplified to better prevent and control diabetes.
- 4.10b. The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) should support large scale natural experiments research -- including cost-effectiveness analysis -- to inform the evidence base related to social and environmental policies that prevent and control type 2 diabetes. Special focus should be paid to "health in all policies" types of interventions relevant to non-health agencies' activities and other public health (non-clinical) interventions. The Centers for Medicare & Medicaid Innovation (CMMI) or alternative federal entities should support demonstration projects in collaboration with non-health agencies related to influencing social determinants of health and reducing diabetes risk, improving diabetes control, and preventing complications (for example, USDA's SNAP interventions, the U.S. Department of Housing and Urban Development's housing interventions, EPA and freshwater interventions, DoT and walkability interventions).
- 4.10c. Investments in research training need to be made by NIH, CDC, and non-health agencies to enhance the workforce skilled in the competencies needed to carry out health impact assessments and related simulation work.
- 4.10d. NIH should expand its initiative on Precision Nutrition to (1) include clinical trials that can inform critical population health questions related to which foods, beverages, ingredients, and additives promote/prevent the development of type 2 diabetes; (2) include studies of communication interventions and (counter) marketing practices to inform which practices work best for which sub-populations

with respect to changing dietary patterns to prevent type 2 diabetes, and which practices elevate diabetes risk; (3) expand the definition of “precision” to go beyond targeting the individual to include targeting cultural and geographic entities (neighborhoods).

- 4.10e. NIH should encourage that nutrition and metabolic research accurately quantify water intake and use this information to better study the associations between water consumption and health across the lifespan. USDA should develop methods to incorporate water consumption into USDA Food Patterns (water is a beverage that currently is not a contributor to USDA food groups or subgroups).
- 4.10f. NIH should support research (in collaboration with other federal agencies) to better understand the role of (1) exposures related to environmental pollutants, toxins, contaminants, unclean water, and endocrine-disrupting chemicals on metabolic function and diabetes risk; and (2) life course trauma (including interpersonal violence, discrimination, racism, and disability) on metabolic function and diabetes risk, and associated interventions to reduce exposure to such trauma and/or mitigate the effects of trauma on diabetes outcomes.

Recommendations for Diabetes Prevention in Targeted Populations (Chapter 5)

Recommendation 5.1: The National Clinical Care Commission recommends increasing support to CDC for its campaign to raise awareness of prediabetes and promote enrollment in the National DPP lifestyle change program.

- To more effectively reach populations disproportionately affected by type 2 diabetes risk, CDC should use multiple methods including social media to increase awareness of prediabetes and the opportunity to delay or prevent type 2 diabetes.
- CDC should continue tracking visits to the Do I Have Prediabetes campaign page and completions of the prediabetes risk test, with an expanded focus on the degree to which populations at increased risk are being reached in order to reduce disparities in awareness and engagement in interventions.

Recommendation 5.2: The National Clinical Care Commission recommends that the Centers for Medicare & Medicaid Services provide coverage for hemoglobin A1c testing when used to screen for prediabetes.

Recommendation 5.3: The National Clinical Care Commission recommends that all federal agencies that directly deliver or influence the delivery of medical care should implement the 2019 American Medical Association-proposed prediabetes quality measures related to screening for abnormal blood glucose, intervention for prediabetes, and retesting of abnormal blood glucose in patients with prediabetes.*

- These agencies should implement a process for systematically using administrative and clinical data to identify patients at risk for or already meeting criteria for prediabetes and to ensure appropriate referral and follow-up.
- To support implementation of these measures, quality-improvement programs should be introduced to improve performance and reduce disparities.

Recommendation 5.4: The National Clinical Care Commission recommends that funding be provided to NIH to collect, analyze, and summarize the available data from the Diabetes Prevention Program study describing the effectiveness and safety of metformin for type 2 diabetes delay or prevention in patients with prediabetes, including subpopulations most likely to benefit. Such a summary (with safety and efficacy data) should then be used to inform an appropriate submitter's request for FDA to review and consider an indication for the use of metformin in high-risk patients with prediabetes.

Recommendation 5.5: The National Clinical Care Commission recommends, consistent with provisions of the Patient Protection and Affordable Care Act, that all insurers be required to provide coverage for participation in and completion of a CDC-recognized diabetes prevention program for those who are eligible.

Recommendation 5.6: The National Clinical Care Commission recommends that Congress promote coverage for all proven-effective modes of delivery (for example, in-person, online, and distance learning [telehealth]) for evidence-based interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards.

Recommendation 5.7: The National Clinical Care Commission recommends that the Medicare Diabetes Prevention Program (MDPP) be approved as a permanent covered benefit (not only a model expansion service) and that coverage of MDPP be expanded to include virtual delivery. Furthermore, the "once in a lifetime" limit on participation in the MDPP should be removed.

* The USPSTF now recommends screening for prediabetes and type 2 diabetes in adults aged 35 to 70 years who have overweight or obesity. (<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/screening-for-prediabetes-and-type-2-diabetes>)

Recommendation 5.8: The National Clinical Care Commission recommends that CDC continues its efforts to streamline the CDC recognition process for the National DPP recognition process while maintaining quality, and that CMS streamline its payment process for the MDPP. Differences in program eligibility, delivery modality, and duration between the National DPP (led by CDC) and the MDPP (led by CMS) should also be eliminated or, at a minimum, reduced.*

Recommendation 5.9: The National Clinical Care Commission recommends that funding be provided to support the testing of new payment models that allow for greater up-front payments and more equitable risk-sharing between CMS and MDPP program delivery organizations. In addition, there should be an increase in payment levels to MDPP program delivery organizations to make MDPP programs financially sustainable.*

Recommendation 5.10: The National Clinical Care Commission recommends that financial incentives be provided for state Medicaid programs to cover the National DPP lifestyle change program and other evidence-based type 2 diabetes prevention interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards. This should include coverage of all proven modes of delivery (that is, in-person, online, and distance learning or telehealth) that produce successful participant outcomes.

