September 4, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, Maryland 21244-1850

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality payment Program; and Medicaid Promoting Interoperability Program (CMS–1693–P)

Dear Administrator Verma:

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 2019 in the Notice of Proposed Rulemaking (NPRM). 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 our members 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 interest to our members:

1) Revisions to the Evaluation & Management Coding and Documentation Requirements
2) Valuation for Fine Needle Aspiration Biopsy
3) Valuation and Practice Expense for Continuous Glucose Monitors
4) Expanding Access to Telehealth Services
   a. Interprofessional Internet Consultations
   b. Brief Communication Technology-based Services
5) Quality Payment Program (QPP)/Merit-based Payment System (MIPS)
   a. Increased Performance Threshold
   b. Low-volume Exclusion Criteria
   c. Promoting Interoperability Performance Category and Future Reporting Considerations
   d. Increased Weight of Cost Category
Revisions to the Evaluation & Management Coding and Documentation Requirements

The Society commends the CMS for recognizing the documentation burden associated with the existing E/M codes and strongly supports the “Patients Over Paperwork” initiative. E/M document and payment changes, if evidence-based, have the potential to improve patient access and satisfaction, as well as reduce physician burden and address workforce shortages. It is imperative that steps be taken to address the endocrinologist workforce. There are fewer than 6500 endocrinologists in the United States available to care for the millions of patients with conditions including diabetes, thyroid disease, osteoporosis, and other hormonal conditions.1 Poor compensation is one of the key factors driving this shortage; compensation for endocrinologists is the lowest of any internal medicine specialty and even lower than the compensation for general internists.2 Our members perform few procedures and rely on E/M level 4 and 5 office visits for billing purposes. These concerns have driven the Society’s participation in the Cognitive Care Alliance (Alliance), a group of eight cognitive specialty societies united in their concern about the definitions and values of E/M services.

The Society appreciates the agency’s recognition that the existing outpatient E/M services and their documentation requirements do not accurately reflect current medical practice:

“...it is clear to us that the burdens associated with documenting the selection of the level of E/M service arise from not only the documentation guidelines, but also from the coding structure itself...We believe that the most important distinctions between the kinds of visits furnished to Medicare beneficiaries are not well reflected by the current E/M visit coding. Most significantly, we have understood from stakeholders that the current E/M coding does not reflect important distinctions in services and differences in resources. At present, we believe the current payment for E/M visit levels...are increasingly outdated in the context of changing models of care and information technologies.”

We recommend

The existing documentation requirements are over 20 years old and do pose real challenges for physicians. However, these challenges cannot be completely divorced from the payment inequities that we attribute to the under-recognition of the cognitive work intensity. The current outpatient E/M codes undervalue the purely cognitive physician work relative to that captured in the thousands of procedure codes. The failure of the current codes to capture the most complex E/M activities and the resultant relative undervaluation of these critical services must both be addressed to ensure that Medicare beneficiaries have continued access to endocrinologists.

Therefore, the Society opposes all of the proposed payment changes for E/M services that the agency states are “intrinsically linked” to the documentation changes. The agency proposed collapsing 99202-05 and 99212-15 and creating a single rate for these services, developing new G codes for primary and certain specialty care, a new G code for prolonged E/M service, and a multiple procedure payment reduction. These changes will do nothing to address the patient access problems and workforce shortages impacting the practice of endocrinology right now. Instead, collapsing five levels of E/M codes into two will exacerbate the existing compensation disparities facing endocrinologists.

Instead, we urge CMS to work with stakeholders to develop an alternative evidence-based approach to E/M payment and documentation that will reduce burden, be appropriate for inclusion in new models of health care delivery, address the compensation inequity of endocrinologists and other cognitive physicians, and support the delivery of high quality patient care that can be included in the proposed CY 2020 Physician Fee Schedule.

