

February 28, 2018

Alex Azar
Secretary, Department of Health and Human Services

Dear Secretary Azar,

On behalf of the Endocrine Society members and leaders, I write to offer our assistance as you lead the Department of Health and Human Services (HHS) in developing and implementing programs that will affect our members who treat patients or conduct research.

Endocrinologists are at the core of solving the most pressing health problems of our time, from diabetes and obesity to infertility, bone health, thyroid conditions, and hormone-related cancers. 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.

We share many of the priorities you highlighted during your confirmation hearings and we would be happy to work with you on these. Attached please find a summary of our policy priorities and positions. If we can be of assistance, please do not hesitate to contact me at bbkeenan@endocrine.org, Robert Lash, MD, Chief Professional and Clinical Affairs Officer at rlash@endocrine.org, or Mila Becker, JD, Chief Policy Officer, at mbecker@endocrine.org when our expertise may be of value.

Sincerely,



Barbara Byrd Keenan
Chief Executive Officer, Endocrine Society

cc: Administrator Seema Verma
Director Francis Collins



Endocrine Society 2018 Policy Priorities & Positions

Making insulin affordable: 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. Average insulin prices have nearly tripled over the past 15 years and patients are becoming increasingly exposed to these costs due to high deductible plans and coinsurance.

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 share the following positions of the Society:

- 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.
- Health plans should exempt insulin from coinsurance/co-pays in high-deductible plans due to its lifesaving nature and high cost.
- 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.
- Congress should consider policies that would reduce patient cost-sharing for insulin and ensure that patients benefit from rebates at point of sale.
- 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.

Addressing the global epidemic of diabetes and obesity: More than 30 million Americans have diabetes and more than 1/3 are obese. Diabetes leads a list of just 20 diseases and conditions that account for more than half of all spending on health care in the United States. US spending on diabetes diagnosis and treatment totaled \$101 billion in 2013 and has grown 36 times faster than spending on heart disease, the country's leading cause of death.¹ The urgency to address this epidemic requires a coordinated effort by the Federal government. We urge you to constitute the newly-established Clinical Care Commission to establish a comprehensive approach to reducing the incidence of diabetes.

Access to preventive care, intensive behavioral counseling and the necessary treatments are crucial to improve early diagnosis and to begin effective treatment before these conditions worsen or costly

¹ Dielman JL, et al. US Spending on Personal Health Care and Public Health, 1996-2013. *JAMA*. 2016;316(24):2627-2646.



complications develop. Provider and patient education must be prioritized to reduce hypoglycemic events, a significant driver of diabetes spending. Because people with diabetes are at risk for costly comorbidities, such as heart disease, stroke and kidney failure, the US must continue researching and building effective multidisciplinary care team models.

We urge the Administration to support:

- Increased funding for the National Diabetes Prevention Program, a proven behavioral intervention that reduces the risk of progressing from prediabetes to diabetes by 71 percent in the Medicare population.
- Coverage for evidence-based obesity treatments.
- Coverage for continuous glucose monitors that allow for monitoring via mobile phones.
- Reauthorization of the Special Diabetes Program at \$300 million to fund type 1 diabetes research at the National Institutes of Health (NIH) and treatment, education, and prevention programs for American Indian and Alaska Native populations, who are disproportionately affected by Type 2 Diabetes. Funding for the program in FY18 has only been allocated through March 31, despite strong bipartisan support.

Ensuring access to affordable health care: We urge HHS to continue to support a health care system that ensures patient access to care that is continuous, high-quality, adequate, and affordable. We want to stress the importance of maintaining insurance market reforms, including the guarantee of health insurance with no annual or lifetime caps or pre-existing condition exclusions, and the opportunity for children to be covered by their parents' insurance until age 26. The ACA has allowed many of these people to obtain affordable insurance coverage; without it, many Americans cannot afford the cost of care for diabetes, which averages \$13,700 per year².

Recognizing the value of endocrinologists: 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. 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, 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. Over 90 percent of endocrinologists' charges are evaluation and management (E/M) codes, but these codes do not account for the non-face-to-face services that cognitive specialists provide to patients with chronic conditions. **We have requested**

² American Diabetes Association. Economic Costs of Diabetes in the U.S. in 2012. *Diabetes Care*. April 2013.



that CMS conduct a comprehensive review 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. We look forward to working with CMS to increase payments for services that are shown to improve outcomes with lower costs.

Women’s health care: 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. Should the ACA be modified, we strongly urge that preventive health services, including hormonal and other contraception, continue to be covered at no cost to the patient.

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 purposes⁴. Hormonal contraception also can reduce a woman’s risk of developing ovarian or endometrial cancer, and may protect against osteoporosis. We believe that all women should have access to contraception, both for health reasons and to control when they choose to have children.

Furthermore, women should not face restrictions on where they are able to access health care services. The January 19, 2018 letter from the Administration to state Medicaid directors related to the “Free Provider of Choice” provision may significantly impact a vulnerable population that needs accessible, high-quality care. We urge you to ensure that all states are abiding by the free-choice provision to protect the health of women.

As the Administration considers changes to Medicaid and the ACA, we strongly urge that preventive health care, including contraception, continue to be covered at no cost and that women have accessible, high-quality care by a provider of their choice.

Federal funding for biomedical research: Endocrine scientists funded by the National Institutes of Health (NIH) continue to make remarkable contributions in areas of critical national interest, including diabetes, obesity, the microbiome, cancer, bone health, and fertility.

President Trump has emphasized the importance of the United States maintaining its place as the global leader in all sectors. Biomedical research is an area where the country is losing its place as the top generator of scientific discovery. The lack of sustained federal support compounded by austerity measures such as sequestration has created a “brain drain,” as gifted scientists pursue other careers or leave the US to develop important breakthroughs and therapies elsewhere, while young people

³ Jones RK, *Beyond Birth Control: The Overlooked Benefits of Oral Contraceptive Pills*, New York: Guttmacher Institute, 2011.

⁴ *Ibid.*



opt out of biomedical research careers. Without steady, sustained increases in federal support for biomedical research and the NIH, other countries will fund groundbreaking new cures and treatments and replace the United States as the global leader in biomedical research.

Future opportunities to cure many diseases will decrease as the government's investment in biomedical research declines. For FY18, we have urged Congress to pass a final spending package that provides at least \$36.2 billion for the NIH. **For FY 2019, we support an increase of at least \$2.2 billion over the final FY 2018 budget to make up for years of flat funding and under-investment, and to maintain America's status as a leading research engine.**

Regulatory burdens in research: Clinical and basic scientists receiving federal support are often negatively impacted by the time and effort required to comply with administrative requirements imposed by granting agencies and their home institutions. For example, grant forms are often not standardized across agencies, creating redundancies, and there can be multiple layers of administrative approval for forms, necessitating advanced due dates.

In addition to the burden on investigators, the excessive administrative burdens waste taxpayer dollars and delay the completion of lifesaving research. The high expense of these administrative and regulatory tasks also results in an increasingly unequal playing field for biomedical researchers at many institutions across the country. **As the Administration examines opportunities to reduce federal regulations, we encourage you to consider opportunities to reduce onerous regulatory burdens faced by researchers.**