ENDOCRINE SOCIETY
Hormone Science to Health

September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

Re: Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements

Dear Administrator Brooks-LaSure:

On behalf of the Endocrine Society, thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) Medicare Physician Fee Schedule (MPFS) proposed rule for calendar year (CY) 2022. 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 (i.e., thyroid, adrenal, ovarian, pituitary) and thyroid disease. Many of the patients our members treat are Medicare beneficiaries; consequently, the payment policies and other revisions in the MPFS are of importance to our members. We welcome the opportunity to work with CMS to address the ongoing needs of Medicare beneficiaries and ask you to consider our comments on the following sections of the proposed rule as you finalize your policies for CY 2022:

- Practice Expense Clinical Labor Pricing Update
- Telehealth Services
- Virtual Check-in
- Principal Care Management and Chronic Care Management
- Split (or Shared) Evaluation and Management Visits
- Medicare Diabetes Prevention Program
- MIPS Value Pathways

Practice Expense Clinical Labor Pricing Update

CMS is proposing to update the practice expense (PE) clinical labor pricing using the most current Bureau of Labor Statistics data in CY 2022 in conjunction with the final year of the update to the supply and equipment pricing inputs. The Endocrine Society commends CMS for ensuring that PE values are set using the best available data as we believe the valuation of all of the components of physician services should be; however, we are concerned that this proposal will significantly decrease the values of a number of services commonly billed by endocrinologists while members are still struggling to address

2055 L Street NW
Suite 600
Washington, DC
20036

T. 202.971.3636
F. 202.736.9705

endocrine.org

the COVID-19 pandemic. Specifically, services, including traditional continuous glucose monitoring, implantable glucose monitoring, and fine needle aspiration, are proposed to see decreases well above the 3.75 percent decrease to the conversion factor with some services set to see cuts of almost 25 percent forcing practices forcing practices to evaluate whether it is still financially viable to deliver these services to patients in the non-facility setting. The Endocrine Society is concerned that many of these services will shift to the more expensive hospital setting if providers cannot afford to offer them in the physician office setting. As diabetes technology evolves and provides better solutions for patients to achieve better glucose control, Medicare reimbursement should support access to clinically appropriate care, not discourage it. To minimize the impact on practices and disruptions in care, we recommend these changes be phased-in over a four-year period as the agency did with the supply and equipment input updates. Further, we recommend CMS work with stakeholders to identify and implement processes to more regularly review these inputs to avoid such significant fluctuations in value in the future.

Telehealth Services

Endocrine Society members have utilized CMS' telehealth flexibilities to deliver high quality care to Medicare beneficiaries during the COVID-19 public health emergency and believe expanded access to appropriate telehealth services has the potential to improve beneficiaries' health and outcomes outside of emergency situations. Expanded access to telehealth will also help in addressing a nationwide shortage of endocrinologists, which has created access issues in many parts of the country. One recent study found that 75% of U.S. counties do not have a practicing endocrinologist.[1] Greater access to telehealth is essential to ensure treatment of patients with endocrine disorders. Therefore, we are pleased CMS is proposing to expand access to certain telehealth services within its statutory authority.

Revised Timeframe for Consideration of Services Added to the Telehealth List on a Temporary Basis
The Endocrine Society supports the agency's proposal to revise the timeframe for Category 3 codes (i.e., services added to the telehealth list on a temporary basis) and allow them to remain on the list until the end of CY 2023. This proposal will allow the agency and stakeholders more time to collect more data on telehealth utilization to make evidence-based decisions when considering these services for permanent addition to the telehealth list. We also ask that the agency consider retaining Category 3 telehealth services after the pandemic which would allow services to be delivered on a temporary basis to Medicare beneficiaries and appropriate utilization data to be collected to evaluate their addition to the telehealth list on a Category 1 or 2 permanent basis.

