ENDOCRINE SOCIETY
Hormone Science to Health

September 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1734-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CMS–1734-P: Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; and Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy

Dear Administrator Verma:

On behalf of the Endocrine Society, thank you for the opportunity to provide comments on the Medicare Physician Fee Schedule (MPFS) proposed rule for Calendar Year 2021. 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, endocrine cancers (ie: thyroid, adrenal, ovarian, pituitary) and thyroid disease. Many of the patients our members treat are Medicare beneficiaries; consequently, the payment policies and other revisions are of importance to our members.

Our members are grateful for the flexibilities implemented by the Centers for Medicare & Medicaid Services (CMS) in response to the pandemic, which have allowed them to continue to deliver high quality care to patients while minimizing their risk of exposure to COVID-19. The Endocrine Society is pleased the agency is proposing additional policies to expand some flexibilities and make other permanent.

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

- Valuation of Codes;
- Evaluation and management (E/M) services;
- Telehealth policies;
- Scope of practice; and
- Medicare Diabetes Prevention Program Expanded Model Emergency Policy.

Valuation of Codes

Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System (Category III CPT codes 0446T, 0447T, and 0448T)

CMS requested information from stakeholders on how to properly value this family of Category III CPT codes for the Insertion, Removal, and Removal and Insertion of an Implantable Interstitial Glucose Sensor System (Category III CPT codes 0446T, 0447T, and 0448T) in the CY 2020 MPFS final rule. Now the agency is proposing national payment amounts for this code family.

The Endocrine Society supports the agency's proposed valuation of the code family. The proposed national payment amount will allow for providers, including many who belong to the Society, to have a wider experience with these codes for when they become Category I codes. We agree with the agency that the work RVUs proposed for the Category III codes should be 1.14, 1.34, and 1.91 respectively, which are based on a crosswalk to the drug delivery implant family (CPT codes 11981-83), and request that these values be finalized.

For the code family's practice expense, the Endocrine Society supports CMS' proposal to add ''implantable interstitial glucose sensor'' (supply code SD334) for Category III CPT codes 0446T and 0448T, with a supply cost of $1,500. We also agree with supply cost of $1,000 for the transmitter, but recommend that the full cost be included in CPT code 0446T only, rather than both CPT codes 0446T and 0448T. Patients will only receive a new transmitter when CPT code 0446T is billed, making it inappropriate to include part of the cost in CPT code 0448T as well.

Evaluation and Management Services

The Endocrine Society appreciates the actions CMS has taken to reduce the burden associated with and to improve the values of the outpatient E/M services. Our members primarily bill level 4 and 5 visits to treat their patients, the majority of which have lifelong chronic conditions, like diabetes and thyroid disease, and the changes finalized in last year's rule will have a positive impact on our members and their patients. We, therefore, recommend that CMS implement the E/M policy without change on January 1, 2021 as planned.

Prolonged Service Add-on Code
The Endocrine Society continues to support the prolonged service add-on code. We request that CMS apply the CPT billing requirements for other time-based codes to this service, so that the add-on code could be billed once more than half of the time in interval has elapsed. While we recognize this would allow this code to be billed more frequently than how the policy is currently finalized, our members have shared that they do not think this will result to a significant increase in utilization from what the agency has already estimated as they only spend time above that for level 5 visits for patients with conditions that require extremely specialized care.

Complexity Add-On Code
The Endocrine Society continues to support the complexity add-on code, GPC1X, which can be added to all outpatient E/M codes to capture additional complexity, and believes it will be useful for endocrinologists. We agree with CMS that the revised outpatient E/M family still does not capture all of work required to treat patients with a single, serious chronic condition, like diabetes or complicated obesity. One potential way to further define the code is that there is added complexity for managing a disease process that can last from one year to the rest of the patient's life, a condition that can end a patient's life, and includes an active monitoring component. We urge the agency to retain the add-on code as finalized and the Endocrine Society would like to continue to be a resource as you further define the code moving forward.

This code will be particularly useful to treat patients with endocrine disorders, which are typically chronic conditions, including both type 1 and type 2 diabetes, and complicated obesity. The Endocrine Society recognizes that the agency specifically requested comments on how to better define the GPC1X add-on service. To assist in this effort, we have developed the following two vignettes are illustrative of how this code would be useful for endocrinologists:

- A 62-year-old woman with diabetes and obstructive sleep apnea presents to her endocrinologist for follow-up. The visit requires a comprehensive review of the patient's blood glucose log, an adjustment to their therapy, education on self-management to ensure effective dosing, a discussion on the impact of lifestyle choices to reduce complications, and treatment of several co-morbid conditions. Since the patient uses an insulin pump, adjustments are made for multiple basal rate settings and for carb ratios, and the patient is educated on these adjustments. The patient will need to closely monitor her blood sugar and report back to the endocrinologist via phone call.
- A 70-year-old man with complicated obesity and non-alcoholic fatty liver disease who recently underwent pituitary surgery presents to his endocrinologist for follow-up. The patient is educated on the medication regimen and potential adverse effects. Discussed health maintenance recommendations, and medication

monitoring plan. The patient will need to closely monitor any adverse events and report back to the endocrinologist on a regular basis via phone call to ensure that the proper medication regimen is being followed.

As CMS considers how to better define this service, the Endocrine Society stands ready to provide additional input as needed.

Telehealth Proposals

Our members treat patients who are particularly vulnerable to COVID-19 infection, and the telehealth flexibilities CMS has implemented have allowed our patients to continue to receive necessary care without unnecessary exposure to the virus. We wish to thank you for your quick action to expand telehealth flexibilities in response to the pandemic and believe that many of these policies should be made permanent to improve patient access and compliance once the pandemic is over. The Endocrine Society urges you to carefully review the data collected during the public health emergency to gain a better understanding of how these telehealth policies can be retained and optimized under regular circumstances.

