June 27, 2016

Andy Slavitt, Acting Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-5517-P

P.O. Box 8013

Baltimore, MD 21244-8013

RE: [Medicare Program: Merit-Based Incentive Payment System and Alternative Payment Model Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models](https://www.regulations.gov/#!documentDetail;D=CMS-2016-0060-0068) (CMS-5517-P)

Dear Mr. Slavitt:

On behalf of the Endocrine Society (Society), representing more than 18,000 physicians and scientists in the field of endocrinology, we appreciate the opportunity to provide comments on the proposed rule implementing the Medicare Access and CHIP Reauthorization Act (MACRA), known as the Quality Payment Program (QPP). Founded in 1916, the Society represents 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 Society’s members care for Medicare patients, and are eager to understand the requirements they will have to meet in either the Merit-Based Incentive Payment System (MIPS) or as clinicians in Alternative Payment Models (APMs).

The Society looks forward to working closely with the Centers for Medicare and Medicaid Services (CMS) as implementation of the QPP moves forward. We offer the following comments related to the new payment system, which focus on the following areas of particular importance to our members:

1. General Comments on MACRA Implementation
2. Merit-Based Incentive Payment System
3. Alternative Payment Models

**General Comments on QPP Implementation**

***Implementation of QPP***

The Society requests that CMS delay the start of the reporting period until April 1, 2017. We understand that the statute requires the new payment system to be implemented in 2019, and this date cannot be altered without Congressional action. However, Congress did not specify that the reporting period occur in 2017. CMS has proposed that the same gap between the reporting and performance periods be implemented under the QPP that exists under the agency’s existing quality reporting programs, requiring first year reporting under QPP to occur in 2017.

Given the timing of this proposed rule, we anticipate a final rule will be released in late October. This timing provides clinicians less than 3 months to digest the final rule and prepare their practices for the major changes required by the QPP; this is not realistic and sets clinicians up for failure.

**Instead, we request that CMS delay the start of the reporting period by 3 months to April 1, 2017, and shorten this initial reporting period to 9 months rather than the full calendar year. We also recommend that the agency reduce the reporting requirements, including the number of patients that must be reported on, by 25 percent, mirroring the reduction of the time in the reporting period.** We believe that most of the quality measures will still be valid during this abbreviated reporting period, but CMS should analyze each measure and exclude those measures; if clinicians have less than 6 measures to report as a result, they should not be penalized. While it will still be challenging for clinicians to prepare for the major changes required by the QPP, we believe that this additional 3 months of preparation will give clinicians a greater opportunity to succeed. We believe this additional time will also be critical for APMs, as APM applications will be due to CMS prior to the publication of the final rule.

***Reporting and Performance Periods and Feedback***

We believe that the implementation of the QPP provides CMS with an opportunity to make significant improvements to its quality reporting program, and we are pleased with many of the agency’s proposals. However, we are concerned that CMS did nothing to address the significant gap between the reporting and performance periods. If a clinician’s performance merits a negative adjustment, they must have actionable information to improve their performance in a timely fashion. For many, a reduction in reimbursement spurs action. While we understand that some gap between reporting and performance is inevitable, we encourage CMS to find a way to make this delay as short as possible.

**Regardless of the length of the delay between reporting and performance periods, we encourage CMS to provide frequent feedback, as it is critical that clinicians receive as close to real time feedback as possible to have sufficient time to correct any deficits and successfully report before the close of the reporting period.** **We urge CMS to provide participating providers with one comprehensive feedback report on a quarterly basis and ensure that the final report is provided no later than October 1 of the reporting year.** This would provide more regular feedback, and also allow those participating to have a more complete picture of where they are succeeding and areas in which they may be subject to penalties. CMS should make these reports available to practice staff designated by the provider, as well as the provider.

***Scoring Composite***

We appreciate the steps CMS took in this proposal to simplify the quality reporting programs under the QPP and provide clinicians with flexibility in how they participate. However, we are concerned that the scoring system for MIPS is unnecessarily complicated. We believe that our members will want to monitor their progress, and the current methodology does not allow clinicians to do this easily. With MIPS, there are different scoring methodologies under which clinicians will have certain scores that then must be converted to percentages**. If CMS cannot simplify this scoring process, we urge the agency to create an interactive electronic tool for clinicians to quickly gauge their progress.** We also think that this tool should be able to help clinicians identify quality measures applicable to their practice, allowing them to know at the outset if there are 6 applicable quality measures in the MIPS measures set.

***Risk Adjustment***

For the QPP to be successful, **a risk adjustment methodology must be devised that is transparent and can be tested**.  Variations in patient need and the costs of care must be accounted for, as well as other factors, including health status, stage and severity of disease, genetic factors, local demographics and socioeconomic status.  This is critical to ensure that providers who treat patients with multiple, chronic conditions have a chance to succeed and do not resort to cherry picking their patients to increase their chance of success in these new payment schemes. We urge CMS to incorporate the findings of the Office of the Assistant Secretary for Planning and Evaluation’s report on risk adjustment as soon as possible in future rulemaking to strengthen the risk adjustment that is already built into many measures.