Recommendation 5.11: The National Clinical Care Commission recommends

- Funding for the Special Diabetes Program for Indians (SDPI) in five-year increments so that evidenced-based tribal diabetes prevention programs have the resources to (1) sustain the effort to combat diabetes and its complications; (2) develop additional culturally appropriate, high-impact type 2 diabetes prevention interventions; and (3) evaluate outcomes.
- An increase in SDPI funding to address inflation costs, which have consumed more than 34% of the program's resources since 2004, the last year Congress increased funding for the Special Diabetes Program. In the future, annual increases in funding should, at a minimum, address the costs of inflation.
- An increase in funding to HRSA's Delta States Network Grant Program to allow the program to include type 2 diabetes prevention as a focus.

* The National Clinical Care Commission notes that the CMS CY 2022 Physician Fee Schedule Proposed Rule, which if adopted, may better align the duration of the MDPP and National DPP, and would increase MDPP payment for participants who attend at least 9 sessions, was recently posted for public comment. (<https://www.govinfo.gov/content/pkg/FR-2021-07-23/pdf/2021-14973.pdf>)

Recommendation 5.12: The National Clinical Care Commission recommends funding type 2 diabetes prevention research to discover how to ensure that all individuals at high risk of developing type 2 diabetes are able to lower their risk for diabetes and its complications. Examples of areas for further research include:

- What impediments prevent participation in effective diabetes prevention programs for communities with the greatest needs?
- Are programs that combine both lifestyle intervention and metformin to prevent diabetes more effective than programs with either lifestyle change or metformin alone?
- What is the best number, frequency, duration, and content of lifestyle intervention sessions to successfully prevent diabetes in the long term?
- What are the barriers to long-term maintenance of weight loss for those people who successfully completed a diabetes prevention program?
- Finally, dissemination and implementation research is needed to determine how to best promote the use of effective in-person and virtual diabetes prevention programs. Such efforts should aim to understand and address barriers at multiple levels, including systemic policies, health care provider referrals, and patient uptake.

Recommendation 5.13: The National Clinical Care Commission recommends

- Funding the Special Diabetes Program (SDP) in five-year increments so that new, innovative research can effectively be developed.
- An increase in SDP program funding to address inflation costs, which have consumed more than 34% of the program's resources since 2004, the last year Congress increased funding for SDP. In the future, annual increases in funding should, at a minimum, address the costs of inflation.

Recommendations for Diabetes Treatment and Complications (Chapter 6)

Recommendation 6.1: The National Clinical Care Commission recommends that CMS update the 2000 Medicare Quality Standards that govern diabetes self-management training (DSMT) and establish a process for ongoing review, updating, and revision, with broad input from persons and parties affected by these standards. CMS should ensure that eligibility, documentation, and reimbursement requirements are clearly defined and

that they are consistently applied across all parties involved in accreditation, billing, and reimbursement, including Medicare Administrative Contractors and auditors. Updates should include a reduction in administrative burden regarding standards, documentation, and reimbursement requirements for DSMT programs.

Recommendation 6.2: The National Clinical Care Commission recommends that CMS develop reimbursement mechanisms for community-based diabetes education programs, as a complement to existing accredited/recognized DSMT programs, when evidence shows that these programs improve diabetes outcomes.

Recommendation 6.3: The National Clinical Care Commission recommends that CMS use existing processes to update and regularly reevaluate (at least every three years) eligibility requirements for various diabetes devices leading to appropriate coverage determinations when there is sufficient evidence to support such national determinations. CMS should ensure that, to the extent there are national requirements established, eligibility, documentation, and reimbursement requirements are clearly defined, and that they are consistently applied across all parties involved, including Medicare Administrative Contractors and auditors. In evaluating the data to revise eligibility requirements, CMS should evaluate the current evidence, including published, peer-reviewed evidence, and consider both glycemic benefits and non-glycemic benefits (including patient-reported outcomes, which may include quality-of-life and diabetes distress).

Recommendation 6.4: The National Clinical Care Commission recommends that steps be taken to ensure an adequate workforce and to enhance and sustain team-based care to improve outcomes for people with diabetes.

- Establish a process within HHS to routinely assess and identify all health care workforce needs and ensure that training program funding across agencies is directed to meet those needs.
- Ensure the Health Resources and Services Administration (HRSA) training programs are designed to meet unmet needs in the team-based health care workforce.
- Evaluate and address regulatory or statutory limitations on HRSA training programs that affect the agency's ability to meet the needs of team-based care and new care models.
- Increase funding for exemplary HRSA programs that support training health care professionals in team-based care in medical shortage areas, such as the HRSA National Health Services Corp.

- Identify and implement mechanisms for involvement of community health workers, clinical pharmacists, and integrated (or collaborative) behavioral health services in existing and future value-based models of care (alternative payment models)
- Enhance funding to AHRQ through Primary Care Extension Programs and other mechanisms to provide technical assistance to medical practices to implement team-based care.

Recommendation 6.5: The National Clinical Care Commission recommends that steps be taken to enhance implementation and sustainability of community health workers (CHWs) as critical members of the diabetes care teams.

