

November 17, 2015

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-3321-NC
PO Box 8016
Baltimore, MD 21244

Re: 42 CFR Part 414 Request for Information Regarding Implementation of the Merit-based Incentive Payment System, Promotion of Alternative Payment Models, and Incentive Payments for Participation in Eligible Alternative Payment Models

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 request for information related to the implementation of the Merit-based Incentive Payment System (MIPS) and promotion of alternative payment models (APMs). Founded in 1916, the Society represents physicians and scientists engaged in the treatment and research of endocrine disorders, such as osteoporosis, diabetes, hypertension, infertility, obesity, and thyroid disease. Many of the Society's members care for Medicare patients, and are eager to learn more about the implementation of the new payment system.

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

1. Quality Reporting Category
2. Clinical Improvement Activities
3. Meaningful Use of CEHRT Performance Category
4. Alternative Payment Models

Quality Performance Category

The Society appreciates that CMS must use lessons learned from the existing quality programs to shape the new system. For instance, CMS should ensure that quality measures are aligned across MIPS, APMs, and third party payers to reduce the burden of reporting multiple measures for different payers. Furthermore, as providers have developed practice systems around a specific reporting mechanism currently offered under the Physician Quality Reporting System, all current reporting mechanisms should remain options under MIPS. However, we encourage CMS to include the Consumer Assessment of Healthcare Providers and Systems (CAHPS) as a Clinical



Improvement Activity. While certain aspects of PQRS should be carried forward, we strongly discourage CMS from wholly recreating the existing programs in MIPS.

The Society recommends that CMS reevaluate the number of measures and National Quality Strategy domains that eligible providers must report. Many specialties, including endocrinologists, still lack a robust set of measures that reflect their practice patterns. As such, requiring all providers to report nine measures in three National Quality Strategy domains is a significant burden for many specialists, often leading to a scenario where the provider must choose measures that do not contribute to improving their quality in order to simply “check a box.” We encourage you to perform an analysis of past reporting to determine how many physicians have successfully undergone the Measure Applicability Validation (MAV) process to determine how common it is for providers to have too few measures that apply to their work. Regardless of the number of measures CMS ultimately determines is realistic, the Society encourages CMS to provide a prospective MAV process that allows providers to determine at the beginning of the reporting period whether there are adequate measures to report. By providing this information in advance of the reporting period, providers will not be penalized for failure to report a measure that they were not aware applied to their patient population.

While the Society supports the use of outcomes measures to improve quality, we are concerned that requiring the reporting on a certain number of outcomes measures or providing greater weight to outcomes measures will negatively impact those specialties for which few outcomes measures exist. Furthermore, CMS must ensure that any measure is adequately risk-adjusted for factors related to health status, stage of disease, genetic factors, local demographics and socioeconomic status. Endocrinologists treat chronically ill patients whose outcomes are largely influenced by patient compliance. Furthermore, socioeconomic factors are barriers to the successful management of many endocrine conditions, such as diabetes and obesity, as the supplies and medications needed on a monthly basis are costly. For example, a patient with diabetes spends on average over \$7,000 annually managing their disease. Patients living in poverty often lack the resources to manage their disease at an optimal level, and this must be reflected in the measurement of care so as to discourage providers from limiting the number of these patients in their patient panel. As such, measures must reflect the role of the patient in his/her care plan and the impact of socioeconomic factors when measuring the quality of the physician.

In order for measurement of quality to have a true impact on improvement in care, all providers must have enough measures that match their practice patterns and patient populations. The Society encourages CMS to work with the medical community to develop measures for those specialties that may lack a breadth of measures related to the work of their specialty. For example, many endocrinologists subspecialize in specific conditions, such as thyroid disease. For these physicians who see very few patients with diabetes, the number of measures from which they have to choose is very small. 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. We



commend CMS for their willingness to accept measures outside of the NQF endorsement process, but urge even greater flexibility for those specialties with few measures specific to their work.

Finally, CMS should not require that all quality data be transmitted by electronic health records (EHRs), and should accept that some practices may only have the capability to collect and calculate the data through an EHR. Many smaller practices may not have the resources to implement an EHR system that has the capability to transmit data, and should not be penalized for this limitation.