Besides risk adjustment, CMS must carefully design its patient attribution methodology.  **The agency should consider requiring annual patient attestation to establish a link between patient and physician.** If attribution is based solely on the assignment of costs and usage patterns, the potential for inappropriate linkages of patients to providers increases.  Inappropriate attribution could be potentially devastating to individual providers and small groups.  We urge CMS to carefully consider this issue as it formulates the required regulations to give all providers the greatest chance to succeed.

***Multi-specialty Group Reporting***

CMS proposes to allow eligible clinicians to report as an individual or as part of a group, and will require that the eligible clinician report in the same way across all performance categories. The Society appreciates that CMS has provided this flexibility for clinicians, but wants to reiterate that clinicians in multi-specialty provider groups must be able to report on measures applicable to their patient population. **To allow clinicians in multi-specialty practices to report on measures that are meaningful to their specialty, we recommend that each clinician in a group be assessed individually and all scores of the clinicians reporting under the same Tax Identification Number (TIN) be aggregated to achieve one score for the entire practice.**

***Small and Rural Practices***

Large multi-specialty practices and clinicians employed by a hospital or health system will more easily adjust to the new payment system. Small and rural practices, however, will face many challenges due to a lack of resources or limitations due to practice location. We appreciate that CMS has made adjustments to requirements for these practices in the proposed rule, including a reduction in the number of Clinical Practice Improvement Activities (CPIAs) required to achieve the full score, and an exemption for the Advancing Care Information (AIC) category if implementation of an EHR system would cause hardship for the practice. We **encourage CMS to engage in a range of outreach activities and support services to ease the transition for these practices.**

**Merit-Based Incentive Payment System (MIPS)**

***Quality Component***

We commend CMS for taking steps to simplify the reporting requirements for the Quality component compared to those under the Physician Quality Reporting System (PQRS). We were pleased to see that clinicians will only be required to report on 6 measures without any requirements to report across certain domains. We believe this step will allow clinicians to report on measures more meaningful and actionable for their patients that will have a true impact on quality.

We were also pleased to see that CMS included specialty-specific measures groups in its proposal; this will help clinicians determine which measures are applicable to their practice. However, there are still not enough measures for many specialists, including endocrinologists; those who do not specialize in the treatment of patients with diabetes have even fewer measures directly applicable to the care they provide their patients. As currently structured, many of our members will not be able to report on a high priority measure meaningful to their practice and have only one outcomes measure that is directly relevant to the work of an endocrinologist (Diabetes: Hemoglobin A1c Poor Control). Without measures specific to a physician’s specialty, it will be extremely difficult to make an accurate assessment of their quality of care. **CMS must continue to work with specialty organizations to identify alternative methods for measure development and testing.**  Many small organizations lack the resources to undertake the time-intensive and costly process to develop and test measures specific to their specialty. **MACRA provided CMS with funds to support measure development by outside organizations; we encourage CMS to prioritize those specialties that do not have a specialty-specific measures group**.

We also encourage CMS to streamline the process for measure inclusion into MIPS beyond the accommodations that have been made for Qualified Clinical Data Registries (QCDR). For those organizations that are unable to fund the development of a QCDR, the process for measure development, testing, application review, and acceptance into MIPS could take at least two to three years. This is too long for clinicians to wait for measures that are directly applicable to the patients that they treat. **CMS should consider the development of an “open source” QCDR that would allow small specialty organizations the opportunity to take advantage of the benefits of QCDRs for measure development, thereby shortening the process for inclusion in MIPS.**

Most endocrinologists have an internal medicine specialty designation, and many of the measures in the internal medicine set do not apply to their practice. The goal of the QPP is to transform the delivery of care with a focus on improving patient outcomes; as currently structured, endocrinologists will be forced to report measures that are not directly relevant to their practice, continuing the flaw of the PQRS whereby clinicians are essentially checking a box to avoid the penalty with no real impact on quality. **We believe that CMS should provide clinicians with a tool to determine which measures are applicable to their practice at the start of the reporting period**, not at the end of the reporting period as the Measure Applicability Validation (MAV) process is currently applied. It is critical for clinicians’ success that they can correctly identify applicable measures. Measures applicability should be determined by analyzing the clinician’s claims, not just their specialty designation. If a clinician believes the measures identified by CMS as being applicable to their practice are not appropriate, CMS should establish an appeals process through which clinicians can challenge measures’ applicability.