- CMS should clarify and build on the 2013 final rule, expanding the scope of Medicaid-reimbursable services by CHWs to include social, behavioral, and economic supports as part of covered services.
 - ◊ Clarify that Medicaid funding is available for CHWs to address social determinants of health (SDOH), building on the January 7, 2021 – CMS SDOH Roadmap.
 - ◊ Clarify that CHW qualifications should focus on life experience, interpersonal skills as natural helpers, community membership, as well as formal education or clinical training.
 - ◊ Develop policies that require CHW services be delivered in accordance with evidence-informed standards for CHW programs such as those developed by the National Committee for Quality Assurance, the CDC CHW Core Consensus (C3) Project, the Community Guide, and the National Association of Community Health Workers (NACHW).
- Increase funding to CDC to expand programs to assist all states in infrastructure development and processes to integrate CHW services in a comprehensive, whole-person approach that includes economic, behavioral, and social supports, as well as clinical and preventive services.

Recommendation 6.6: The National Clinical Care Commission recommends that Congress support use of virtual care modalities in the following ways:

- Remove geographic and originating site restrictions so that CMS can provide access to telehealth services as appropriate.
- Make permanent the ability for Federally Qualified Health Centers and Rural Health Centers to provide services by telehealth.
- Make permanent the telehealth waiver for Diabetes Self-management Education and Support (DSMES)/Diabetes Self-management Training (DSMT); and

- Maintain coverage for audio-only visits to comply with the Executive Order on Advancing Racial Equity and Support for Underserved Communities.

Recommendation 6.7: The National Clinical Care Commission recommends that the Centers for Medicare & Medicaid Innovation (CMMI) fund a demonstration project with the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS) that utilizes a technology-enabled collaborative learning and capacity building model (for example, Project ECHO-type model) to support uptake and implementation of diabetes care best practices among primary care providers and care teams. The project should include training of community health workers, payment for both hub and spoke participants' time, collection and analysis of interim data, and utilization of a shared-services approach for training on the telementoring model, infrastructure, and data collection to inform broader implementation.

- In collaboration with HRSA, provide diabetes-related telementoring to small or rural health clinics (spokes) to include focus on social determinants of health and behavioral health issues that impact diabetes outcomes and leverage existing academic center hubs to support uptake and implementation of diabetes care best practices.
- In collaboration with IHS and tribal and urban Indian clinics, create supportive learning and mentorship relationships to assist in implementing diabetes care best practice and leverage the existing Tribal Epidemiology Centers and academic center hubs.

Recommendation 6.8: The National Clinical Care Commission recommends that CMS develop and implement a quality measure to assess potential overtreatment, inappropriate treatment, or risk of harm among Medicare beneficiaries with diabetes and life-limiting conditions to reduce the incidence of severe hypoglycemia and improve patient safety.

Recommendation 6.9: The National Clinical Care Commission recommends that federal policies and programs remove cost barriers to ensure that insulin is affordable for all people with diabetes and that no one with diabetes who needs insulin cannot get it because of cost.

Recommendation 6.10: The National Clinical Care Commission recommends that HHS establish a process to determine and regularly reevaluate high-value diabetes services and treatments to be fully covered (pre-deductible) by health insurance based on their ability to prevent development or progression of diabetes complications.

Recommendation 6.11: The National Clinical Care Commission recommends that the National Institutes of Health prioritize funding for research to identify and address factors that affect referrals to and patient uptake of DSMES such as patient-, clinician-, and systemic-level barriers, quality measures and incentives, and patient-reported outcomes and perspectives.

Examples of research approaches to be tested include:

- Address social determinants of health and racial and systemic inequities that prevent populations disproportionately burdened with diabetes from engagement in DSMES
- Use novel care delivery paradigms that may involve integration and collaboration of community and clinic systems to broaden referral and uptake of DSMES
- Enhance health care system processes to ensure provider understanding of the need for DSMES and provide support for making and increasing referrals
- Improve provider communication with people with diabetes and foster shared decision making to encourage uptake and engagement in DSMES
- Leverage and engage key family members and peer support to enhance engagement of people with diabetes in the DSMES process

Recommendation 6.12: The National Clinical Care Commission recommends increased funding for implementation research across federal agencies (for example, AHRQ, NIH, CMS, HRSA, IHS, CDC, VA, and DoD) to better translate team-based care into practice and test new team-based care models and payment systems to improve diabetes care and outcomes.

Recommendation 6.13: The National Clinical Care Commission recommends that digital connectivity be investigated as a social determinant of health affecting the development and progression of diabetes.

- The Federal Communications Commission (FCC), the U.S. Department of Agriculture (USDA), and the U.S. Department of Health and Human Services (HHS) should expand the scope of an inter-agency memorandum of understanding (MOU) beyond the Rural Telehealth Initiative or establish another mechanism to bring together the appropriate federal agencies to share information on and investigate (1) the relationship between digital connectivity and health; and (2) the types of digital services and the level of adoption of digital services needed to make a positive impact on health.
- FCC should conduct research to better understand the associations of digital connectivity, diabetes prevalence, and improved diabetes health outcomes.

Alignment Between National Clinical Care Commission's Recommendations and Charter/Duties *

Charter/Duties	Recommendations
	Foundational Recommendations (Chapter 3)
1, 2, 3, 4, and 5	Recommendation 3.1: The National Clinical Care Commission recommends the creation of the Office of National Diabetes Policy (ONDP) to develop and implement a national diabetes strategy that leverages and coordinates work across federal agencies and departments to positively change the social and environmental conditions that are promoting the type 2 diabetes epidemic. The National Clinical Care Commission further recommends that the ONDP be established at a level above the U.S. Department of Health and Human Services (HHS) and be provided with funding to facilitate its effectiveness and accountability.
1, 2, 3, and 4	Recommendation 3.2: The National Clinical Care Commission recommends that federal policies and programs be designed to ensure that all people at risk for and with diabetes have access to comprehensive, high-quality, and affordable health care and that no one at risk for or with diabetes who needs health care cannot get it because of cost.