Clinical Improvement Activities under the Medicare Incentive Payment System (MIPS)

CMS has requested stakeholder input on measuring and reporting of Clinical Improvement Activities. The new category of Clinical Improvement Activities has the potential to reward providers for work they are currently doing to improve the care of their patients. The Society encourages CMS to define the activities that qualify as clinical improvement activities as broadly as possible to allow for variation in practice settings, patient populations, and specialties. CMS should also require a relatively low threshold to achieve the maximum score, and should allow providers to attest to their activities annually, rather than report specific metrics, in order to reduce administrative burdens. Qualified registries, QCDRs, EHRs, or other health systems should also be able to transmit the results of the activities on behalf of the provider.

CMS will have the authority to identify specific activities that will qualify under this section of the MIPS. The Society recommends that CMS consider recognition of tools and activities that allow the patient to play a greater role in their care, such as the use of shared decision making tools and transitions of care resources. These tools will encourage buy-in from patients for their care plans, and will ensure that relevant information is shared with the other providers in the patient's care team, leading to higher-quality of care, fewer complications, and reduced costs. The Society has developed resources to encourage shared decision making for patients starting on mealtime insulin (Accurate Insulin Decisions at www.accurateinsulin.org), and aid the transition for patients moving from the care of a pediatric endocrinologist to an adult endocrinologist (www.endocrinetransitions.org). We have also partnered with the American College of Physicians to develop toolkits to facilitate more effective, high value, patient-centered care coordination between primary care and specialty practices (hvc.acponline.org).

CMS should also consider diabetes self-management training (DSMT) as a clinical improvement activity. 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 physician 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.

Specialty societies also provide tools and resources to their members that are meant to improve quality and benefit patient care. The Society encourages CMS to include qualified programs developed by these organizations as options under the Clinical Improvement Activities subcategory, and allow the specialty organization to submit information to CMS on behalf of the provider. Should CMS determine that such a program is eligible under this category, the process for approving the program must be straightforward and simple.

Finally, CMS should require a lower threshold for small and rural practices that lack sufficient resources to implement an extensive array of clinical improvement activities. While these practices should not be exempt from participation in this category, they should not be penalized for being unable to offer the same programs, resources, or specialized staff to their patients as larger practices.

Meaningful Use of CEHRT Performance Category

The law as passed by Congress includes a measurement of meaningful use of certified electronic health record technology (CEHRT). As with the PQRS program, the Society recommends against the implementation of the current Meaningful Use program in the new system. Although the current system has advanced the goal of increasing use of CEHRT in practices and hospitals, the Stage 2 and Stage 3 criteria are onerous and difficult to achieve for all but the most advanced practices. We encourage CMS to look critically at the current criterion to identify those most likely to result in true meaningful use of the technology, and return to the core of the program as originally envisioned by Congress.

The Society encourages CMS to grant partial credit for achieving some of the requirements of the new system under MIPS. The current pass/fail system discourages many providers from implementing components of the program into their practices that could result in an improvement in care as they realize that they will receive a penalty for being unable to meet all the requirements. The Society and its members support the ultimate goal of improving quality of care through the use of health IT, but believe that penalizing physicians who are unable to meet these requirements despite their best efforts is counterproductive.

Finally, as many small and rural practices are unable to meet the requirements of the Meaningful Use program, CMS should continue to offer hardship exemptions based on specific criteria.

Alternative Payment Models

In further defining alternative payment models (APMs), the Society encourages CMS to consider models that support delivery system improvements, avoid administrative and cost burdens for patients and physicians, and improve quality and reporting systems. The American Medical Association has released a guidance outlining examples of these APMs; the Society recommends



that CMS evaluate these models for inclusion in its final rulemaking on MACRA. In addition, these models should recognize patient diversity, provide a choice of payment models, and be both stable and transparent in providing predictable resources for redesigning practices. The Society supports the inclusion of medical homes as one such APM option that promotes care coordination between primary care and specialists. We have been involved in the development of the Patient-Centered Medical Home (PCMH) and Patient-Centered Medical Home-Neighbor (PCMH-N) and believe that these models promote the delivery of longitudinal, integrated care and enable primary physicians to provide continuous care for the patient. However, because the model requires primary care physicians to work closely with specialists and subspecialists to communicate the ongoing needs of patients, the Society strongly believes that a complementary system, the PCMH-N, should also be included as an APM option. Under the PCMH-N model, specialty practices should 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 physicians and other health care professionals.