As an alternative payment scheme is being devised, we urge the agency to implement the following documentation changes that are not tied to E/M payment changes on January 1, 2019:

- Allow physicians to document visits based solely on the level of medical decision making or the face-to-face time of the visit as an alternative to the current 1995/1997 guidelines;
- If physicians choose to continue to document under the current guidelines, limit required documentation of the patient’s history to the interval history since the previous visit (for established patients);
- Eliminate the requirement for physicians to re-document information that has already been included in the medical record by practice staff or by the patient; and

Finalizing these changes is a significant first step towards CMS’ stated goal of reducing administrative burden. They can also easily be adopted by commercial payers who the agency correctly recognizes tend to adopt Medicare payment policies. This will also eliminate the possibility that physicians will be forced to document E/M visits under requirements for each payer, representing an increase in physician burden.

Proposed Documentation Changes
As we previously stated, the Society is appreciative of the agency’s efforts to reduce the documentation burden associated with E/M codes. We provided comment on this topic in response to the CY 2018 Physician Fee Schedule proposed rule and stressed the importance of medical decision making in documentation for our members.

The agency has proposed to allow physicians to document medical necessity and either medical decision making, time, or the current 1995/1997 guidelines for a level 2 visit to reduce burden.
This change, the agency claims, will reduce the time physicians spend documenting office visits by 51 hours.

Many of our members spend time on nights and weekends completing the documentation for their office visits. As a result, this reduced documentation time will not increase their time available to see new or existing patients. The waitlist to see an endocrinologist is typically long, and the institutions where our members practice would encourage them to see new patients rather than spend additional time with their established patients. Therefore, it is unlikely this proposal will improve patient access to endocrinologists.

Changes to documentation requirements may be detrimental to patient care, as our members do not document just to fulfill CMS’ billing guidelines. There are also legal and patient care reasons driving documentation. Limiting documentation to level 2 requirements will undermine good patient care for much of the work our members do.

**Single Payment Level Proposal**

CMS proposed a single payment amount for codes 99202-25 and 99212-15 of $135 and $93 respectively. These values were determined by a weight average of the work RVUs based on specialty utilization for levels 2-5. To address the reimbursement shortfalls that some specialties would experience as a result of the code collapse, the agency proposes to create complexity add-ons for primary care of $5 and for certain specialty care of $13.70. To remain budget neutral, these add-on codes will be funded by a multiple procedure payment reduction for any E/M service billed with modifier 25 on the same day as a procedure.

In the proposal, CMS states that “E/M visits comprise approximately 40 percent of allowed charges for PFS services, and office/outpatient E/M visits comprise approximately 20 percent of allowed charges for PFS services.” Given the significant amount of PFS spending represented these services, we believe an evidence-based approach should be pursued for changes that would reallocate such a large portion of PFS spending. The proposed payment changes were made to comply with the budget neutrality requirement and the program integrity concerns that would result from allowing physicians to document medical necessity and either medical decision making, time, or the current 1995/1997 guidelines for a level 2 visit. Furthermore, these proposed changes to E/M coding and payment are not resource-based, which may be a violation of the Social Security Act.

We are deeply concerned that these payment changes will result in provider behavior changes that may have unintended consequences for patients. It is not clear from the rule if the agency has fully
considered this impact, although they are described by the CMS Office of the Actuary. Our members treat patients with multiple complex and chronic conditions, many of whom are frail and elderly and require their endocrinologist to spend significant time with them in the evaluation and management of their health conditions. The reduced payment for level 4 and 5 visits may force them to spend less time during each clinical encounter or to limit each visit to 1 or 2 problems, resulting in the need for additional visits to discuss their remaining health conditions. This is not only a time and financial burden on the patient, it exacerbates the supply and demand challenges facing our specialty. Additionally, patients will either be overpaying or underpaying their co-payments for these services since their share will no longer vary with the service level.

The reduced reimbursement may also cause some institutions and providers to choose not to care for the complex patients because E/M reimbursement will no longer recognize the resources required to treat them. Academic medical centers and other large referral centers may end up being the only institutions that will treat the sickest and most complex Medicare beneficiaries. Besides the financial strain it may place on these institutions, it will likely create an additional burden on patients who may be forced to travel longer distances to find a physician who will treat them.

