ENDOCRINE SOCIETY
Hormone Science to Health

September 6, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1654-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model (CMS-1654-P)

Dear Mr. Slavitt:

On behalf of the Endocrine Society (Society), we appreciate the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed revisions to the payment policies under the Medicare physician fee schedule (PFS) for calendar year 2017. Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, hypertension, infertility, obesity, osteoporosis, and thyroid disease. Many of the patients we treat are Medicare beneficiaries; consequently, the payment policies and other revisions are of importance to our members.

The Society looks forward to working closely with CMS as this proposed rule moves towards implementation and offers the following comments that focus on areas of particular interest to our members:

1. Professional and Technical Components of Certain Services
2. Collecting Data on Resources Used in Furnishing Global Services
3. Improving Payment Accuracy for Primary Care, Care Management Services, and Patient-Centered Services
4. National Diabetes Prevention Program
5. Diabetes Self-Management Training Services

Professional and Technical Components of Certain Services

For many covered services, CMS separates global CPT codes into separate professional and technical components, each of which can be billed separately. The Society believes that CMS has

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the sole authority to decide which global CPT codes can be split into professional and technical components as well as how this division should be performed.

Under present CMS rules, the professional component consists of the physician work involved in a given service, and the technical component consists of everything else involved in the service (e.g. clinical staff time, equipment, supplies, etc). The standard today is that a service that includes no physician work cannot be split into professional and technical components.

In current medical practice, however, many professional tasks that used to be performed by physicians are now performed instead by highly trained clinical staff. Therefore, we suggest that, when considering the division of a global CPT code into professional and technical components, CMS continue to split the global code into professional and technical components, but with the highly trained clinical staff being assigned the professional component. The remainder of the service would be assigned to the "technical" component.

For example, consider continuous glucose monitoring, CPT code 95250. This service includes no physician work. However, there is a considerable amount of professional work performed by highly trained clinical staff rather than physicians. Splitting the global code 95250 into professional and technical components would permit more accurate billing in the many situations in which the medical supplies and equipment are provided by a separate entity other than the one providing the professional work.

For these reasons, we ask that CMS split 95250 into professional and technical components, and that CMS consider such splits for other services in which highly-trained non-physicians are performing the professional work.

Collecting Data on Resources Used in Furnishing Global Services

The Society supports CMS' proposal to collect data on the resources used and care delivered to patients during the 10 and 90 day global periods. As a member of the Cognitive Care Alliance (Alliance), we have proposed that CMS commit to developing an evidence base from which E/M services can be redefined and valued to more accurately describe and value the work performed by cognitive physicians.

The "vigorous data collection effort" for the proposed research effort establishes an important precedent for CMS to address the deficiencies within the families of E/M service codes. To maintain the accuracy and validity of the PFS, CMS's payment policies must be based on a well-constructed, valid and representative knowledge base. The data collection and subsequent analysis of the E/M activities within the 10 and 90 day global periods will equip CMS with the investigational tools and the review processes required to complete meaningful health services

research. Experience exploring the E/M work included in the global periods is a first step toward the more substantial research for which the Alliance has advocated.

We appreciate the agency's recognition of our core position. The proposed rule states, "It is essential that the RVUs under the PFS be based as closely and accurately as possible on the actual resources involved in furnishing the typical occurrence of specific services." To ensure this is the case, an evidence- based founded on health services research is necessary; this applies equally to the services delivered as part of the global periods as to E/M services delivered by endocrinologists and other cognitive physicians.

As the agency appropriately notes, the global periods rely on crosswalks to E/M services based on the assumption that the resources, including work, are similar. The Society firmly believes that the follow up work performed within the global periods and the continuity work performed by cognitive physicians should not be represented by the same codes. The care required by a patient recovering from a procedure is fundamentally different from the typical follow-up of an established outpatient, especially when dealing with a patient with diabetes and other co-morbidities. We anticipate that the data collected as part of this research initiative will demonstrate that only one set of E/M codes is being used to represent substantially different types of work.

With respect to this data collection and research effort, the proposed rule states, "To the extent that such mechanisms prove valuable, they may be used to collect data for valuing other services." The Society believes that the research focused on the global E/M should in fact anticipate the very specific E/M research proposed by the Alliance. The proposal to collect a robust data sample, requiring 5,000 practitioners to report on 20 pre- and post-visits each, reflects a substantial effort. This sample will provide a clear picture of the work and resources utilized during global periods, and we commend the agency for committing to collect such a robust data set. Data reported on claims at the end of the global period will allow the agency to explore the variations in activities, time, intensity, and resources required to deliver these services. While the agency's proposed data collection is robust, we would recommend that direct observation also be used as a tool to capture information on the work performed.

