

September 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1715-P
P.O. Box 8016
Baltimore, Maryland 21244-8016

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

Re: Medicare Program; CY 2020 Revisions to 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; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations (CMS-1715-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 2020 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 the agency implements this proposed rule and offers the following comments that focus on areas of interest to our members:

- Payment for Evaluation and Management (E/M) Services
- Care Management Services
- Online Digital Evaluation Services (e-Visits)
- Merit-based Payment System (MIPS) Value Pathways (MVP)
- Qualified Clinical Data Registry Measure Standards



- Endocrinology Specialty Measure Set

Payment for Evaluation and Management (E/M) Services

In last year's rulemaking, CMS finalized the first significant changes to how outpatient E/M services are documented and paid since the codes were first placed on the PFS. Under this policy, which would be effective January 1, 2021, physicians would no longer be required to document these services according to the 1995/1997 guidelines and instead would have the choice to document according to the level 2 requirements for medical decision making, time or the 1995/1997 guidelines for any level 2 through 4 service. However, CMS also finalized a single payment level for all level 2 through 4 visits. The Society, whose members primarily bill outpatient E/M services, supported CMS' efforts to reduce the administrative burden associated with these services, but had significant concerns that the single payment level policy would reduce reimbursement for endocrinologists. We are already observing significant workforce shortages in endocrinology and strongly opposed any policy that may exacerbate these shortages and further limit patient access to endocrinology services.

The Society thanks CMS for responding to our concerns and those of other cognitive specialties by revising the single payment level policy finalized for 2021 and instead proposing to retain separate payment for the individual E/M services. Society representatives participated in the American Medical Association (AMA) Current Procedural Terminology (CPT) Editorial Panel's and the Relative Value Scale Update Committee's (RUC) efforts to revise the outpatient E/M code family and recommend new values for these services. We urge CMS to finalize its proposal to adopt the revised outpatient services and associated documentation requirements and the RUC recommended values. The Society is confident that the documentation requirements as revised by the CPT Editorial Panel will meet the agency's goal of reducing administrative burden.

With respect to the RUC recommended values, the Society appreciates the significant increases in values proposed for level 4 and 5 visits. Our members primarily bill these higher-level services for the complex care they provide to patients, and we believe these values will appropriately capture the care they provide to patients with chronic conditions like diabetes and thyroid disease. For patients with diabetes, each visit requires a comprehensive review of their 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 often treatment of several co-morbid conditions. Some of these patients also use diabetes technology to manage their disease, which requires additional time and complexity.

Prolonged Service Add-On Code

The Society supports the implementation of the prolonged service add-on code that may be billed when providers choose to bill by time and exceed the time for a level 5 new or established E/M service. We believe it will be especially useful for endocrinologists, who treat complex diseases



that require significant care management. The scenario mentioned above about a diabetes patient could take more than an hour for complex patients, particularly those with type 1 diabetes or those who use diabetes technology. The Society urges CMS to finalize the code descriptor and value for this service, as well as the policy that allows it to be billed multiple times if the time spent on the date of service warrants it.

Complexity Add-On Code

In the CY 2019 PFS, CMS created two complexity add-on services, one for primary care and the other for certain types of specialty care. The Society supports CMS' proposal this year to consolidate the two previously finalized services into GPCX1, a single complexity add-on code that is tied to the patient's condition rather than the type of primary or specialty care being received. The Society believes the revised add-on code is needed to ensure E/M services accurately reflect the cognitive work provided by endocrinologists. This work is innately more complex than some other visits and should be recognized as such.

As just discussed, the Society believes this add-on service will be applicable to the work of our members, however, we do request clarification from CMS on the specific circumstances providers will be eligible to bill these services and what documentation must be included in the medical record.

Request for Comment on Revaluing Outpatient E/M Visits within Transitional Care Management (TCM), Cognitive Impairment Assessment/Care Planning and Similar Services

CMS identified a number of services that are closely tied to E/M values in addition to the other E/M code families and surgical global services for re-evaluation. Of the services listed, our members may utilize the Transitional Care Management Services (CPT codes 99495-6) and the other E/M code families, particularly the inpatient E/M codes. The agency requests comment on how to adjust the RVUs for these services and on systemic adjustments that may be needed to maintain relativity between these services and outpatient E/M services.

The Society recommends that CMS incorporate the updated outpatient E/M values into those services that are closely tied to this code family, like TCM. We also urge CMS to apply similar documentation changes and increase the service values by the same percentage seen in the outpatient setting to the other E/M code families until a schedule can be established to have the CPT Editorial Panel and RUC consider these other E/M code families. The Society cautions against sending all of these code families to the CPT Editorial Panel and RUC together since the same specialties will most likely be responsible for completing the surveys. The RUC survey of the outpatient E/M services was a significant undertaking as we just witnessed.