Endocrinologists typically rely on level 4 and 5 visits. The agency provided its estimated impact in Table 22 of the rule, but this differed significantly from the analysis conducted by the American Medical Association (AMA) included in Appendix A. In both analyses, endocrinology will be held harmless, unlike many other specialties. However, this is not reassuring to the Society. This is the first major change to E/M coding and payment since the inception of the Resource Based Relative Value Scale (RBRVS) in 1992; however, it does nothing to improve compensation for endocrinologists who primarily bill E/M services at a time when the number of Medicare beneficiaries with endocrine disorders, like diabetes, is growing. Any major changes to E/M coding and payment must have a positive impact on the endocrinology workforce shortage and access challenges our patients are facing.

The existing E/M code set does not accurately reflect the cognitive intensity required to care for the most complicated, challenging, and vulnerable patients our members treat. Preliminary analysis of this proposal confirms our belief. For endocrinology and other specialties that rely on level 4 and 5 visits, significant reimbursement decreases could be devastating to patients and providers. The more demanding work load coupled with lower payments for this high intensity work will be another reason that medical students with growing student debt choose not to enter

endocrinology. We cannot support a proposal that has not been fully vetted and will exacerbate the supply and demand issues facing endocrinology.

For all of these reasons, the Society does not support the single payment rate for both 99202-05 and 99212-15.

Add-on Proposals
The Society recognizes that the agency proposed the primary care and specialty complexity add-on codes (GPC1X and GCG0X) to address the cuts to reimbursement that would have resulted from collapsing the level 2 through 5 office visits. However, we cannot support the add-on services as proposed because they do not capture the added work inherent in cognitive services and they imply that the added work associated with some specialties is greater than others. We also believe the application of both these codes as defined by the agency is arbitrary.

We have significant concerns about GCG0X. CMS proposed that this add-on with a proposed value of 0.25 RVUs be billed with both new and established patient visits. The agency defines the proposed code’s descriptor to be: Visit complexity inherent to evaluation and management associated with endocrinology, rheumatology, hematology/oncology, urology, neurology, obstetrics/gynecology, allergy/immunology, otolaryngology, cardiology, or interventional pain management centered-care. In follow up discussions, the agency has stated GCG0X applies to care related to these specialties rather than the specific specialty.

Even if this proposed add-on does not violate the legal prohibition on creating specialty-specific payment rates, it fails to recognize the complex care delivered by cognitive physicians. CMS valued this add-on at $13.40. When billed in conjunction with the single payment “established patient” visit worth $93, this still falls short of the current level 4 reimbursement of $109 and level 5 reimbursement of $148. This reduction, while small, will have a significant impact on a practice that typically bills level 4 and 5 visits over the course of a year. The value of this code also assumes that all specialty visits have the same level of complexity.

While endocrinology is on the list of specialties included in the description of the complexity add-on, there are several complex specialties, like nephrology and infectious disease, that are not. A complexity adjuster may be more appropriate if it were tied to the complexity of the patient rather than the work of certain specialties. This will recognize that complexity is driven by the patient’s condition, not a particular specialty. If CMS were to devise an alternative method of complexity based on this concept, the Society would welcome the opportunity to work with the agency to appropriately value it.

A better measure of complexity must be developed and must be captured by any new E/M coding and payment scheme. The complex cognitive work our members deliver to patients is not
reflected by the existing E/M codes or in what is being proposed by the agency. We welcome the opportunity to work with other stakeholders and the agency to explore how to code and appropriately value complex work.

The agency also proposes the creation of a new 30-minute prolonged service G code (GPRO1) that can be billed with longer visits. The Society appreciates the agency’s intent to recognize there are circumstances where longer visits are necessary, as this add-on could be particularly relevant for our members. However, we had difficulty determining when and how this code could be billed because of the lack of clarity around the time required for the single payment rate E/M services.

The agency requested feedback on the time required for the collapsed codes, either the weight averaged times of 38 and 31 minutes for the new and established level 2-5 services or the existing times for the individual codes. Evaluating how often a practice or specialty will utilize GPRO1 is dependent upon knowing how to account for the time of the base E/M code. We have significant concerns that some individuals might game the system and bill the add-on code for level 2 visits that last 26 minutes: the first 10 minutes would satisfy the time requirement for a level 2 visit and the additional 16 would meet the add-on code time requirement. The Society does not think this was the agency’s intent and believes that the add-on code was intended to compensate the physicians for longer visits required to treat medically complex patients, like those treated by our members. We request that the agency clearly articulate the time requirements for any new E/M and add-on codes that may be considered in future rulemaking.

