



February 3, 2020

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National Clinical Care Commission  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Health  
Office of Disease Prevention and Health Promotion  
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**RE: Docket ID HHS-OS-2019-0015—Solicitation for Public Comments on Questions from the National Clinical Care Commission.**

Thank you for the opportunity to provide comments to the National Clinical Care Commission (Commission) on the policies to improve the prevention and treatment of diabetes and its complications. The Endocrine Society represents more than 18,000 scientists and clinicians who research and treat endocrine diseases, including diabetes. We ask the Commission to consider supporting the following policy changes to improve the lives of people with diabetes.

**Diabetes Prevention Program**

Despite the vital role of endocrinologists in the care of patients with chronic diseases, there are currently fewer than 4,000 clinical endocrinologists in the United States to care for the more than 100 million potential patients who suffer from diabetes and prediabetes alone. Prevention of type 2 diabetes is a top policy priority because slowing the number of new cases of diabetes is vital for decreasing the human and economic burden of diabetes in America. Scientific research has demonstrated conclusively that type 2 diabetes can be prevented or delayed in adults with prediabetes through both community-based and online settings.

We have been a long-time supporter of the Centers for Disease Control and Prevention's National Diabetes Prevention Program (National DPP) and have advocated for increased federal funding in addition to expanded coverage in the Medicare population. However, since the expansion of National DPP into Medicare, utilization has been limited. We believe the following reforms are needed to increase the number of organizations enrolled in the Medicare DPP and the beneficiaries who use it.

- CMS should align Medicare DPP services with the CDC National DPP
- CMS should target underserved communities who are disproportionately at-risk for diabetes and prediabetes
- CMS should remove the once-per-lifetime limit
- Virtual programs should be available for Medicare beneficiaries

**Telehealth**

The Society believes there is an opportunity to improve the health outcomes associated with diabetes in pregnancy through telehealth in the Medicaid population. Women with diabetes who become pregnant are at a significantly greater risk of maternal and fetal complications, particularly if their diabetes is uncontrolled. As a result, these individuals often require insulin therapy and frequent visits to an endocrinologist or high-risk obstetrician (every 1-2 weeks in addition to routine OBGYN appointments,



which are typically monthly). During these visits, the physician will review blood glucose logs and adjust insulin doses as needed. Members of the care team and/or the physician may also provide diabetes education to the patient.

Telemedicine could be utilized for a significant proportion of these visits as blood glucose log review and therapy adjustment can be conducted remotely. Patients who require visits weekly could see their endocrinologists or high-risk obstetrician every other week and utilize telemedicine (telephone or video visit) for the remaining visits from their home. Patients who require bi-weekly visits can utilize telemedicine visits once per month. The Society believes that the use of telehealth in this population would ease the burden on patients who would find it difficult to miss work or be away from home each week. Easing this burden would reduce the high rate of noncompliance in this patient population and avoid costly complications, unnecessary hospitalizations and C-sections, and improve outcomes in their babies.

We strongly encourage you to explore the implementation of telehealth pilots for patients with diabetes in pregnancy to reduce costs and improve health outcomes. This would require waiving the originating site requirements, which have been a barrier in accessing care for effective disease management.

### **Innovative Diabetes Technology & Access to Supplies**

Rapid advances in diabetes technology space have outpaced Medicare's existing coverage and reimbursement guidelines resulting in overly complicated reimbursement processes or lack of access for patients, health care professionals and suppliers. We are concerned that CMS lacks flexibility to cover innovative diabetes technologies and recommend that the Commission explore areas related to Medicare coverage and reimbursement. In addition, federal regulatory policies must be flexible enough to accommodate newly FDA-approved medical devices and treatments in a timely manner so they can be covered by federal health programs.

We believe that there are outdated codes for diabetes technologies, overly onerous requirements for insulin pumps, no coverage criteria for artificial pancreas device systems, and inconsistent policies for accessing diabetes test strips. For example, CMS requires Medicare beneficiaries to test their blood sugar at least four times per day to have access to a continuous glucose monitor; however, the agency only covers three strips per day. These issues will require a coordinated, long-term strategy to understand future needs in coding, access, and reimbursement.