Because the Society believes that the study method outlined in this proposal will be applicable to the study of E/M services delivered by cognitive physicians, the lessons learned from this research should be applied directly to the research proposed by the Alliance: CMS should engage in research to assess the resources and work required to deliver the E/M services provided by cognitive physicians.

Improving Payment Accuracy for Primary Care, Care Management Services, and Patient-Centered Services

Non-Face-To-Face Prolonged Evaluation and Management Services
CMS is proposing to make separate payments for codes 99358 and 99359. Until now, payment for this work was assumed to be bundled into the payment for other services. The Society applauds CMS for proposing to pay separately for these services at the RUC recommended value. We have argued that the existing E/M services do not appropriately reflect and reimburse the non-face-to-face care required by endocrinologists who treat patients with chronic illnesses; proposing separate payment for some of this work shows the agency has recognized these concerns. However, we view this as a temporary solution until cognitive E/M services can be properly evaluated.

While this proposal is an important step towards accurately paying endocrinologists and other cognitive physicians for services they provide, the Society is concerned with the agency's proposal to require that these services be billed on the same day as the office visit. The CPT code descriptor does not require that these services be billed on the same day as an E/M service. Requiring an hour of non-face-to-face care on the day of the E/M visit will severely limit the utilization of these codes. Also, a patient's needs may require that this non-face-to-face care occur over a number of days between office visits. We suggest that CMS allow the code to be billed between office visits. If CMS were to alter these requirements, we would welcome the opportunity to work with CMS to develop workable documentation requirements that address any program integrity concerns.

Chronic Care Management Services
Endocrinologists treat patients with both acute and chronic needs. An endocrinologist may be required to manage the ongoing treatment of a patient with a chronic disease such as diabetes or thyroid disease. In those cases, the endocrinologist often manages care because the chronic condition can provide complications for other medical issues. The Society is very pleased that CMS is proposing steps to improve the chronic care management (CCM) services first billable in 2015. Generally, the Society supports the agency's efforts to simplify the billing requirements for these services and is hopeful that these changes will improve utilization by our members of this service. However, we believe there are further issues for the agency to address, which we will discuss in more detail.

The Society appreciates that the proposed rule recognizes that stakeholders have advised CMS that the Part B coinsurance for the CCM services should be waived. We recognize that CMS does not have the statutory authority to do so without Congressional action and will support legislative efforts to provide CMS with this authority.

We support CMS' proposal to more appropriately recognize and pay for the other codes in the CPT family of CCM services (99487 and 99489). By providing reimbursement for the other services in this family that better reflect the needs of complex patients, we anticipate that we may see increased utilization of these services. However, we remain concerned about the documentation requirements for the CCM service for which CMS currently reimburses as well as the two codes that CMS proposes to reimburse for the first time in this rule.

The Society looks forward to working with CMS to find other solutions to simplify the documentation requirements related to the time spent delivering these services. These services all require a physician to spend a defined amount of time delivering these services per calendar month. Patient care coordination needs may vary considerably from month to month. Over a year, the average time that may be spent on non-face-to-face services may be 20 minutes per month or more. However, it could vary widely from month to month. We believe that this requirement for monthly documentation imposes an unrealistic expectation that challenges practices and potentially generates unnecessary documentation. Documenting short phone calls or other interactions could interrupt the workflow of a practice and potentially disrupt the care delivered to patients. We have previously recommended that the reporting period for CCM services be one year, and that the payment be made based on a monthly average of time spent across the year. Again, we ask CMS to consider this recommendation.

Medicare Diabetes Prevention Program

The Society strongly supports CMS' proposal to expand coverage for the Diabetes Prevention Program (DPP) to Medicare beneficiaries. The DPP is a cost-effective solution to help prevent the diabetes epidemic from continuing to expand and has been shown to be particularly successful among at-risk seniors. The Society urges CMS to align its proposal with the benefit and supplier standards included in the Centers for Disease Control and Prevention's National DPP as closely as possible. The National DPP was established under the Affordable Care Act and requires National DPP suppliers to meet high standards outlined in the Diabetes Prevention Recognition Program (DPRP). The Society believes that it would be confusing to impose conflicting standards from those already in place. Conflicting criteria could have a detrimental impact on access to programs administered to both privately insured and Medicare enrollees. The Society also urges CMS to clarify whether the designation of the DPP as an "additional preventive service" under Medicare Part B also waives cost-sharing for eligible participants. We believe that providing this benefit with no cost-sharing is a critical element for ensuring access to the program for those most at-risk for developing diabetes.