Public Nominations of Potentially Misvalued Codes: Fine Needle Aspiration



In June 2017, the AMA CPT Editorial Panel revised CPT code 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 the majority of the codes in the family in the CY 2019 Physician Fee Schedule. However, the agency did not accept the RUC recommendations for CPT codes 10005 (Fine needle aspiration biopsy, including ultrasound guidance; first lesion) or 10021 (Fine needle aspiration biopsy, without imaging guidance; first lesion).

The Society, along with American Association of Clinical Endocrinologists and the American Thyroid Association, nominated these two services as potentially misvalued and is pleased that CMS agrees with this nomination. In our nomination letter, we asserted that the values CMS finalized in last year's rulemaking resulted from a faulty process based on flawed and incorrect assumptions. Specifically, we believe that CMS' stated reasons for the decreases are flawed: the estimation of total changes in the total work pool for the FNA code family; a disproportionate change in time and work; and use of an alternate crosswalk and comparator service.

- CMS estimated that the RUC recommendations would lead to an increase of 20 percent in the total work pool for the FNA code family, but this is incorrect. The AMA RUC staff had presented to CMS its own calculation showing that the RUC recommendations would actually lead to a 15 percent **decrease** in the total work pool for the FNA family.
- Another of the CMS justifications given for its decision to reduce the value for some FNA codes below the RUC recommendations was the seeming disproportion between changes in time and changes in work ensuing from the RUC recommendations. For example, the RUC recommendations reduced the total time for 10021 by 32 percent from the previous value while reducing the work RVU by 5 percent.

However, there has been a significant increase in intensity of the FNA procedure between the original 1995 values and the present time which serves to explain this discrepancy. In particular, new clinical practice guidelines have emphasized the critical role of FNA in diagnosis. Consequently, FNA is now frequently being performed on many lesions that are much smaller and/or much deeper than was the case 20 years ago. In addition, the equipment has become more complicated to use and the specimen requirements are now more stringent. These factors have greatly increased the average complexity of the FNA procedure and explain the increase in intensity as compared to 20 years ago.

- CMS chose to establish the value of 10021 by cross-walking to 36440 (neonatal push transfusion). The agency then established the value for 10005 by adding an increment of 0.46 to the value of 36440 in order to cover the extra work of the ultrasound guidance. Thus, the valuation of both codes is heavily dependent on the selection of 36440 as a crosswalk code. We strongly disagree with the selection of 36440 as the crosswalk code on



which to base the value of 10021 because the intensity and complexity of CPT code 36440 is not comparable to that of 10021. An appropriate crosswalk would be to codes for similar procedures.

During last year's PFS rulemaking, the Society, as well as other stakeholders, urged CMS to support the RUC recommendations. Given that the RUC has submitted recent recommendations for these codes, we believe that CMS may have all the relevant information in hand to make a decision now to reinstate the RUC recommendations as part of the Final Rule for the 2020 Medicare Physician Fee Schedule rather than sending these codes back to the RUC for valuation.

Care Management Services

The Society supports CMS' efforts to expand the use of care management services, including TCM, chronic care management (CCM), and remote physiologic monitoring services. Our members and their clinical staff spend a significant amount of time managing patients' care outside of face-to-face visits. These non-face-to-face care management services provide a significant opportunity to equitably reimburse members for this uncompensated care. We are confident that when used appropriately they will improve our members' ability to manage the complex care patients with endocrine-related diseases require and improve patients' health outcomes.

The primary barrier to utilization of these services to date has been the documentation requirements; physicians do not believe that the time and infrastructure needed to provide these services is ultimately worth the reimbursement provided for these services. The Society believes the changes being proposed to these services is an important step to reducing the burden associated with their delivery.

Principal Care Management

The Society appreciates CMS' proposal to create a principal care management (PCM) service for the care management services delivered to patients with one chronic condition and recommends finalizing this proposal. However, the agency does not provide significant detail about the documentation requirements to bill these proposed services. The Society urges CMS to develop less burdensome requirements for PCM services than those that were originally developed for other care management services. For instance, the CCM requirements to develop a lengthy care plan, provide 24/7 patient access to care and health information, and certain electronic health record requirements have disincentivized the use of these services. The Society urges CMS to ensure the requirements imposed for PCM services are not disproportionate to their reimbursement.

Online Digital Evaluation Services (e-Visits)

The Society supports the agency's proposal to pay for six new e-Visit codes to reimburse physicians and qualified non-physician healthcare professionals for the non-face-to-face work they routinely



perform that includes a clinical decision that would typically be provided in the office. These services are patient-initiated digital communications that result in an online digital E/M service. The Society believes these services can be billed for the work they are already doing when they respond to patients through their practice's patient portal. Again, we urge CMS to minimize the documentation required as unduly burdensome requirements will disincentivize providers from billing these services.