We recognize that other services added to the telehealth list on an interim basis will be removed when the public health emergency expires; these services include the telephone visit services (CPT codes 99441-3). The telephone evaluation and management (E/M) services have been an important tool our members have used to ensure patients continue to receive necessary care during the COVID-19 pandemic. CMS coverage of audio-only services during the health emergency also addresses health

[1] Oser, S. M., & Oser, T. K. Diabetes Technologies: We Are All in This Together. *Clinical Diabetes: A Publication of the American Diabetes Association*, 2020, 38(2), 188–189. Retrieved from: https://doi.org/10.2337/cd19-0046

inequities by providing greater access to underserved populations, particularly in rural areas where patients lack reliable broadband access. We believe audio-only services will continue to have a role in improving access and adherence for patients with chronic conditions like diabetes after the public health emergency concludes but understand Congress must act to provide CMS with the statutory authority to maintain coverage of these services outside of the mental health space in a non-emergency situation. The Society will continue to advocate for Congress to provide the agency with this authority; however, we request the agency share the utilization data for these services during the public health emergency to provide stakeholders with a better understanding of how they have been utilized outside of treatment for mental health conditions in the interim. This data will also allow the Endocrine Society to work with CMS to address any fraud and abuse concerns stemming from a potential expansion of audio-only services.

Expanded Access to Mental Health Medicare Telehealth Services
The Endocrine Society is aware that the Consolidated Appropriations Act of 2021 provided for the elimination of the originating site and geographic restrictions for mental health services which the agency is implementing in the proposed rule. Additionally, the agency is proposing to allow mental health services to be delivered to established patients using the audio-only modality with an appropriate modifier when a simultaneous audio and visual connection cannot be established for reasons outlined in the proposal and the originating site is their home.

The Endocrine Society is continuing to advocate that Congress eliminate the originating site and geographic restrictions more broadly as well as authorize CMS to continue covering audio-only services in appropriate circumstances. The latter is particularly important for the patients our members treat who lack access to the technology required for video visits, or who need to use a translator for medical visits. Our members can attest that audio-only visits address health disparities by protecting vulnerable patients, who may not have access to the internet, or whose internet does not support video. We believe that telehealth services are an important tool to improve patient access and compliance based on information being shared by our members. One member reported he practices in a large academic medical center's division of endocrinology, and they have witnessed their no-show rate decrease from between 11-15% to 5-6% as the rate of telehealth visits increased. The Endocrine Society looks forward to working with you and Congress to retain these benefits. However, the Society is concerned that CMS' definition of the home as it pertains to the audio-only proposal may be too limited. Many individuals, particularly those who are unable to establish simultaneous audio and visual connections, experience housing insecurity or homelessness which could potentially disqualify them from receiving necessary medical care should the definition of home be too narrow. The Society recommends that the definition be crafted in a manner to ensure that patients receiving these services are in a location that is private and safe, even if it that location is not a home in the traditional sense, and may include rehabilitation centers, long term care facilities, and even the patient's workplace. Further, providers will face additional burden verifying a patient is in their home under a limited definition. The Society respectfully requests the agency provide a clear definition of the home taking these issues into consideration.

Virtual Check-in

The Endocrine Society continues to support the virtual check-in HCPCS code G2252 (Brief communication technology-based service, e.g., virtual check-in service, by a physician or other qualified health care professional who can report evaluation and management services, provided to an

established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion). We recommend CMS finalize its proposal to permanently adopt this code. This virtual check-in would not take the place of an in-person visit but would allow for time to provide blood sugar review, adjustment of insulin regimens, and other aspects of chronic disease management. Despite the Society's support for this policy, we believe that utilization may be limited for this service as the required co-pay may pose a barrier to greater provider adoption of this service. We recognize CMS does not have the authority to waive this co-pay but want to highlight this for the agency. As previously discussed, we do not believe this service takes the place of the audio-only E/M services (CPT codes 99441-3) and will continue to urge Congress to provide the agency with the statutory authority to allow providers to deliver these services in medically appropriate circumstances.

