ENDOCRINE SOCIETY
Hormone Science to Health

October 27, 2017

John R. Graham
Acting Assistant Secretary
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Strategic Planning Team
200 Independence Avenue SW, Room 415F
Washington, DC 20201

Dear Acting Assistant Secretary Graham,

On behalf of the Endocrine Society, we appreciate the opportunity to provide comments on the Department of Health and Human Service (HHS) Strategic Plan for FY 2018-2022. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. The Society works to foster a greater understanding of endocrinology among the general public and practitioners of complementary medical disciplines, and to promote the interests of all endocrinologists at the international and national scientific research and health policy levels of government. Endocrinologists are at the core of solving the most pressing health problems of our time, from diabetes and obesity to infertility, bone health, and hormone-related cancers.

Our members care for people with complex, chronic diseases, such as diabetes, obesity, osteoporosis, infertility, rare cancers and thyroid conditions. These diseases affect growing numbers of people, placing stress on the health care system. Our more than 18,000 members care for patients and are dedicated to advancing hormone research and excellence in the clinical practice of endocrinology. We promote policies to help ensure that all individuals with endocrine diseases have access to high quality, specialized care and adequate, affordable health insurance. Affordable, high-quality, and adequate care is vital to the patients we represent.

Objective 1.1: Promote Affordable Health Care While Balancing Spending on Premiums, Deductibles, and Out-of-Pocket Costs

Rising insulin costs and changing formularies have created a challenging environment for endocrinologists to provide optimal care and for patients to access therapies to appropriately manage their diabetes. Over the past 15 years, average insulin prices have nearly tripled and patients are becoming increasingly exposed to these costs due to high deductible plans and coinsurance. In addition to rising insulin costs, formulary changes throughout the coverage period have made it difficult for physicians to determine the cost of medications, what insurance will cover, and what lower cost alternatives may be available. The lifesaving nature of insulin and the millions of Americans who rely on it to effectively treat their diabetes makes it uniquely important in several regards. Physicians need access to additional information to make appropriate, patient-centered prescribing decisions that do not create an additional burden on their patients because of high out-of-pocket

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costs. A first step to increase access to such information is working with health plans, manufacturers, and pharmacy benefit managers to understand the true cost of insulin, why these costs have increased dramatically, and what policies can be enacted to help reduce burdens on patients and providers. As HHS considers new approaches to healthcare delivery and opportunities to reduce the burden of drug costs on Americans with chronic conditions like diabetes, we would like to offer the following recommendations:

1. The Centers for Medicare and Medicaid Services, along with private insurers, should work with electronic medical record vendors to provide up-to-date formulary and coverage information, including out-of-pocket costs and deductible information. Such changes would enable physicians to make appropriate prescribing decisions based on the needs of the patient.
2. Health plans should exempt insulin from coinsurance/co-pays in high-deductible plans due to its lifesaving nature and high cost.
3. Insurance companies and federal programs should maintain formularies for a minimum of one year to reduce non-medical switching; or patients who have well-controlled blood glucose levels on their current insulin should be able to stay on that insulin for at least one year.
4. Congress should consider policies that would reduce patient cost-sharing for insulin and ensure that patients benefit from rebates at point of sale.
5. Patient Assistance Programs for insulin should be less restrictive and more accessible. A first step in this accessibility could be developing a common application for all programs that can be saved for subsequent applications to the same or different programs. These programs should be expanded to include Medicare and Medicaid beneficiaries, and patients on any insurance plan.

Objective 1.3: Improve Americans' Access to Health Care and Expand Choices of Care and Service Options

Multiple HHS strategies address the need to increase the use of primary and secondary preventive health services like diabetes self-management training (DSMT). The Endocrine Society supports HHS' strategy to expand participation by older adults and adults with disabilities in self-management education interventions like DSMT.

Diabetes is a complex disease that requires ongoing self-management by patients, including making numerous decisions throughout the day, as part of their management and treatment regimen. Diabetes self-management training (DSMT) is an evidence-based service that teaches people with diabetes how to effectively self-manage their diabetes and cope with the disease. The service, covered by Medicare Part B and most private health insurance plans, includes teaching the person with diabetes how to self-manage healthy eating, physical activity, monitoring blood glucose levels and using the results for self-management decision making, adhering to medications, coping and problem solving with every day struggles to help reduce risks for diabetes complications.