* National Clinical Care Commission Charge/Duties

1. Federal programs of the Department of Health and Human Services that focus on preventing and reducing the incidence of complex metabolic or autoimmune diseases that result from insulin-related issues and represent a significant disease burden in the United States, including complications due to such diseases
2. Current activities and gaps in federal efforts to support clinicians in providing integrated, high-quality care to individuals with these diseases and complications
3. The improvement in, and improved coordination of, federal education and awareness activities related to the prevention and treatment of these diseases and complications, which may include the use of existing and new technologies
4. Methods for outreach and dissemination of education and awareness materials that:
 - a. Address these diseases and complications
 - b. Are funded by the federal government
 - c. Are intended for health care professionals and the public
5. Opportunities for consolidating any inappropriately overlapping or duplicative federal programs related to these diseases and complications

Charter/Duties	Recommendations
1, 2, 3, and 4	Recommendation 3.3: The National Clinical Care Commission recommends that achieving health equity be a component of all federal policies and programs that affect people at risk for and with diabetes.
Recommendations for Population-Level Diabetes Prevention and Control (Chapter 4)	
1, 2, and 3	Recommendation 4.1: The National Clinical Care Commission recommends that the USDA SNAP program be enhanced to both reduce food insecurity and improve nutrition sufficiency, both of which will help prevent type 2 diabetes and diabetes complications.
1 and 2	Recommendation 4.2: The National Clinical Care Commission recommends that USDA non-SNAP feeding programs be better leveraged to prevent diabetes in women, children, and adolescents by (1) enhancing Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); (2) further harnessing the National School Lunch and Breakfast Programs to improve dietary quality; and (3) expanding the Summer Nutrition Programs and the Fresh Fruit and Vegetable Program.
1 and 2	Recommendation 4.3: The National Clinical Care Commission recommends that resources be provided to the USDA to create an environmentally friendly and sustainable U.S. food system promoting the production, supply, and accessibility of foods such as “specialty crops” (fresh fruits, dried fruits, vegetables, tree nuts) that will attenuate the risk for type 2 diabetes and the complications of diabetes.
1, 2, 3, and 4	Recommendation 4.4: The National Clinical Care Commission recommends that all relevant federal agencies promote the consumption of water and reduce the consumption of sugar-sweetened beverages in the U.S. population, and that they employ all the necessary tools to achieve these goals, including education, communication, accessibility, water infrastructure, and sugar-sweetened beverage taxation.

Charter/Duties	Recommendations
<p>1, 2, 3, and 4</p>	<p>Recommendation 4.5: The National Clinical Care Commission recommends that the U.S. Food and Drug Administration (FDA) improve its food and beverage labeling regulations that influence both food and beverage industry practices and consumer behavior to better prevent and control diabetes.</p>
<p>1, 2, 3, 4, and 5</p>	<p>Recommendation 4.6: The National Clinical Care Commission recommends that the Federal Trade Commission - in order to prevent children’s exposure to, and consumption of, calorie-dense and nutrient-poor foods and beverages that can lead to obesity and type 2 diabetes -- be provided the authority, mandate, and requisite resources to (a) create guidelines and rules regarding the marketing and advertising practices of the food and beverage industry and associated communication networks and platforms targeted to children younger than 13 years old, (b) restrict industry practices based on these rules, (c) fully monitor these practices, and (d) enforce such rules.</p>
<p>1, 2, 3, 4, and 5</p>	<p>Recommendation 4.7: The National Clinical Care Commission recommends that federal agencies promote and support breastfeeding to (a) increase breastfeeding rates, (b) enhance the intensity and duration of breastfeeding among mothers who breastfeed, and (c) reduce disparities in breastfeeding rates, duration, and intensity. Additional funding should be provided for federal programs that promote and support breastfeeding to overcome persistent societal and employment-based obstacles to breastfeeding.</p>
<p>1, 2, and 5</p>	<p>Recommendation 4.8: The National Clinical Care Commission recommends that all federal agencies whose work influences the ambient (air, water, land, and chemical) and built environments modify their policies, practices, regulations, and funding decisions so as to lead to environmental changes to prevent and control diabetes.</p>
<p>1 and 2</p>	<p>Recommendation 4.9: The National Clinical Care Commission recommends that, to reduce type 2 diabetes incidence and diabetes complications, housing opportunities for low-income individuals and families be expanded, and that such individuals and families be housed in health-promoting environments.</p>

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Recommendations for Diabetes Prevention in Targeted Populations (Chapter 5)	
3 and 4	Recommendation 5.1: The National Clinical Care Commission recommends increasing support to CDC for its campaign to raise awareness of prediabetes and promote enrollment in the National DPP lifestyle change program.
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2 and 4	Recommendation 5.3: The National Clinical Care Commission recommends that all federal agencies that directly deliver or influence the delivery of medical care should implement the 2019 American Medical Association-proposed prediabetes quality measures related to screening for abnormal blood glucose, intervention for prediabetes, and retesting of abnormal blood glucose in patients with prediabetes.