***Advancing Care Information Component***

We are pleased to see that the Advancing Care Information (ACI) component provides clinicians with greater flexibility than they currently have in the Meaningful Use program and allows them to have more choice on what they report in this category. We appreciate that CMS is trying to provide flexibility for clinicians to use EHR technology in a manner that makes the most sense for their practice and believe that this will put clinicians in a better position to succeed in this category. However, we believe that CMS must take more steps to encourage interoperability. Until health information technology is more widespread, the ACI component will not be transformative for the delivery of care; it will merely require clinicians to check the box to succeed.

To earn credit towards the base score, we agree with CMS eliminating the reporting requirement for the Clinical Decision Support and the Computerized Provider Order Entry objectives. However, we are concerned that the base score in this category requires clinicians to attest to all of the remaining components to receive credit without an option for partial credit. To avoid repeating some of the mistakes of the Meaningful Use program, we believe that scoring should not be so rigid.

Overall, we believe that the scoring for this category is too complicated; many clinicians will have a difficult time monitoring their progress using this methodology. CMS should look to further simplify the scoring in this category.

We are also concerned about the Certified Electronic Health Record Technology (CEHRT) requirements being imposed in this category. Although the use of EHRs continues to increase, many clinicians are still implementing and adapting their practices to this technology. The requirement that all clinicians use 2015 CEHRT by 2018 may be too aggressive in light of this. **We encourage CMS to re-evaluate this proposal when developing the 2017 NPRM on the Quality Payment Program to determine if the majority of clinicians will be ready to move to this more advanced version on January 1, 2018.** If the goal of CMS is to encourage meaningful use of this technology, it is important that clinicians feel that they have the time to implement the technology in a way that actually improves quality. Furthermore, the proposal specifying when Stage 2, the alternate Stage 2, and Stage 3 measures should be used is extremely confusing. **CMS should develop tools and resources for clinicians that clearly define which level they should report.**

We also wish to commend CMS on the recognition that some clinicians have little to no control over their EHR selection, and propose to exempt those clinicians from the ACI category. As proposed, the category will be down weighted to 0 for hospital-based clinicians (90 percent of services coded as inpatient or emergency care) or for those clinicians for whom implementing EHR technology would pose a hardship. We urge CMS to broaden the definition of “hospital-based clinician” to include those clinicians who are employed by a hospital, but still bill outpatient services. In almost all cases, the choice of EHRs and how they are used will be determined by the hospital or health system with little to no input by the clinician themselves, which is the rationale that CMS uses to exempt hospital-based clinicians.

***Resource Use Component***

We have significant concerns about the patient attribution to a clinician or APM, which we already addressed in these comments. We understand that CMS is in the process of revising this methodology but that it will not be complete when the reporting period is scheduled to begin on January 1, 2017. **As accurate attribution of costs to a specific clinician will be a challenge, we recommend that this category by down weighted to 0 until an accurate attribution methodology is developed and reviewed.** As attribution methodologies are applied, the Society encourages CMS to consider attributing costs to an entire practice when they have selected the group reporting option, rather than an individual physician. By doing so, practices will have greater incentive to implement team-based models of care in their practices.

Also, **we recommend that CMS exclude the cost of both Part B and Part D drugs from an evaluation of the costs attributed to a clinician.** We believe that including drug costs in this calculation will cause clinicians to prescribe drugs based on their costs and the potential impact on the clinician’s resource use than on the needs of the patient. Patients should always receive the most appropriate therapy for his or condition regardless of the cost.

We reviewed all of the new episode-based measures on which clinicians will be evaluated in this category. The only measure applicable to endocrinology is the osteoporosis episode measure, which will apply to only a narrow subset of endocrinologists. **We encourage CMS to develop more episode measures applicable to endocrinology, but do appreciate that CMS has proposed to down weight the category if no episode-based measure applies to a clinician’s practice.**

***Clinical Practice Improvement Activities Component***

We commend CMS for providing clinicians with a wide range of activities that will satisfy the CPIA component. We believe that, in this category, CMS succeeded in its goals of providing flexibility and simplicity for providers, which will increase their ability to succeed in this component. We appreciate that CMS has proposed to award full credit to practices that are NCQA Patient-Centered Medical Homes (PCMH) or PCMH-Neighbor (PCMH-N). Care coordination is essential to providing the best possible care and reducing redundant tests and services.

We do have several specific recommendations for CMS to consider expanding the CPIA options for endocrinologists, primary care physicians, specialists, and other program providers.

**CMS should consider diabetes self-management training (DSMT) as a CPIA**. DSMT provides critical knowledge and skills training to patients with diabetes, helping them manage medications, address nutritional issues, facilitate diabetes-related problem solving, and make other critical lifestyle changes to effectively manage their diabetes. Evidence shows that individuals participating in DSMT programs are able to progress along the continuum necessary to make sustained behavioral changes in order to manage their diabetes. DSMT has been proven effective in helping to reduce the risks and complications of diabetes and is a vital component of an overall diabetes treatment regimen. Patients who have received training from a certified diabetes educator are better able to implement the treatment plan received from a clinician skilled in diabetes treatment. Despite its effectiveness in reducing diabetes-related complications and associated costs, DSMT has been recognized by CMS as an underutilized Medicare benefit, even after more than a decade of coverage. Providing credit through the MIPS program for practices that offer DSMT to their patients may encourage more providers to offer this service.