The benefits of DSMT are undisputed. Studies have found that DSMT is associated with improved diabetes knowledge and self-care behaviors, lower hemoglobin A1c, lower self-reported weight, improved quality of life, healthy coping and reduced health care costs.[1] There are four critical points of time for Diabetes Self-Management Education and Support delivery: at diagnosis; annually for assessment of education, nutrition and emotional needs; when complicating factors arise that influence self-management; and when transition in care occur.[2] Unfortunately, despite its critical importance for people with diabetes and the fact that DSMT has been a covered benefit under Medicare for over 15 years, a recent study found only five percent of Medicare beneficiaries with newly diagnosed diabetes used DSMT services.[3] According to another source, among fee-for-service Medicare beneficiaries age 65 and older with diagnosed diabetes, only 1.7% had a Medicare claim for DSMT in 2012.[4]

The Centers for Medicare & Medicaid Services (CMS) highlighted the "significant underutilization" of DSMT in the CY 2011 Medicare Physician Fee Schedule, in which the agency noted the effectiveness of DSMT services and the importance of facilitating access to DSMT. In July 2016, as part of the proposed CY 2017 Medicare Physician Fee Schedule rule, CMS once again highlighted the low utilization of DSMT and solicited public comment on barriers contributing to access and the under-utilization of the benefit. We strongly support HHS' intent to increase the use of secondary preventive health services like DSMT but addressing these barriers is critical if HHS seeks to increase the use of DSMT. Potential solutions to overcome these barriers include:

- using hemoglobin A1c as an eligible criteria for diagnosing diabetes;
- allowing DSMT to be provided in additional clinical and non-clinical settings including the ability of hospital outpatient DSMT programs to be provided in local community settings;
- extending the availability of the initial 10 hours beyond the first year and covering additional hours of DSMT based on individual need;
- eliminating the restrictions on who is eligible for individual DSMT; and
- expanding the list of providers eligible to refer for DSMT.

We strongly believe that clarifications and updates to the benefit are needed to help improve utilization rates. We look forward to continuing to work with HHS and CMS to reduce barriers to utilization and educate Medicare beneficiaries about the benefits of DSMT.

Objective 1.4 Strengthen and expand the healthcare workforce to meet America's diverse needs.
We support the investment by HHS in strategies to strengthen and expand the healthcare workforce, but we urge you to consider strategies that support all physician specialties that are facing shortages rather than focus exclusively on primary care providers. Primary care is the backbone of the health care system, and access to a primary care physician is important to avoid developing chronic conditions. Having access to a specialist to treat and manage the more complex patient with multiple chronic conditions is also important.

Care by endocrinologists is associated with lower morbidity rates, fewer readmissions, and lower healthcare costs. Endocrinologists provide this cost- and time-effective treatment without the use of unnecessary diagnostic testing and procedures. Endocrinologists also improve quality and reduce costs by coordinating care for patients with co-morbidities. Approximately 40 percent of the total US population has at least one chronic disease and 30 percent of Medicare beneficiaries with diabetes have 5 or more chronic conditions, including osteoporosis and thyroid disease. Endocrinologists are often the primary care provider for these patients, as these conditions and associated complications are often too complex for a general practitioner to treat.

Despite the vital role of endocrinologists in the care of patients with these chronic diseases, there are currently fewer than 4,000 clinical endocrinologists in the United States to care for the 100 million potential patients that suffer from diabetes and prediabetes alone. These workforce shortages can be partially attributed to the low compensation for endocrine care and the administrative burden associated with practice. Compensation is similar to that of primary care physicians, as over 90 percent of endocrinologists' charges are evaluation and management (E/M) codes. Currently, these codes do not account for the non-face-to-face services that cognitive specialists provide to patients with chronic conditions. We have requested that CMS conduct a comprehensive review of cognitive E/M visits to understand care required by the chronically ill patient. Such data will allow for more accurate reimbursement and reduced documentation for services that cognitive specialists provide.

Future earning potential also impacts the number of medical residents who choose to pursue a fellowship in endocrinology. The prospect of repaying hundreds of thousands of dollars in medical school loans on the average salary of an endocrinologist causes many who are interested in endocrinology to choose a higher-paying specialty. We encourage HHS to also offer grants and student loan repayment options for specialists who are willing to practice in underserved and rural communities.