The Society wants to reiterate that there are typically long waitlists to see our members. If GPRO1 were to be implemented as we believe the agency intended, endocrinologists likely would be unable to spend the time required to bill the service with patients. The institutions where endocrinologists practice encourage them to see as many patients off the waitlist as possible. Therefore, this service would not fully compensate for any shortfalls in the cut to level 4 and 5 reimbursement as the agency posits.

**A Path Forward**

The Society cannot support coding and payment changes that reduce reimbursement for level 4 and 5 office visits our members bill to see medically complex patients and would exacerbate physician workforce shortages and create new patient access challenges. We stand ready to work with CMS to develop a new coding and payment scheme for E/M services that both reduces administrative burden and equitably reimburses physicians for the services they provide to Medicare beneficiaries. We propose CMS implement the documentation changes articulated in these comments on January 1, 2019.

Rather than implement the payment changes outlined in the rule that will have many unintended consequences, including limiting patient access to appropriate cognitive care, the Society urges
CMS to collaborate with stakeholders to develop evidence-based alternative new and established outpatient E/M service codes that accurately reflect the breadth and depth of the clinical care provided by all specialties, including the endocrinology.

There are a range of coding and payment options that should be modeled and thoroughly evaluated, including the following:

- Combining levels 2/3 and 4/5
- Combining levels 2-4 and leaving 5
- Combining levels 2/3 and leaving 4 and 5

We will work with other stakeholders to present a new coding payment structure in time to be included in the CY 2020 Physician Fee Schedule proposed rule.

**Modernizing Medicare Physician Payment by Recognizing Communication Technology-Based Services**

The Endocrine Society applauds CMS for its proposals to expand medical care using telecommunications technology, specifically for the creation of the Brief Communication Technology-based Service, e.g. Virtual Check-in (GVCI1) and Remote Professional Evaluation of Recorded Video and/or Images (GRAS1). We believe that these codes will increase patient access and provide new options for our members to treat patients. Our members frequently consult with patients outside of office visits and currently do not receive separate compensation for those services; this proposal is a step towards improving compensation for the care our members already provide.

We request that CMS provide clarification about whether these services can be billed during the same time period that a physician may be providing Chronic Care Management (CCM) services. As we understand the proposal, GVCI1 and GRAS1 would be considered separate from the care provided as part of the CCM service and could be billed, but we would appreciate further guidance from the agency on this point.

**Valuation of Specific Services**

*Fine-Needle Aspiration (10021, 10X12)*

In June 2017, the AMA CPT Editorial Panel revised 10021 and created nine new codes to describe fine-needle aspiration procedures with and without imaging guidance. CMS accepted the RUC recommended work values for 7 of the 10 codes in the family. However, CMS did not accept the RUC recommendations for 10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion) or 10X12 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion).
The agency rejected the RUC recommended value of 1.20 RVUs for 10021; this value was based on a robust survey. Instead, CMS proposed a 1.03 RVUs based on a direct crosswalk to 36440 (Push transfusion, blood, 2 years or younger). We believe this is an inappropriate crosswalk for 10021 because it has no Medicare utilization and a volume of only 41 in Medicaid. It also has an extremely low performance rate by the RUC survey participants. Other concerns about this crosswalk are that 36440 is not used in the adult population or the outpatient setting as 10021 is utilized. If CMS proceeds with crosswalking this code, we recommend the agency consider using one of the following more appropriate codes that will better approximate the work involved:

- 78451 (1.38 wRVU)
- 95865 (1.57 wRVU)
- 53855 (1.64 wRVU)
- 40490 (1.22 wRVU).