Principal Care Management and Chronic Care Management

The American Medical Association RVS Update Committee (RUC) resurveyed the Chronic Care Management (CCM) code family, including Complex Chronic Care Management (CCCM) and Principal Care Management (PCM), and added five new CPT codes 99X21, 99X22, 99X23, 99X24, and 99X25, and the agency is proposing to adopt the work and PE values as recommended by the RUC. These services capture work delivered to patients with complex conditions, like diabetes, and as such, the Society urges to finalize this policy as proposed.

Split (or Shared) Evaluation and Management Visits

CMS is proposing changes to its split (or shared) E/M visit policy in this proposed rule. Specifically, the agency is redefining its rules when these services are delivered in the facility setting, limiting the billing practitioner to either the physician or non-physician provider (NPP) who provides more than half of the patient visit as indicated by time. Split (or shared) services may be employed in endocrine practices for the treatment of diabetes. As an example, this visit would take place with an endocrinologist and a diabetes educator for the continuing glucose monitor placement and education. The Society is concerned that this may become burdensome for physicians and NPPs who will become clock watchers to determine which practitioner performed the majority of the visit. Under the new E/M documentation guidelines, it is more common to select visit level by medical decision making rather than time, so this proposal represents a significant disruption to usual practice patterns. We request CMS reconsider this policy and develop an alternate that does not increase burden on providers and recognizes typical practice patterns.

Medicare Diabetes Prevention Program

The Endocrine Society supports the changes proposed to the Medicare Diabetes Prevention Program (MDPP) expanded model to help make this program more widely accessible for beneficiaries. CMS has proposed shortening the MDPP services period to one-year by removing the Ongoing Maintenance sessions phase in the second year of the MDPP set of services. We support this change because it will align the MDPP with the National DPP making the program more attractive to eligible organizations and beneficiaries. We also support the proposals to waive the provider enrollment fee and to increase performance payments for MDPP beneficiary achievement which will improve supplier enrollment and increase beneficiary access.

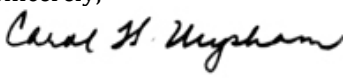
While we support these proposed changes, there continues to be a lack of full alignment between the MDPP and the National DPP at the Centers for Disease Control (CDC). There are two areas where we think alignment is needed to ensure greater use of the program. We ask CMS to remove the once-per-lifetime limit on benefits which restricts access to this program for beneficiaries who would are in the greatness need of MDPP services. The once-per-lifetime rule also does not align with other Medicare programs for behavior change, including smoking cessation and obesity counseling. We also support allowing CDC recognized virtual DPP providers to participate in the MDPP. Allowing virtual providers to participate in the program would address beneficiary needs for more virtual access to DPP services due to the COVID-19 pandemic.

MIPS Value Pathways

CMS is continuing to move forward with the development of MIPS Value Pathways (MVPs) but is proposing to delay the transition to MVPs to the CY 2023 performance year due to the COVID-19 pandemic. The Society supports this decision as many practices are still grappling with the long-term effects of the pandemic and a significant change to a practice's quality reporting would be disruptive at this time. Further, CMS has proposed to sunset traditional MIPS at the end of the CY 2027 performance period and will require mandatory MVP reporting in the CY 2028 performance period and subsequent years. We believe CMS should further delay the requirement for MVP reporting to be mandatory and provide additional time for the transition. Eliminating traditional MIPS and requiring MVP reporting in CY 2028 is too short a timeline given the small number of MVPs currently available and the time required to develop MVPs that represent the full range of medical practice. As an example, multiple MVPs, including for diabetes, thyroid disorders, osteoporosis, and hypogonadism, will be required to cover the full range of our members' practices. CMS should not finalize this timeline as proposed and instead should propose a policy when the agency and stakeholders have a clearer understanding of the timing for MVP development and deployment

Thank you again for the opportunity to provide comments on this proposed rule. We are committed to working with you on the development of these payment policies. Should you have any questions or require additional information, please direct your correspondence to Rob Goldsmith, Director of Advocacy and Policy, at rgoldsmith@endocrine.org.

Sincerely,



Carol H. Wysham, MD
President
Endocrine Society