Charter/Duties	Recommendations
1 and 2	<p>Recommendation 5.4: The National Clinical Care Commission recommends that funding be provided to NIH to collect, analyze, and summarize the available data from the Diabetes Prevention Program study describing the effectiveness and safety of metformin for diabetes delay or prevention in patients with prediabetes, including subpopulations most likely to benefit. Such a summary (with safety and efficacy data) should then be used to inform an appropriate submitter’s request for FDA to review and consider an indication for the use of metformin in high-risk patients with prediabetes.</p>
2	<p>Recommendation 5.5: The National Clinical Care Commission recommends, consistent with provisions of the Patient Protection and Affordable Care Act, that all insurers be required to provide coverage for participation in and completion of a CDC-recognized diabetes prevention program for those who are eligible.</p>
2	<p>Recommendation 5.6: The National Clinical Care Commission recommends that Congress promote coverage for all proven-effective modes of delivery (for example, in-person, online, and distance learning [telehealth]) for evidence-based interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards.</p>
2	<p>Recommendation 5.7: The National Clinical Care Commission recommends that the Medicare Diabetes Prevention Program (MDPP) be approved as a permanent covered benefit (not only a model expansion service) and that coverage of MDPP be expanded to include virtual delivery. Furthermore, the “once in a lifetime” limit on participation in the MDPP should be removed.</p>
2 and 5	<p>Recommendation 5.8: The National Clinical Care Commission recommends continued efforts to streamline the CDC recognition process for the National DPP and CMS payment process for the MDPP while maintaining quality. Differences in program eligibility and duration between the National DPP (led by CDC) and the MDPP (led by CMS) should be eliminated or, at a minimum, reduced.</p>

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2	<p>Recommendation 5.9: The National Clinical Care Commission recommends that funding be provided to support the testing of new payment models that allow for greater up-front payments and more equitable risk-sharing between CMS and MDPP program delivery organizations. In addition, there should be an increase in payment levels to MDPP program delivery organizations to make MDPP programs financially sustainable.</p>
2	<p>Recommendation 5.10: The National Clinical Care Commission recommends that financial incentives be provided for state Medicaid programs to cover the National DPP lifestyle change program and other evidence-based interventions that produce successful participant outcomes that meet or exceed those of the National DPP quality standards. This includes coverage of all proven modes of delivery (that is, in-person, online, and distance learning or telehealth) for evidence-based interventions that produce successful participant outcomes.</p>
1 and 4	<p>Recommendation 5.11: The National Clinical Care Commission recommends</p> <ul style="list-style-type: none"> • Funding for the Special Diabetes Program for Indians (SDPI) in five-year increments so that evidenced-based tribal diabetes prevention programs have the resources to (1) sustain the effort to combat diabetes and its complications; (2) develop additional culturally appropriate, high-impact diabetes prevention interventions; and (3) evaluate outcomes. • An increase in SDPI funding to address inflation costs, which have consumed more than 34% of the program’s resources since 2004, the last year Congress increased funding for the Special Diabetes Program. In the future, annual increases in funding should, at a minimum, address the costs of inflation. • An increase in funding to HRSA’s Delta States Network Grant Program to allow the program to include diabetes prevention as a focus.

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3 and 4	Recommendation 5.12: The National Clinical Care Commission recommends funding type 2 diabetes prevention research to ensure that all individuals at high risk of developing type 2 diabetes are able to lower their risk for diabetes and its complications.
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Recommendations for Diabetes Treatment and Complications (Chapter 6)	
1, 3, and 4	Recommendation 6.1: The National Clinical Care Commission recommends that CMS update the 2000 Medicare Quality Standards that govern diabetes self-management training (DSMT) and establish a process for ongoing review, updating, and revision, with broad input from persons and parties affected by these standards. CMS should ensure that eligibility, documentation, and reimbursement requirements are clearly defined and that they are consistently applied across all parties involved in accreditation, billing, and reimbursement, including Medicare Administrative Contractors and auditors. Updates should include a reduction in administrative burden regarding standards, documentation, and reimbursement requirements for DSMT programs.

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1 and 2	Recommendation 6.4: The National Clinical Care Commission recommends that steps be taken to ensure an adequate workforce and to enhance and sustain team-based care to improve outcomes for people with diabetes.
2, 3, and 4	Recommendation 6.5: The National Clinical Care Commission recommends that steps be taken to enhance implementation and sustainability of community health workers (CHWs) as critical members of the diabetes care teams.

Charter/Duties	Recommendations
<p>2, 3, and 4</p>	<p>Recommendation 6.6: The National Clinical Care Commission recommends that Congress support use of virtual care modalities in the following ways:</p> <ul style="list-style-type: none"> • Remove geographic and originating site restrictions so that CMS can provide access to telehealth services as appropriate. • Make permanent the ability for Federally Qualified Health Centers and Rural Health Centers to provide services by telehealth. • Make permanent the telehealth waiver for Diabetes Self-management Education and Support (DSMES)/Diabetes Self-management Training (DSMT); and • Maintain coverage for audio-only visits to comply with the Executive Order on Advancing Racial Equity and Support for Underserved Communities.
<p>1, 2, and 3</p>	<p>Recommendation 6.7: The National Clinical Care Commission recommends that the Centers for Medicare & Medicaid Innovation (CMMI) fund a demonstration project with the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS) that utilizes a technology-enabled collaborative learning and capacity building model (for example, Project ECHO-type model) to support uptake and implementation of diabetes care best practices among primary care providers and care teams. The project should include training of community health workers, payment for both hub and spoke participants' time, collection and analysis of interim data, and utilization of a shared-services approach for training on the telementoring model, infrastructure, and data collection to inform broader implementation.</p>