For 10X12, CMS rejected the RUC recommended value of 1.63 RVUs and instead proposed a value of 1.46 based on adding the incremental difference between the RUC recommended work RVUs for codes 10021 and 10X12 (0.43 work RVU difference). We request that CMS increase the value of this service based on a new value for 10021 using one of the crosswalks suggested above or based upon a crosswalk to one of the following appropriate services:

- 30905 (1.97 wRVU)
- 64642 (1.65 wRVU)
- 64646 (1.80 work RVU).

**Diabetes Management Training**

The Society is also disappointed CMS did not address barriers in Medicare impacting beneficiary utilization of the diabetes self-management training (DSMT) benefit. CMS solicited comments from stakeholders in the CY17 Medicare Physician Fee Schedule proposed rule and the Society has been part of ongoing conversations with CMS about this issue, through in-person meetings and written communications, over the past two years. We were hopeful CMS would use this opportunity to address barriers to DSMT given that utilization of the DSMT benefit stands at only 5% of eligible Medicare beneficiaries. The Society will continue to work with CMS to address these barriers and improve utilization of this important benefit.

**Interprofessional Consultations (994X0, 994X6, 99446, 99447, 99448, 99449)**

The Society applauds the agency for proposing to reimburse physicians for this family of services that describe interprofessional telephone/internet/electronic medical record consultation services. The agency previously considered 99446-9 to be bundled services and were not separately payable. We support the agency’s proposal to separately pay for these services. Again, our members have been providing these services without separate reimbursement and appreciate the agency’s
recognition of the need to reimburse for this previously uncompensated care. We urge CMS to provide clear guidance to physicians on how to appropriately utilize these codes.

Changes to Direct Practice Expense Inputs for Specific Services
Market-Based Supply and Equipment Pricing Update
The Protecting Access to Medicare Act of 2014 (PAMA) provided that the Secretary may collect or obtain information from any eligible professional on the resources directly or indirectly related to the delivery of fee schedule services. CMS hired a contractor to conduct a market research study to update the direct PE inputs for supply and equipment pricing for CY 2019. The rationale for this study was that the prices were last updated in 2004-05. Based on this study, the agency is proposing to adopt the updated PE inputs.

Based on this study, CMS is proposing to reduce the prices for both the continuous glucose monitoring (CGM) device and sensor. The direct PE input for the CGM device decreased from $1171 to $836 and for the CGM sensor from $53 to $44. The Society is very concerned with these proposed decreases, particularly those for the CGM sensor, particularly because both were recently subject to RUC review. In such instances of very recently completed individual CMS reviews, it would seem to be logical for CMS to rely on its own detailed individual analyses to establish the prices for supplies and equipment.

For example, in the Final Rule for the 2018 Medicare Physician Fee Schedule, which was released less than a year ago (82 FR 53069), CMS established a new price for “glucose monitoring interstitial sensor” (SD-114) of $53.08, based in part on its analysis of 19 invoices for this specific item. The survey recommends a further reduction in this price down to $43.95.

We strongly encourage CMS continue to use the current value for SD-114, which it developed very recently after its individual analysis of this item, rather than the contractor-suggested price that was developed as part of a massive survey of over 2000 items.

Similarly, in the Final Rule for the 2018 Medicare Physician Fee Schedule released last November (82 FR 53069), CMS indicated that it had conducted a detailed analysis of the cost of the continuous glucose monitoring system (EQ-125), including literature review and evaluation of vendor prices, and it established a new price of $1170.54 for EQ-125, which represented a cut of more than 50% from the previous allowed price. The contractor has proposed a further reduction in this price down to $835.53.

Once again, we encourage CMS to continue to use the current value for EQ-125, which it developed very recently after its detailed individual analysis of this item, rather than the contractor-suggested price that was developed as part of a massive survey.
Quality Payment Program/Merit-based Payment System

The Society thanks CMS for its continued efforts to reduce the administrative burden associated with the Medicare payment system through its “Patients Over Paperwork” initiative. We recognize that many of the provisions in the NPRM are designed to reduce administration burden and enhance patient care, but we are concerned that there may be unintended consequences that could be detrimental to providers, and, ultimately, patients. Also, the agency is proposing many policies to streamline participation and reduce reporting burden. However, the Society remains concerned that the complexity of the program still poses challenges for small practices and rural providers. We urge CMS to continue to focus on reducing burden for these practices in particular.