Permanent and Temporary Telehealth Lists

The Endocrine Society applauds the agency for increasing the number of services available to be provided via telehealth during the public health emergency. We also support the agency's proposal to permanently add eight services to the telehealth services list, including GPC1X and 99XXX as well as the proposal to create a new category of services to be added to the telehealth services list on a temporary basis through the end of the year when the public health emergency ends. Encouraging both patients and providers to utilize telehealth services will not only help protect the health and safety of patients, but will allow providers to appropriately bill for these services without risking their own health. Furthermore, the creation of a temporary Medicare telehealth list will allow Medicare to collect the data needed to appropriately determine whether these services should eventually be added to the permanent telehealth list.

Virtual Check-in

The Endocrine Society supports the agency's proposal to develop and value a code to describe a virtual check-in that is longer than the existing virtual check-in described in G20X2. We recommend a virtual check-in of 11-20 minutes, which would allow for time to provide blood sugar review, adjustment of insulin regimens, and other aspects of chronic disease management. This longer virtual check-in would not take the place of an in-person visit.

Audio-only Visits

The Society's members appreciate the flexibility that CMS has provided for expanded use of telehealth through both audio/video and audio-only visits. The expanded telehealth

flexibilities have been particularly useful for patients with chronic care conditions to continue to have access to care while minimizing their risk. It is also helpful outside of the public health emergency for those who not only are high risk patients (diabetes, endocrine cancers on immunocompromizing chemotherapy), but also those who live a significant distance from the provider or are not able to get leave from work to go to the doctor. This flexibility has also allowed a practice's dietitians to continue to treat patients with obesity and diabetes.

The Endocrine Society recognizes that audio-only E/M services cannot be considered a communications technology-based service because they take the place of an in-person visit and the telehealth regulations require a simultaneous audio/visual connection, and therefore, we request that CMS amend its telehealth regulation to allow for audio-only E/M outside of the public health emergency. These audio-only visits have been particularly beneficial to our patients who are over the age of 70, who lack access to technology required for video visits, or who need to use a translator for visits. Audio-only visits protect the most vulnerable patients, who may not have access to the internet, or whose internet does not support video. This digital divide will continue to be a concern post-pandemic, and therefore these patients for whom continuity of care is extremely important will benefit from the continued ability to utilize audio-only visits.

Direct Supervision

The Endocrine Society appreciates that the agency has allowed direct supervision to be provided using real-time interactive audio and video technology during or immediately after the patient visit. We also support that the agency updated the list of services that are payable when furnished by a resident. These provisions were critical for continued training of fellows at academic centers, as faculty and trainees were not in the same location during the visits. We request that these policies be continued beyond the public health emergency to allow for the continued enhancement of professional educational activities and to allow for the range of teaching modalities to continue to be supported. This is particularly important to ensure that hospitals have adequate supplies of PPE and to not overburden hospital systems. The judgment of the supervising physician should be a sufficient guardrail to prevent fraud and abuse, and the agency could require that the supervising physician provide an explanation for why the real-time audio and video technology is used in the future.

Remote Physiologic Monitoring Services

The Endocrine Society appreciates that the agency has expanded access to remote physiologic monitoring (RPM) services during the public health emergency by adding flexibilities for which patients can receive RPM services and for when patient consent is required. Currently, endocrinologists frequently utilize both CGM monitoring and blood pressure (BP) monitoring to provide improved care to patients. As new technology

continues to evolve, access to RPM services will be increasingly important for endocrinologists and our patients.

Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy
The Endocrine Society appreciates that the agency has provided broader flexibility for MDPP in-person suppliers to offer their services virtually during the public health emergency. These flexibilities will help ensure that beneficiaries can access diabetes prevention program (DPP) services virtually through an in-person provider during the pandemic. However, the Endocrine Society is concerned that the proposed rule prohibits virtual providers from participating in the expanded model during the public health emergency. Before the pandemic beneficiaries experienced geographic barriers in accessing in-person suppliers. Some states have very few in-person suppliers resulting in a lack of access depending on a person's zip code. The pandemic has resulted in a greater need for virtual access to DPP services. People with diabetes are at greater risk of experiencing severe complications from COVID-19. Given this, the Society urges the agency to allow Center for Disease Control (CDC) recognized virtual DPP providers to participate in the expanded model for the duration of the public health emergency.

MIPS Value Pathways (MVP)
The Endocrine Society continues to support CMS' efforts to streamline the reporting programs and allow physicians to focus on measures that can truly improve the health of their patients, rather than checking a box on measures that are not particularly relevant in order to fulfill reporting requirements. We support the agency's proposal to postpone the transition to MIPS Value Pathways (MVP) until CY 2022, due to the COVID-19 public health emergency. In our comments on the CY 2020 MPFS proposed rule, we had expressed concern with the short timeline for MVP implementation, and requested that the agency hold harmless those who choose to participate in an MVP in year 1. We continue to request this transition period once implementation begins in CY 2022. The Society would like to reiterate our other recommendations for the MVP framework, and continues to offer to work with the agency to ensure that MVPs work for all physicians.

Thank you for the opportunity to comment on the Medicare Physician Fee Schedule proposed rule. The Endocrine Society looks forward to working with you on these important payment policies. If we can be of further assistance, please contact Rob Goldsmith, Director of Advocacy and Policy, at rgoldsmith@endocrine.org.

Sincerely,

Gary D. Hammer, MD, PhD
President
Endocrine Society