In the proposed rule, CMS states that "MDPP services do not meet the requirement in section 1861(ddd)(1)(B) of the Act that they have received a recommendation with a grade of A or B by the USPSTF." The final guideline issued by the U.S. Preventive Services Task Force (USPSTF) in October

2015, entitled *Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Screening*, provided a B rating to "intensive behavioral counseling interventions" for patients with abnormal blood glucose to promote a healthful diet and physical activity.[1] This recommendation is based on National DPP and Diabetes Prevention Program clinical trial evidence. The Society, in conjunction with a broad coalition of diabetes stakeholders, has met with USPSTF officials to confirm that the intent of this guidance was to enable coverage and clinical decision-making guided by the full recommendation included in the "clinical considerations" section. This section specifically indicates that behavioral counseling programs like the DPP should be considered for patients with abnormal blood glucose (e.g. prediabetes). Private health plans, including Anthem Blue Cross of California, are correctly interpreting the USPSTF guideline and providing coverage of National DPP to enrollees with no cost-sharing beginning as soon as July 2016. The Society asks CMS to revise its interpretation of the USPSTF recommendations.

In the MDPP guidance, CMS proposes that MDPP be a one-time benefit for Medicare beneficiaries at risk for type 2 diabetes. We encourage CMS to include in future rule-making an exception for participants who experience a major life event that may impact his/her ability to attend MDPP sessions. Examples of major life events may include: a newly developed health condition by the participant or a loved one, relocation, or death of a loved one. Finally, in describing the curriculum requirements, the proposed rule suggests that "each MDPP session be at least an hour in duration." CMS should focus on completion of modules in the required curriculum, not session-based time standards, since module completion requires active participation, while a time-based standard does not. There is evidence that time spent completing a module does not correlate with impact on outcomes. Instead, it is the participant's comprehension and ability to turn learning into action that is a greater predictor of their success in achieving clinically-meaningful weight loss. This recommendation is consistent with the CDC standards, which require that "each session must be of sufficient duration to convey the session content OR approximately one hour in length."

CMS proposes "value-based payments" tied to session attendance and weight loss. The CDC's National DPP, as well as the Diabetes Prevention Program clinical trial that was its model, is a year-long lifestyle intervention for the prevention of type 2 diabetes. We request additional clarification from CMS on how MDPP suppliers will be reimbursed for the second 6 months of the year-long intervention if a beneficiary fails to achieve the minimum 5 percent weight loss. We want to ensure that beneficiaries have access for the entire year-long intervention and we are concerned the proposed rule suggests an unsustainable program and reimbursement structure.

We also note that the proposed "required minimum weight loss" for Medicare beneficiaries is a higher bar than that set by the CDC DPRP. While the proposed rule would require a minimum 5%

[1] Sui AL, on behalf of the U.S. Preventive Services Task Force. Screening for abnormal blood glucose and type 2 diabetes mellitus: U.S. preventive services task force recommendation statement. Ann Intern Med 2015; 163(11):861-868.

weight loss per participant, the CDC DPRP requires DPP organizations to demonstrate an average 5% weight loss across program participants. We encourage CMS to align its proposed weight loss requirements with CDC DPRP standards – rather than creating its own new standard – to ensure consistency across programs; to reflect scientific evidence indicating that weight loss of less than 5% can still be effective in reducing the risk of chronic disease; and to ensure that all eligible patients have access to MDPP regardless of any demographic or social factors that may make it harder for them to lose weight.

We acknowledge the proposed rule defines an eligible individual as someone having a fasting plasma glucose (FPG) level of 110-125 mg/dL. This aligns with the World Health Organization's definition of prediabetes but is not consistent with the American Diabetes Association's (ADA) evidence-based Standards of Medical Care, which defines prediabetes as a FPG of 100-125 mg/dL. The discrepancy between the DPRP eligibility standards, which follows the ADA's definition of prediabetes, and the proposed MDPP standards could cause immense confusion for physicians and other individuals who may refer participants to the program. The Society encourages CMS to prioritize education of providers and beneficiaries in order to reduce the potential confusion that may arise from these varying definitions of diabetes risk.