Objective 2.2: Prevent, treat, and control communicable diseases and chronic conditions.

Over 30 million Americans have diabetes and an additional 84 million adults are at risk of developing the disease. By 2050, it is estimated that one out of every three Americans will have diabetes. In addition, the annual cost of this public health emergency has skyrocketed to $322 billion and will continue to rise unless something is done. Further, the Medicare program and older adults are disproportionately affected by diabetes. Approximately 12 million Americans over the age of 65 (nearly 30 percent) have diagnosed diabetes and half of all those over the age of 65 have prediabetes. Medicare currently spends one out of every three dollars on care for people with diabetes.[1]

We support HHS' strategy to improve early detection and treatment of those with or at risk for a range of diseases including diabetes through widespread implementation of evidence-based interventions. The Society also encourages HHS to focus efforts on improving diabetes screening rates in both private and public health

programs. This effort will help reduce the number of Americans with undiagnosed diabetes and prediabetes allowing these individuals to seek treatment or enroll in diabetes prevention programs.
As previously mentioned, over 30 million Americans have diabetes. Unfortunately, 24% of people with diabetes – 7.2 million – are undiagnosed. In addition, only 11.6% of the 84 million Americans with prediabetes know they have it. Despite the fact that the U.S. Preventive Services Task Force (USPSTF) recommends screening adults aged 40 to 70 years who are overweight or obese for diabetes[2] and Medicare covers two diabetes screening tests a year for eligible beneficiaries, millions of Americans remain undiagnosed and are not receiving the care and treatment they need. Given the sheer number of people living with diabetes or at risk of the disease and the hundreds of billions of dollars spent on diabetes, we recommend HHS focus efforts on promoting both the USPSTF diabetes screening guideline and existing Medicare coverage for diabetes screening.

Objective 2.1 Empower people to make informed choices for healthier living.
We support HHS' focus on increasing access to women's health and preventive services. While strategies are being developed to increase access to these services, we encourage you to also ensure access to hormonal contraception. Endocrinologists treat many conditions affecting women that are caused by a loss of normal hormonal function, including menopause, infertility, breast cancer, and Polycystic Ovary Syndrome. Ensuring that all women have access to necessary health care services, contraception, and preventative screenings is a top priority for the Society.

Endocrinologists prescribe hormonal contraception to treat a myriad of conditions; 58 percent of oral contraceptive (OC) users cite non-contraceptive health benefits, such as reduced menstrual bleeding or pain, and acne, as reasons for using the method.[3] In fact, 1.5 million women (14 percent of OC users) use this method exclusively for non-contraceptive purposes[4]. Hormonal contraception also can reduce a woman's risk of developing ovarian or endometrial cancer, and may protect against osteoporosis.[5] We believe that all women should have access to contraception, both for health reasons and to control when they choose to have children.

With the proposed rule that broadens the types of organizations that can claim an exemption from providing insurance coverage that offers contraception at no cost to their employees, we are concerned that losing access to that benefit will prevent women from being able to effectively manage their health and reproductive planning. If this rule is finalized, HHS must put in place strategies that allow those impacted by their employer's choice to continue to have access to hormonal contraception at no-cost.

Objective 4.2 Expand the capacity of the scientific workforce and infrastructure to support innovative research.
We are deeply concerned by emerging data and analysis demonstrating a decline in the number of physician-scientists participating in the biomedical workforce. Physician-scientists make valuable contributions to the biomedical research enterprise; however, they also face unique challenges and barriers to their participation in research. To ensure that physician-scientists are able to be recruited and retained in the research workforce to

respond to current and future demands, the HHS Strategic Plan should support solutions to some of the issues facing this community. Recommended solutions include:

- New models to compensate or preserve time for research activities
- New methods for streamlining the conduct of clinical trials
- Mentorship opportunities for physician-scientists at mid-career stages
- Expanded interdisciplinary training to broaden the perspectives and impact of MDs and PhDs
- Public education about the value of NIH's investment in physician-scientist education

A complete consideration of the needs of and the challenges faced by physician-scientists is a tremendous but important effort, and we are encouraged that the NIH has established the Working Group on the Physician Scientist Workforce. The Endocrine Society appreciates the challenges faced by the NIH and other stakeholders as we work together to sustain a robust biomedical research enterprise that includes the valuable contributions of physician-scientists.