As systems of care develop and integrate, they will need an internal framework for care coordination that is used by most systems to allow for easier communication between different institutions and allow for more clarity in communication and in expectations for services. As new payment models are tested and implemented, care coordination processes will be important to their success. The Society supports frameworks and care models, like the medical home and neighbor, which formalize the principles of team-based care and we recommend the inclusion of such specialty practices as an acceptable APM under MACRA.

As APMs are further defined, and the payment mechanisms for complex, chronic disease management are considered, compensation for care coordination and consultations will be a critical component in improving care. Successful diabetes treatment is often contingent on the utilization of team-based approaches to ensure effective treatment of a patient across the care continuum. Patients with diabetes often have multiple physicians who provide care for them and have input on the patient's treatment approach. However, these services (e.g. telehealth, interprofessional telephone consultations, e-consult programs etc.) are not currently covered under the Medicare program. These services, including a review of patient data from meter/pump/continuous glucose monitoring should



count toward a physician's clinical improvement activities. The Society strongly supports the inclusion of APMs that provide compensation for services that support team-based care and non-face-to-face services that provide care coordination and/or effective patient care.

For these APMs 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 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 excluding the sickest patients to increase their chance of success in these new payment schemes. The Society believes that physicians who participate in APMs with one-sided risk should have this considered more than nominal financial risk because of the upfront investment. Furthermore, non-billable costs should also count when assessing a practice's financial risk.

Besides risk adjustment, CMS must carefully design its patient attribution methodology. The agency should consider a mutual consent process in which both the provider and the patient must consent before a patient is attributed to the provider or his practice. 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.

CMS has stated that all APMs must include measurement of quality, which the Society supports. We encourage CMS to maintain consistency of eligible measures between the MIPS and APMs to ease transition between the two tracks, and allow APM developers to choose which measures apply to their model. However, APMs should be able to add additional validated measures that reflect the goals and designs of the APM in order to ensure that participating physicians are working towards the established goals of the model rather than "checking a box" to fulfil a reporting requirement set forth by CMS.

Additional Points of Interest

1. We recommend that CMS utilize existing identifiers (NPI/TIN) or a combination of identifiers to track participation of eligible providers. Using identifiers familiar to physicians will ease the administrative burden of the new system, and providers should only be required to update the current PECOS system annually.
2. CMS should not place a limit on the number of virtual groups eligible to participate as a virtual group, and physicians of differing specialties or in different geographic areas should be allowed to form a group. This new option could be of great value to small practices, and CMS should allow as much flexibility as possible to afford this benefit to all who are interested. If CMS is concerned about managing large numbers of virtual groups in the first year, the Society would support a limit on the number of groups ONLY in the first year.



Furthermore, these groups should have a unique group identifier in the event that not all providers under a specific TIN choose to participate in the virtual group.

3. CMS should require that qualified registries, QCDRs, and health IT systems undergo review and qualification by CMS to ensure that the data of those physicians using that system will be accurately and efficiently transmitted to CMS. A provider should not be held accountable for the failure of a system to which they have entrusted their data.
4. Peer group benchmarking for resource use or quality improvement should be based on the most specific specialty designation applicable to a provider's specialty. For instance, if a specialty has subspecialty designations recognized by CMS, those providers who claim that subspecialty should be considered a peer group. The Society encourages CMS to prioritize the creation of subspecialty designations to ensure that all subspecialties are recognized prior to the implementation of MACRA. If no subspecialty exists, providers should be compared to their peers in their specialty based on their region and practice setting.
5. We encourage CMS to provide frequent feedback, as it is critical that physicians 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. The Society urges 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.

The Society appreciates the opportunity to provide comments to CMS on implementation of MIPS and APMS, and appreciates the amount of effort CMS faces as it works towards full implementation in 2019. 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 may provide any additional information or assistance as CMS moves forward in this process.

Sincerely,

Lisa H. Fish, MD
President, Endocrine Society