In the proposed rule, CMS sets forth the following criteria for MDPP eligible beneficiaries: (1) are enrolled in Medicare Part B; (2) have as of the date of attendance at the first Core Session a body mass index (BMI) of at least 25 if not self-identified as Asian and a BMI of at least 23 if self-identified as Asian. The Society would like to note that these BMI thresholds are inconsistent with the thresholds set in the CDC's DPRP. The CDC requirements state that "all of a program's participants must be 18 years of age or older and have a BMI of greater than or equal to 24 (greater than or equal to 22 if Asian)."[2] We urge CMS to align the MDPP eligibility standards with the CDC program standards and ask that CMS clarify why the BMI measures differ between the DPRP and MDPP and to allay confusion about the benefit.

We are pleased that the eligibility criteria CMS is proposing allow for screening and diagnosis of prediabetes using the following tests: hemoglobin A1c, fasting plasma glucose, or oral glucose tolerance. It is important that health care professionals and patients have a range of blood glucose test options to screen for prediabetes and determine eligibility. However, we urge CMS to clarify in the final rule that Medicare will begin reimbursing for hemoglobin A1c as a screening test for prediabetes and diabetes. Currently, Medicare covers and reimburses fasting blood sugar tests to screen for diabetes. The hemoglobin A1c test is only covered and reimbursed under Medicare if a patient has already been diagnosed with diabetes and the test is ordered by a doctor.

[2] Centers for Disease Control and Prevention. Centers for Disease Control and Prevention Diabetes Prevention Recognition Program – Standards and Operating Procedures. January 2015. Available online: http://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf

We support CMS' proposal allowing for self-referral, community-referral, or health care practitioner referral to obtain MDPP services. In addition, we are pleased that CMS allows for a beneficiary with previous diagnosis of gestational diabetes (GDM) to be eligible for MDPP. A recent study shows an increase in GDM prevalence from 0.3% in 1979 to 1980 to 5.8% in 2008 to 2010.[3] We urge CMS to clarify that individuals with previous GDM will be able to self-report their history of GDM to become eligible for MDPP.

The Society commends CMS for proposing to allow in-person and remote/virtual delivery of MDPP services. One reason the CDC's National DPP has been so successful is that it is modality neutral. As CMS prepares to roll-out a benefit for which approximately half of all Medicare beneficiaries may be eligible, patient access to eligible programs – and the flexibility to choose the modality which best fits their lives – will be critical in the implementation, participation levels, and ultimate success of the program. We urge CMS to be mindful of the practical implications of its proposed requirements in both in-person and virtual settings, taking care to craft the program so that a variety of providers are able to offer compliant services to Medicare beneficiaries.

The Society urges CMS to align quality monitoring and reporting standards for MDPP suppliers with that of the CDC National DPP. In addition, in order to increase awareness of this benefit and increase participation by patients with prediabetes in evidence-based lifestyle change programs, we recommend that CMS develop and adopt a quality measure (or measures) for prediabetes/diabetes screening and referral to MDPP.

Diabetes Self-Management Training (DSMT) Utilization

The Society shares CMS' concern that only about 5 percent of Medicare patients with newly diagnosed diabetes utilize diabetes self-management training (DSMT) services. DSMT services are an important educational resource for patients with diabetes who must manage this complicated disease. There are a number of barriers that impact the utilization of DSMT including confusion about how and when to make referrals, lack of access to and affordability of these services, including a lack of or poor reimbursement for 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;

[3] Lavery JA, Friedman AM et al. Gestational diabetes in the united states; temporal changes in prevalence rates between 1979 and 2010. BJOG 2016: 123(10).

- 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 urge CMS to increase efforts to make the benefit more accessible to Medicare beneficiaries with diabetes and improve utilization of DSMT. The Society look forward to the clarifications and opportunities to provide feedback to CMS.

The Society appreciates the opportunity to provide comments to CMS on its proposed rule for the 2017 Medicare physician fee schedule. Should you have any questions, please contact Meredith Dyer, Associate Director, Health Policy, at mdyer@endocrine.org or 202-971-3637.

Thank you,

Henry Kronenberg, MD
President, Endocrine Society