Given recent regulatory decisions by the U.S. Preventive Services Task Force and CMS to expand screening for diabetes and to provide coverage of prevention programs for prediabetes, **we believe that patient referral to lifestyle intervention programs like the National Diabetes Prevention Program (NDPP) (and the resulting follow-up activities) should also be included in the CPIA category.** The expansion of screening for diabetes will result in more patients being diagnosed with prediabetes, a disease that can be prevented with modest weight loss. Studies have shown that a 5-7% reduction in weight can prevent or delay the onset of diabetes by 71% in the Medicare population. It is critical that these programs are effectively utilized to stop the diabetes epidemic in America. Currently 86 million Americans have prediabetes and another 29 million have diabetes in the United States alone—and these rates are only expected to accelerate.

The NDPP has proven to be a cost-effective program that can reduce healthcare expenditures stemming from diabetes. Annual medical costs for people with diabetes average $13,700, with $7,900 being directly attributable to the disease. The annual cost for a lifestyle intervention program, on the other hand, averages around $500 and can reduce a person's risk for getting diabetes significantly. Screening for diabetes and referral to a lifestyle intervention programs for at-risk patients is one of the many important activities that can help improve care and reduce healthcare costs. **We request that these activities be included in the CPIA category and that CMS consider the inclusion of a quality measure to track these activities in the future.**

Like diabetes, obesity has also become an epidemic in America and many clinicians have not been trained to counsel or treat patients with this disease. Given new resources like intensive behavioral counseling programs and pharmacological therapies to treat obesity**, we recommend that obesity screening, counseling, and referral to these programs be included in the list of eligible CPIA activities.** In addition, CME activities that help to teach clinicians these skills should also be included.

**Alternative Payment Models**

Under the proposed criteria, most clinicians will not be able to participate in an advanced APM in 2017. The Society recognizes that CMS believes the MIPS program will provide an on ramp for clinicians to transform their practice and its capabilities that will enable them to become an advanced APM. However, **we believe that CMS should provide more opportunities for clinicians, particularly specialists, to participate in the advanced APM track from the outset.**

We are concerned about the costs clinician practices will face to transform their practices to become either a MIPs APM or an advanced APM. These costs will be particularly hard to absorb for smaller specialty practices. **We request that CMS consider including the practice investments and costs of running an APM in the financial risk calculation for at least the first 5 years of the program, if not longer.**

We have been involved in the development of the PCMH and PCMH-N and believe that these models promote the delivery of longitudinal, integrated care and enable primary clinicians to provide continuous care for the patient. However, because the PCMH requires primary care physicians to work closely with specialists and subspecialists to communicate the ongoing needs of patients, **we strongly believe that a complementary system, the PCMH-N, should also be included as an advanced APM option when they work with closely with practices that qualify as advanced APMs through their participation in Comprehensive Primary Care (CPC) Plus**. These PCMH-N practices should be evaluated under the same risk model as the CPC Plus practices. Under the PCMH-N model, specialty practices engage in processes that:

* Ensure effective communication, coordination, and integration with PCMH practices in a bidirectional manner to provide high-quality and efficient care;
* Ensure appropriate and timely consultations and referrals that complement the aims of the PCMH practice;
* Ensure the efficient, appropriate, and effective flow of necessary patient and care information;
* Effectively guide determination of responsibility in co-management situations
* Support patient-centered care, enhanced care access, and high levels of care quality and safety; and
* Support the PCMH practice as the provider of whole-person, primary care to the patient and as having overall responsibility for ensuring the coordination and integration of the care provided by all involved clinicians and other health care professionals.

Besides recognizing certain PCMH-N practices as advanced APMs, **we recommend that CMS provide for expedited review of advanced APM proposals for specialties to quickly develop more advanced APM options for specialists.** These proposals should receive prioritized review not only by the agency, but also the Physician-focused Payment Technical Advisory Committee (PTAC). Clear direction should be given for the requirements for these models, and CMS should work closely with specialty organizations throughout the process of APM development to provide feedback on their approach.

We appreciate the opportunity to provide comments to CMS on this proposed rule. Please do not hesitate to contact Stephanie Kutler, Director, Quality Improvement at skutler@endocrine.org or Meredith Dyer, Associate Director, Health Policy, at mdyer@endocrine.org, if we can provide any additional information or assistance as CMS moves forward in this process.

Sincerely,



Hank Kronenberg, MD

President, Endocrine Society