### **Diabetes Self-Management Education and Support (DSMES)**

Even though DSMES is a covered benefit under the Medicare program, only 5% of Medicare beneficiaries with newly diagnosed diabetes participate in this evidence-based service. We have identified several barriers to utilizing DSMES and urge CMS to implement regulatory reforms to expand access to prevent costly complications. We urge the Commission to support policies that would:

- extend the initial 10 hours of DSMES covered by Medicare beyond the first year until fully utilized and cover additional hours based on individual need;
- allow medical nutrition therapy and DSMES to be provided on the same day;
- remove patient cost-sharing;
- broaden which providers can refer to DSMT beyond the provider managing the beneficiary's diabetes to include other providers caring for the patient;
- clarify agency policy that hospital outpatient department based DSMT programs can expand to community-based locations, including alternate non-hospital locations; and



- pilot virtual DSMT through the Innovation Center.

### **Special Diabetes Program**

The reauthorization of the Special Diabetes Program (SDP) is critical to finding a cure for diabetes and ensuring that the populations at greatest risk have access to prevention, treatment, and education programs in their communities. The lives of more than 114 million Americans are living with or at-risk for developing diabetes have been fundamentally changed through the SDP, which has been funded since 1997 to advance research for type 1 diabetes and to address the disproportionate burden of type 2 diabetes in American Indians and Alaska Natives (AI/AN).

SDP is comprised of two programs—the Special Diabetes Program for Type 1 Diabetes and the Special Diabetes Program for Indians. Funding for the Special Diabetes Program for Type 1 Diabetes is administered through the National Institute of Diabetes and Digestive and Kidney Disorders (NIDDK). Through this program, NIDDK has advanced research on how to: delay the full onset of type 1 diabetes, better understand the underlying causes of the disease, and prevent, treat, and reverse complications associated with the disease. This research has accelerated progress on an artificial pancreas, advanced therapies to reverse vision loss, and discovered nearly 50 genes that influence the risk of developing type 1 diabetes.

SDP funding has also helped determine that hemoglobin A1C standardization improves care, identify new blood glucose monitoring tools for controlling blood glucose levels, advance islet transplantation as a therapeutic approach, and test novel prevention strategies. Moving forward, SDP-Type 1 seeks to identify molecular pathways of disease progression, therapeutic agents to target molecular pathways, pre-clinical drug development and testing, and promising therapies in people with type 1 diabetes. As a result of the past two decades of research, people with type 1 diabetes are living longer, healthier lives and experiencing lower rates of disease complications, but more needs to be done and there are great research opportunities that should be explored.

Through the Special Diabetes Program for Indians (SDPI), more than 400 evidence-based treatment and education programs on type 2 diabetes have been implemented in AI/AN communities, who have the highest prevalence of diabetes. SDPI Community-Directed Diabetes Programs provide funds to the Indian Health Service's (IHS) Tribal and Urban Health Programs in all 12 IHS areas to begin or enhance local diabetes treatment and prevention programs. The SDPI Diabetes Prevention and Health Heart Programs translate current science on diabetes prevention and cardiovascular disease risk reduction to AI/AN communities.

These programs have implemented proven lifestyle change interventions to reduce the risk of diabetes in those at the greatest risk for being diagnosed. As a result, the SDPI has successfully reduced A1c levels, cardiovascular disease, and promoted healthy lifestyle behaviors. Diabetic eye disease has decreased 50%, reducing vision loss and blindness. Obesity and diabetes rates in youth have not increased in more than 10 years, while diabetes rates have not increased in adults since 2011. Kidney failure rates have decreased by 54%, reducing the need for dialysis. Data has shown that these positive clinical outcomes in program participants has reduced the risk for blindness, amputations, kidney failure, as well as preventing the onset of type 2 diabetes.

Together, these programs have proven to be a critical pathway to preventing and treating diabetes and its complications. SDP has enabled resources to go towards innovative research that has not only



revolutionized care but could also lead to a cure for one of our most prevalent diseases. We urge the Commission to support the continuation of this important program over a five-year period to expand on the successes of the program and to ensure continued research that will help to find a cure for diabetes.

Thank you for requesting feedback on policies that could help improve the lives of people living with diabetes. Should you have any questions, please contact Meredith Dyer, Director of Health Policy, at [mdyer@endocrine.org](mailto:mdyer@endocrine.org).

Sincerely,

A handwritten signature in blue ink that reads "E. Dale Abel". The signature is fluid and cursive, with the first name "E. Dale" written in a more compact, stylized manner and "Abel" written in a more open, flowing script.

E. Dale Abel, MB.BS., D. Phil. (M.D., Ph.D.)  
President  
Endocrine Society