MIPS Value Pathways (MVP)

The Agency has proposed a new framework, the MIPS Value Pathways (MVP), that would integrate measures and activities across the four MIPS performance categories. The goals of the new framework are to reduce the complexity of the MIPS program and physician's reporting burden, allow physicians to report on measures that are most relevant to the conditions they treat, and generate quality information that is comparable across providers. The MVP framework would also provide enhanced data and feedback to physicians.

The Society supports 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 the reporting requirements. We also appreciate that physicians will be provided with more relevant feedback on performance in a timely manner. This will allow for easier identification of areas where improvement is needed in a timeframe that will allow physicians to adjust performance before the reporting year ends. However, we do have concerns with the proposed framework, which are detailed below.

- MVP assignment – according to the Agency, physicians will be assigned to an MVP based on their previous claims. We strongly object to this, rather CMS should continue to allow physicians to choose how they wish to participate in MIPS. We recommend that CMS identify the most appropriate MVP for a physician but allowing the physician to opt-in to that MVP, choose a different MVP that they feel better reflects the focus of their work, or continue to report through the traditional MIPS pathway. Furthermore, CMS should base the suggested MVP on a combination of past MIPS reporting data, physician specialty designation, and claims history.
- Limited choice of MVPs - CMS has acknowledged that there will not be an MVP that is relevant to the work of every physician, meaning that some physicians will have to continue to report through the traditional MIPS reporting structure. With few quality measures in the MIPS inventory that focus on the work of endocrinologists, only endocrinologists who treat diabetes or osteoporosis have any chance of having an MVP that is applicable to their work. While we support offering alternate reporting options to the MVP, we are concerned that there will be no relief from the complex scoring system and the burden of reporting to four different performance categories that continue to function like four separate programs. Furthermore,



they will not benefit from the improved performance feedback, thereby not giving them the opportunity to make timely adjustments to their care.

We urge CMS to make changes to the traditional reporting framework to allow those physicians for which there is no relevant MVP to benefit from reduced reporting burden. As an example, a physician should be able to attest that they are using certified electronic health record technology (CEHRT) or health IT that interacts with CEHRT, rather than reporting on individual Promoting Interoperability measures. Furthermore, when practices report on quality measures through the EHR or a registry, they are automatically using CEHRT.

- Transition period – CMS proposes to transition into the MVP framework in stages, with implementation of the first stage in 2021. This is too soon to transition to a new program that could have a negative impact on a physician’s payments. As they did in the first years of MIPS, CMS should hold harmless those who choose to participate in an MVP in year 1. Just as it did with the transition to MIPS, it will take time for physicians to understand and adapt their practices to the new framework and time to develop and refine the MVPs. Furthermore, physicians have invested significant time and resources into their practice to meet the requirements of MIPS, and four years after the start of MIPS is too soon to ask physicians to adapt to a new payment system.
- Choice of measures – CMS requests feedback on whether physicians in an MVP should have a choice of quality measures to choose from within the MVP. We believe that some choice is important to allow physicians to choose the measures that best apply to their work and make participation meaningful to them. However, we caution against providing too many choices as this would 1) increase the reporting burden and 2) make it more difficult to compare physicians against their peers.

Qualified Clinical Data Registry measure standards

CMS proposes to make the process to include measures in a QCDR more stringent, requiring measure testing, harmonization, and clinical feedback to the reporting physicians. While the Society supports opportunities to provide more frequent feedback to physicians on their performance, we cannot support the other proposals for QCDRs. Measure development is costly and time-intensive, making it very difficult for most specialty organizations to develop measures that are relevant to the work of their members. As a result, many specialties have very few measures in the MIPS inventory that are meaningful to the work they do. The ability to include measures that have not gone through the full testing and validation process in a QCDR provided a route to allow physicians to report on measures that are not in the CMS measure inventory. Adding these additional requirements will make it virtually impossible for measures developed by specialty societies to be used by physicians in the MIPS program and will discourage specialty societies from developing measures.



Endocrinology specialty measure set

The Society appreciates that CMS is proposing a specialty measure set for endocrinology and is pleased to see that the majority of the measures that the Society recommended were included in the measure set. Offering a measure set is one step in making the reporting process slightly less burdensome for endocrinologists.

Thank you for considering our comments on the NPRM. If we can be of assistance, please contact Stephanie Kutler, Director of Advocacy & Policy at skutler@endocrine.org or Meredith Dyer, Director of Health Policy at mdyer@endocrine.org.

Sincerely,

A handwritten signature in blue ink that reads "E. Dale Abel".

E. Dale Abel, MB.BS., D.Phil. (M.D., Ph.D.)
President, Endocrine Society