Charter/Duties	Recommendations
1, 2, and 5	Recommendation 6.8: The National Clinical Care Commission recommends that CMS develop and implement a quality measure to assess potential overtreatment, inappropriate treatment, or risk of harm among Medicare beneficiaries with diabetes and life-limiting conditions to reduce the incidence of severe hypoglycemia and improve patient safety.
1, 2, and 5	Recommendation 6.9: The National Clinical Care Commission recommends that federal policies and programs remove cost barriers to ensure that insulin is affordable for all people with diabetes and that no one with diabetes who needs insulin cannot get it because of cost.
1 and 2	Recommendation 6.10: The National Clinical Care Commission recommends that HHS establish a process to determine and regularly reevaluate high-value diabetes services and treatments to be fully covered (pre-deductible) by health insurance based on their ability to prevent development or progression of diabetes complications.
1, 3, and 4	Recommendation 6.11: The National Clinical Care Commission recommends that the National Institutes of Health prioritize funding for research to identify and address factors that affect referrals to and patient uptake of DSMES such as patient-, clinician-, and systemic-level barriers, quality measures and incentives, and patient-reported outcomes and perspectives.
1, 2, 3, and 4	Recommendation 6.12: The National Clinical Care Commission recommends increased funding for implementation research across federal agencies (for example, AHRQ, NIH, CMS, HRSA, CDC, VA, and DoD) to better translate team-based care into practice and test new team-based care models and payment systems to improve diabetes care and outcomes.
1, 2, 3, 4, and 5	Recommendation 6.13: The National Clinical Care Commission recommends that digital connectivity be investigated as a social determinant of health affecting the development and progression of diabetes.

Appendix D. National Clinical Care Commission Act

PUBLIC LAW 115-80—NOV. 2, 2017 • 131 STAT. 1261

Public Law 115-80
115th Congress

Nov. 2, 2017

[S. 920]

National Clinical Care Commission Act.

Evaluation. Recommendations.

An Act

To establish a National Clinical Care Commission.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “National Clinical Care Commission Act”.

SEC. 2. NATIONAL CLINICAL CARE COMMISSION.

(a) ESTABLISHMENT.—There is hereby established, within the Department of Health and Human Services, a National Clinical Care Commission (in this section referred to as the “Commission”) to evaluate and make recommendations regarding improvements to the coordination and leveraging of programs within the Department and other Federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

(b) MEMBERSHIP.—

(1) IN GENERAL.—The Commission shall be composed of the following voting members:

(A) The heads of the following Federal agencies and departments, or their designees:

- (i) The Centers for Medicare & Medicaid Services.
- (ii) The Agency for Healthcare Research and Quality.
- (iii) The Centers for Disease Control and Prevention.
- (iv) The Indian Health Service.
- (v) The Department of Veterans Affairs.

- (vi) The National Institutes of Health.
- (vii) The Food and Drug Administration.
- (viii) The Health Resources and Services Administration.
- (ix) The Department of Defense.
- (x) The Department of Agriculture.
- (xi) The Office of Minority Health.

(A) Twelve additional voting members appointed under paragraph (2).

(1) **ADDITIONAL MEMBERS.**—The Commission shall include additional voting members, as may be appointed by the Secretary, with expertise in the prevention, care, and epidemiology of any of the diseases and complications described in subsection

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(a) , including one or more such members from each of the following categories:

(A) Physician specialties, including clinical endocrinologists, that play a role in the prevention or treatment of diseases and complications described in subsection (a).

(B) Primary care physicians.

(C) Non-physician health care professionals.

(D) Patient advocates.

(E) National experts, including public health experts, in the duties listed under subsection (c).

(F) Health care providers furnishing services to a patient population that consists of a high percentage (as specified by the Secretary) of individuals who are enrolled in a State plan under title XIX of the Social Security Act or who are not covered under a health plan or health insurance coverage.

(3) **CHAIRPERSON.**—The members of the Commission shall select a chairperson from the members appointed under paragraph (2).

(4) **MEETINGS.**—The Commission shall meet at least twice, and not more than four times, a year.

(5) **VACANCIES.**—A vacancy on the Commission shall be filled in the same manner as the original appointments.

(c) **DUTIES.**—The Commission shall evaluate and make recommendations, as appropriate, to the Secretary of Health and Human Services and Congress regarding—

(1) Federal programs of the Department of Health and Human Services that focus on preventing and reducing the incidence of the diseases and complications described in subsection (a);

(2) current activities and gaps in Federal efforts to support clinicians in providing integrated, high-quality care to individuals with the diseases and complications described in subsection (a);

(3) the improvement in, and improved coordination of, Federal education and awareness activities related to the prevention and treatment of the diseases and complications described in subsection (a), which may include the utilization of new and existing technologies;

(4) methods for outreach and dissemination of education and awareness materials that—

(A) address the diseases and complications described in subsection (a);

(B) are funded by the Federal Government; and

(C) are intended for health care professionals and the public; and

(1) whether there are opportunities for consolidation of inappropriately overlapping or duplicative Federal programs related to the diseases and complications described in subsection (a).

(d) **OPERATING PLAN.**—Not later than 90 days after its first meeting, the Commission shall submit to the Secretary of Health and Human Services and the Congress an operating plan for carrying out the activities of the Commission as described in subsection (c). Such operating plan may include—

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(1) a list of specific activities that the Commission plan to conduct for purposes of carrying out the duties described in each of the paragraphs in subsection (c);

(2) a plan for completing the activities;

(3) a list of members of the Commission and other individuals who are not members of the Commission who will need to be involved to conduct such activities;

(4) an explanation of Federal agency involvement and coordination needed to conduct such activities;

(5) a budget for conducting such activities; and

(6) other information that the Commission deems appropriate.

(e) FINAL REPORT.—By not later than 3 years after the date of the Commission's first meeting, the Commission shall submit to the Secretary of Health and Human Services and the Congress a final report containing all of the findings and recommendations required by this section.

(f) SUNSET.—The Commission shall terminate 60 days after submitting its final report, but not later than the end of fiscal year 2021.

Approved November 2, 2017.

Appendix E. National Clinical Care Commission Charter



THE SECRETARY OF HEALTH AND HUMAN SERVICES

WASHINGTON, D.C. 20201

CHARTER

NATIONAL CLINICAL CARE COMMISSION

COMMITTEE'S OFFICIAL DESIGNATION

National Clinical Care Commission

AUTHORITY

The National Clinical Care Commission (hereafter referred to as the Commission) is required under the National Clinical Care Commission Act (Public Law 115-80). The Commission is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Secretary of Health and Human Services (Secretary) is required to establish a committee to evaluate and make recommendations regarding improvements to the coordination and leveraging of programs within the Department and other Federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the United States, which may include complications due to such diseases.

