

February 26, 2016

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: Draft Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)

Dear Mr. Slavitt:

On behalf of the Endocrine Society (Society), representing more than 18,000 physicians and scientists in the field of endocrinology and diabetes, we appreciate the opportunity to provide comments on CMS' Draft Quality Measure Development Plan (MDP). 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. Improving quality of care through development of clinical practice guidelines, educational content, care coordination tools, and shared decision-making resources is a priority for the Society.

The Society looks forward to working closely with CMS as implementation of the final Quality Measure Development Plan moves forward. We offer the following comments related to draft plan, which focus on areas of particular importance to our members.

I. Executive Summary

As stated in the draft plan, the MDP puts forth a strategic vision and operational approach to fulfill the requirements set by the Medicare Access and CHIP Reauthorization Act (MACRA). The Society supports many of the priorities for future measure development outlined in the report, including a focus on chronic conditions, care coordination, alignment of measures across payers, and reduction of administrative burden by focusing on data generated from EHRs. Our comments will address each of these elements in more detail.

Although the current federal quality incentive programs (Physician Quality Reporting System (PQRS), EHR Meaningful Use Program (MU)) are focused on improving quality of care, there continue to be many administrative challenges associated with these programs. As such, the Society encourages CMS to build a new program through MACRA, rather than simply rolling the tenets of the existing programs and associated quality measures into the new system.



II. Introduction

Through the MDP, CMS has committed to ensuring that all specialties have measures relevant to the work they do in the new program. As a specialty with many subspecialties, endocrinology will benefit from this commitment as relevant specialty measures currently exist only in diabetes, obesity, and osteoporosis care. The Society is looking forward to working with CMS to identify gaps in endocrine-specific measures and managing the development of these measures. As CMS considers areas for further development, the Society cautions that new measures should have a meaningful impact on quality of care, rather than simply requiring physicians to “check a box” in order to meet reporting requirements.

Specifically, the Society recommends measures be developed in the following areas.

Cross-cutting Measures

The Society encourages CMS to prioritize the development of measures that apply across specialties, and track meaningful outcomes. Important measures in this category already exist, including medication reconciliation, hemoglobin A1c (A1C) measurement, body mass index (BMI) measurement, and receipt of specialist report following referral. However, the opportunity exists to develop measures that are within priority areas identified by CMS, such as patient- and family-centered care. Measures in this area can focus on shared decision making (i.e., care plans that account for patient and caregiver goals and are shared with all providers involved in care), person-centered communication (i.e., information that is provided at appropriate times and is aligned with patient preferences), and quality of life and functional status (i.e., pain/symptom management, management of depression, and determination of functional status of individuals with multiple chronic conditions).

CMS should also consider integrating a set of measures focused on avoidance and treatment for hypoglycemia in patients with type 1 and type 2 diabetes into MACRA. Hypoglycemia is a major health problem in patients treated with insulin, patients with type 1 diabetes, and the elderly and infirm, and must be addressed by many specialists and primary care providers. Developing a set of cross-cutting measures focused on hypoglycemia would address CMS’ goal of prioritizing patient-centered measures and functional status.

Care Coordination

As the optimal delivery of care becomes more focused on multidisciplinary care teams managing the care of an individual, it is important that providers integrate care coordination processes into their practice. A measure on closing the referral loop through a specialist report already exists; however, the Society encourages CMS to develop additional measures in this area. These should help ensure that there is a) bi-directional sharing of relevant information across all providers and settings, b) sharing of relevant information during the patient transition (between providers and/or care settings), c) documentation that providers involved in the care of the patient are made aware of changes to the patient’s care plan, and d) a care team that takes responsibility for managing care to avoid hospital admissions and readmissions.



Diabetes Screening

Numerous measures exist that measure the quality of care of patients with diabetes. As the number of people with the disease continues to grow, the Society urges the inclusion of these measures moving forward. We also encourage CMS to develop a measure focused on diabetes prevention in an effort to identify those individuals with pre-diabetes who are at risk of developing diabetes. Approximately 28% of patients with type 2 diabetes in the US are undiagnosed and thus lacking appropriate treatment. The United States Preventive Services Task Force updated its recommendations for type 2 diabetes screening in 2015 to recommend screening for adults aged 40-70 years old who are overweight or obese and who are screened as part of a cardiovascular risk assessment. While the Society believes that this recommendation falls short of identifying individuals with pre-diabetes in other high-risk patient populations, such as minorities and adults aged 20-44, the USPSTF screening recommendation provides needed evidence for the development of a quality measure. The Society also encourages CMS to develop a measure on whether a patient was given information on and/or offered a referral to an evidence-based lifestyle intervention program to further reduce the likelihood of those individuals with pre-diabetes from developing diabetes. The USPSTF recommended referral of patients to these programs in their recent type 2 diabetes screening recommendations.