a. Increased Performance Threshold

CMS proposes to increase the performance threshold that determines whether an eligible provider receives a positive, neutral, or negative increase from 15/100 to 30/100. We are concerned that this increase is too aggressive, particularly as providers are still adjusting to and understanding how the program applies to their practice. The statute does not require a specific pace for increasing the threshold; we therefore urge CMS to either maintain the 15/100 threshold or increase it a nominal amount until granting providers adequate time to adjust their practice to meet the program’s requirements.

b. Low Volume Exclusion Criteria

The NPRM continues the low volume exclusion criteria related to number of patients and number of Part B allowed charges and adds a new exclusion criterion focused on the number of services provided. As the QPP is a complex payment system, we appreciate that CMS continues to provide accommodations for small practices. Beginning with the 2021 payment year, if an eligible clinician, group or APM Entity group in a MIPS APM meets or exceeds at least one, but not all three, of the low-volume threshold determinations, then the eligible clinician or group may choose to opt-in to MIPS. This provides an important opportunity to small practices that believe they can succeed under the MIPS system to earn a payment bonus. We urge CMS to allow even those practices that meet all three exclusion criteria to elect to participate in MIPS.

c. Promoting Interoperability Performance Category and Future Reporting Considerations

CMS proposes to require use of 2015 certified electronic health record technology (CEHRT) by all eligible providers. Through program year 2016 of the Medicare EHR Incentive Program, 354,395 eligible providers participated in the program. Eighty-two percent of these providers had 2014 CEHRT while less than 0.02 percent used 2015 CEHRT. While more providers may now be using 2015 CEHRT, the vast majority of providers are likely still using 2014 technology. Requiring all eligible providers to switch to 2015 CEHRT before January 1, 2019 is unrealistic and will be a significant burden on providers, particularly those with limited resources. We support CMS’ effort to reduce burden by better streamlining workflows and utilizing more comprehensive functions to
meet patient safety goals and improve care coordination, but we believe that providers must be
given at least a one-year notice before requiring use of 2015 CEHRT.

CMS is also proposing a new simplified scoring methodology for this category as MIPS participants
have expressed frustration with the overly-complicated methodology currently used. The Society
supports efforts to reduce the complexity of the scoring methodology, and we favor a system that
provides the flexibility for eligible providers to select the measures most relevant to their practice
and patient population and are the least burdensome to implement.

The Society supports CMS’ intent to create MIPS public health priority sets across the four
performance categories. We are pleased that CMS has identified diabetes as one of the first few
public health priority sets to develop, and we encourage the development of measures that move
beyond hemoglobin A1c. We also encourage CMS to consider a public health priority set that
expands beyond a single condition, to those that are common comorbidities, such as prediabetes,
diabetes, obesity and cardiovascular disease, and encourage a more holistic approach to
identification and management of the set of conditions.

d. Increased Weight of Cost Category
CMS proposes to increase the weight of the Cost Performance Category to 15 percent, an increase
of 5 percent. While this is a modest increase, we are concerned that providers, and CMS, are not
ready for a greater emphasis on this category. This is a complex category and providers are still
learning how the two existing measures are applied to their practice while CMS has proposed to
implement 8 episode-based cost measures for performance year 2019 and is still developing other
episode-based cost measures that will become part of the measurement criteria. We urge CMS to
maintain the current weight of 10 percent for the Cost category until CMS has developed more
episode-based measures and applied them to the category score for at least two years.

We appreciate the opportunity to provide comments to CMS on this proposed rule. Please contact
Stephanie Kutler, Director, Advocacy & Policy at skutler@endocrine.org if we can provide any
additional information or assistance as CMS moves forward in this process.

Sincerely,

Susan Mandel, MD
President, Endocrine Society

[1] Office of the National Coordinator for Health Information Technology. ‘Certified Health IT Developers and Editions
Reported by Health Care Professionals Participating in the Medicare EHR Incentive Program,’ Health IT Quick-Stat #30.