DESCRIPTION OF DUTIES

The Commission shall evaluate and make recommendations, as appropriate, to the Secretary and Congress regarding:

1. Federal programs of the Department of Health and Human Services that focus on preventing and reducing the incidence of complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant

- disease burden in the United States, which may include complications due to such diseases;
2. Current activities and gaps in Federal efforts to support clinicians in providing integrated, high-quality care to individuals with the diseases and complications;
 3. The improvement in, and improved coordination of, Federal education and awareness activities related to the prevention and treatment of the diseases and complications, which may include the utilization of new and existing technologies;
 4. Methods for outreach and dissemination of education and awareness materials that
 - a. address the diseases and complications;
 - b. are funded by the Federal Government; and
 - c. are intended for health care professionals and the public; and
 5. Whether there are opportunities for consolidation of inappropriately overlapping or duplicative Federal programs related to the diseases and complications.

AGENCY OR OFFICIAL TO WHOM THE COMMISSION REPORTS

The Commission shall provide recommendations to the Secretary and Congress.

Not later than 90 days after its first meeting, the Commission shall submit to the Secretary and the Congress an operating plan for carrying out the activities of the Commission. Such operating plan may include:

1. A list of specific activities that the Commission plans to conduct for purposes of carrying out the duties described above;
2. A plan for completing the activities;
3. A list of members of the Commission and other individuals who are not members of the Commission who will need to be involved to conduct such activities;
4. An explanation of Federal agency involvement and coordination needed to conduct such activities;
5. A budget for conducting such activities; and
6. Other information that the Commission deems appropriate.

By not later than three years after the date of the Commission's first meeting, the Commission shall submit to the Secretary and the Congress a final report containing all of the findings and recommendations required.

SUPPORT

The Assistant Secretary for Health (ASH) shall provide guidance and oversight for the Commission's function and activities. Management and support services for the Commission's activities shall be provided by the Office of Disease Prevention and Health Promotion (ODPHP). ODPHP is a program office within the Office of the Assistant Secretary for Health (OASH), which is a staff division within the Office of the Secretary in the Department of Health and Human Services.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Commission, including travel expenses for members but excluding staff support is \$435,036. The estimated annual staff support required for the Commission is 1.30 at an estimated annual cost of \$289,400.

DESIGNATED FEDERAL OFFICER (DFO)

The ASH shall select the Designated Federal Officer (DFO) from among permanent full-time or part-time staff within OASH, who has knowledge of the subject matter and skills and experience necessary to manage the Commission. The ASH may appoint an Alternate DFO who shall carry out these duties in the event that the appointed DFO cannot fulfill the assigned responsibilities for the Commission. In the absence of the appointed DFO or Alternate DFO, the ASH shall temporarily appoint one or more permanent full-time or part-time program staff to carry out the assigned duties.

The DFO shall schedule and approve all meetings of the Commission and any subcommittees that may be established by the Commission. The DFO shall prepare and approve all meeting agendas. The DFO may collaborate with the Commission Chair in this activity, and when deemed appropriate, with chairs of any existing subcommittees that have been established by the Commission. The DFO, Alternate DFO, or designee shall attend all meetings of the Commission and all meetings of any subcommittees that have been established to assist the Commission. The DFO has authority to adjourn meetings, when it is determined to be in the public interest, and the DFO can be directed by the Secretary or designee to chair meetings of the Commission.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

The Commission shall meet at least twice and not more than four times a year. These meetings will be in person, but may be conducted by teleconference or videoconference at the discretion of the DFO. The meetings shall be open to the public, except as determined otherwise by the Secretary, or other official to whom authority has been delegated, in accordance with the guidelines under Government in the Sunshine Act, 5 U.S.C. 552b(c). Notice of all meetings shall be provided to the public in accordance

with the FACA. Meetings shall be conducted and records of the proceedings shall be kept, as required by applicable laws and departmental policies. A quorum is required for the Commission to meet to conduct business. A quorum shall consist of a majority of the Commission's voting members.

When the Secretary or designee determines that a meeting shall be closed or partially closed to the public, in accordance with stipulations of Government in the Sunshine Act, 5 U.S.C. 552b(c), then a report shall be prepared by the DFO that includes, at a minimum, a list of members and their business addresses, the Commission's functions, date and place of the meeting, and a summary of the Commission's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Establishment of the Commission was mandated under the National Clinical Care Commission Act (Public Law 115-80). The Commission shall operate pursuant to the stipulations in the authorizing legislation.

TERMINATION

Unless extended by Congress, the Commission shall terminate 60 days after submitting its final report, but not later than the end of fiscal year 2021. Unless renewed by appropriate action, the charter for the Commission will expire two years from the date it is filed.

MEMBERSHIP AND DESIGNATION

The Commission shall consist of 23 voting members. The composition shall include eleven ex-officio members and twelve non-federal members. The ex-officio members shall consist of the heads of, or subordinate officials designated by the heads of, the following federal departments, agencies, or components: The Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Indian Health Service, the Department of Veterans Affairs, the National Institutes of Health, the Food and Drug Administration, the Health Resources and Services Administration, the Department of Defense, the Department of Agriculture, and the Office of Minority Health.

The twelve non-federal members shall be appointed as special government employees (SGEs) by the Secretary and shall have expertise in prevention, care, and epidemiology of any of the diseases and complications described in Section 2(a) of the National Clinical Care Commission Act. The non-federal members shall include at least one individual from each of the following categories: physician specialties, including clinical endocrinologists, that play a role in the prevention or treatment of diseases

and complications; primary care physicians; non-physician health care professionals; patient advocates; national experts, including public health experts; and health care providers furnishing services to a patient population that consists of a high percentage (as specified by the Secretary) of individuals who are enrolled in a State plan under title XIX of the Social Security Act or who are not covered under a health plan or health insurance coverage. One of the non-federal members shall be selected by the members of the Commission to serve as the Chair.

The ex-officio members and non-federal members shall be appointed to serve for the duration of the time that the Commission is authorized to operate. Any vacancy of a non-federal member shall be filled in the same manner as the original appointments. Any non-federal member who is appointed to fill the vacancy of an unexpired term shall be appointed to serve for the remainder of that term.

Pursuant to advance written agreement, each non-federal member of the Commission will waive his or her right to compensation for performing services as a member of the Commission.

However, non-federal members shall receive per diem and reimbursement for travel expenses incurred in relation to performing duties for the Commission, as authorized by FACA and 5 U.S.C. §5703 for persons who are employed intermittently to perform services for the Federal government and in accordance with Federal travel regulations. Ex-officio members of the Commission remain covered under their current compensation system.

SUBCOMMITTEES

In carrying out its function, the Commission (with the approval of the DFO) may establish subcommittees composed of members of the Commission, as well as other individuals who have expertise and knowledge about the topics and issues that are pertinent to the mission of the Commission. The established subcommittees may consider issues in accordance with the mission of the Commission, and shall, as appropriate, make recommendations and/or reports to the Commission for consideration. Recommendations and/or reports of the subcommittee that are provided to the Commission shall be discussed at an open public meeting that is held by the Commission. No established subcommittee of the Commission may report directly to the Secretary or another federal official unless there is specific statutory authority for such reporting. The Department Committee Management Officer shall be notified upon establishment of each subcommittee, and shall be given information regarding its name, membership, function, cost, and estimated frequency of meetings.

RECORDKEEPING

Records of the Commission and any established subcommittees shall be handled in accordance with the General Records Schedule 6.2, Federal Advisory Committee Records or other approved agency records disposition schedule. Applicable records shall be made available to the public for inspection and copying, subject to the Freedom of information Act, 5 U.S.C. 552.

FILING DATE:

April 3, 2020

APPROVED:

APR 01 2020

Date



Alex M. Azar II

Appendix F. Acronyms and Abbreviations

Acronyms & Abbreviations	Definitions
ACA	Affordable Care Act
AHRQ	Agency for Healthcare Research and Quality
C3 Project	CHW Core Consensus Project
CDC	Centers for Disease Control and Prevention
CGM	Continuous glucose monitor
CHIP	Children's Health Insurance Program
CHW	Community health worker
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare & Medicaid Services
CPI-U	Consumer Price Index U.S. city average
DFO	Designated Federal Officer
DKA	Diabetic ketoacidosis
DMICC	Diabetes Mellitus Interagency Coordinating Committee
DoD	United States Department of Defense
DOL	United States Department of Labor
DOT	United States Department of Transportation
DPP	Diabetes Prevention Program
DSMES	Diabetes Self-Management Education and Support
DSMT	Diabetes Self-Management Training
ECHO	Extension for Community Healthcare Outcomes
EDC	Endocrine disrupting chemical
EPA	United States Environmental Protection Agency
FACA	<i>Federal Advisory Committee Act</i>
FCC	Federal Communications Commission
FDA	United States Food and Drug Administration
FFV	Fresh Fruit and Vegetable
FNS	Food Nutrition Service
FTC	Federal Trade Commission

Acronyms & Abbreviations	Definitions
GusNIP	Gus Schumacher Nutrition Incentive Program
HbA1c	Hemoglobin A1c
HDL	High-density lipoprotein
HFFI	Healthy Food Financing Initiative
HHFK	Healthy, Hunger-Free Kids Act
HHS	United States Department of Health and Human Services
HIA	Health Impact Assessment
HiAP	Health in All Policies
HOPD	Hospital outpatient department
HRSA	Health Resources and Services Administration
HUD	United States Department of Housing and Urban Development
IHS	Indian Health Service
IMPACT	Infrastructure for Maintaining Primary Care Transformation
IRS	Internal Revenue Service
LCD	Local coverage determination
MCO	Managed care organization
MDPP	Medicare Diabetes Prevention Program
MNT	Medical Nutrition Therapy
NACHW	National Association of Community Health Workers
NCCC	National Clinical Care Commission
NCD	National coverage determination
NHANES	National Health and Nutrition Examination Survey
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NSDSMT	National Standards for Diabetes Self-Management Education and Support
OASH	HHS Office of the Assistant Secretary for Health
ONDP	Office of National Diabetes Policy
OWH	Office on Women's Health
PCEP	Primary Care Extension Program

Acronyms & Abbreviations	Definitions
PFS	Physician Fee Schedule
QAP	Qualified Allocation Plan
SCRI	Specialty Crop Research Initiative
SDOH	Social determinants of health
SDP	Special Diabetes Program
SDPI	Special Diabetes Program for Indians
SNAP	Supplemental Nutrition Assistance Program
SNAP-Ed	Supplemental Nutrition Assistance Program Education
SSB	Sugar-sweetened beverage
TFP	Thrifty Food Plan
U.S.	United States of America
UNICEF	United Nations Children's Emergency Fund
USDA	United States Department of Agriculture
USPSTF	United States Preventive Services Task Force
VA	United States Department of Veteran Affairs
VBP	Value-based payment
WIC	Special Supplemental Nutrition Program for Women, Infants and Children

Appendix G. References

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National Clinical Care Commission

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