Obesity Measures

While a measure exists in federal quality programs that tracks measurement of BMI, there is nothing to encourage providers to take follow-up action for those individuals who are identified as being overweight or obese. The Society encourages CMS to integrate a measure that tracks the percentage of patients with a BMI greater than or equal to 25 (or lower depending on other demographic or risk factors) who received education and counseling for weight-management strategies that may include nutrition, physical activity, lifestyle changes, medication therapy and/or surgical considerations. However, in order for this measure to have impact and be feasible for implementation, CMS must ensure that relevant weight loss services are covered by Medicare and Medicaid.

Thyroid Disease and Thyroid Cancer

The prevalence of thyroid diseases in the US is 4.6 percent of the population (for hypothyroidism) and 1.3 percent (for hyperthyroidism), and rates are 5 to 10 times higher in females than males. Furthermore, thyroid disease treatment costs in 2008 for US females over the age of 18 totaled \$4.3 billion. Although the prevalence of thyroid disease may be low compared to other diseases, its impact on the patient can be tremendous. Patients diagnosed with thyroid disease often struggle to find the medication regimen to manage their disease. The Society encourages CMS to develop measures on thyroid disease to measure the quality of care these patients receive and identify areas for improvement. Furthermore, many endocrinologists focus their practice on patients with thyroid disease and currently only have general measures to report. Measures focused on thyroid disease will allow these providers to gain a meaningful benefit from their participation in the Merit-based Incentive Payment System (MIPS).



III. CMS Strategic Vision – Measure Development Priorities

In the Physician Quality Reporting Programs Strategic Vision, CMS noted that five statements define the CMS strategic vision for the future of its quality reporting programs:

- CMS quality reporting programs are guided by input from patients, caregivers and healthcare professionals.
- Feedback and data drives rapid cycle quality improvement.
- Public reporting provides meaningful, transparent, and actionable information.
- Quality reporting programs rely on an aligned measure portfolio.
- Quality reporting and value-based purchasing program policies are aligned

The Society supports these goals, and has long advocated for their application to PQRS and MU. To ensure that the new system developed under MACRA truly reflects the priorities of patients and the practice patterns of providers, the measures used must be developed by multi-stakeholder groups. In addition, providers must have frequent and rapid access to their quality data in order to allow for changes in practice that address areas of deficiencies. Not only will this allow for rapid cycle quality improvement, it will also allow providers to make adjustments before problems affect their quality score and impacts payments under MACRA. Finally, quality measure requirements must be aligned among public and private payers to ensure that providers are able to focus on making improvements to the quality of their care rather than focus on meeting the reporting requirements for multiple payers that each have a slightly different measure for the same disease.

The Society appreciates that CMS has outlined the general and technical principles in the MDP for measures developed with MACRA funding. The Society supports many of these principles, including adoption of a risk-adjustment model for the measure. 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. 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 out-of-pocket each year 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.

While we appreciate that CMS has provided explicit development principles, the Society cautions that these principles are extensive, and may be challenging for organizations with little experience developing measures to meet. We encourage CMS to provide development resources, in the form of tools and expert assistance, to measure developers who are new to the process of working with these principles.



IV. Operational Requirements of the Quality Measure Development Plan

Multi-Payer Applicability of Measures

As previously mentioned, the Society is supportive of CMS' efforts to align measures across public and private payers. Although not all in use, there are over 100 diabetes measures in existence, many of which are duplicative with similar or partially aligned technical specifications. The more time that providers must spend reporting similar measures to different payers, the less time they will have to focus on making improvements to their practice to address areas of need. The Society applauds CMS' most recent effort to identify a core set of measures through the Core Quality Measures Collaborative that can be supported by public and private payers. Further, we encourage CMS to solicit existing measures from all stakeholders to fill identified gaps to further align measures across programs.

Coordination and Sharing Across Measure Developers

As previously mentioned, the Society is concerned that the technical principles outlined in the MDP may be challenging for some measure developers to meet. We are encouraged by the efforts of CMS to share knowledge and best practices across measure developers by convening measure development task forces, maintaining a comprehensive inventory of measures under development and a measure developer library containing materials developed by other measure developers, and supporting the Electronic Clinical Quality Improvement Resource Center. In order to ensure that new measures are integrated into MIPS as quickly as possible, CMS must offer measure developers the support needed, through tools and expert assistance, to fully understand the requirements.

Quality Domains and Priorities

The quality domains mandated for use in MIPS align with the National Quality Strategy priority areas and CMS Quality Strategy goals. Additionally, MACRA prioritizes outcome measures, patient experience measures, care coordination measures, and measures of appropriate use of services, such as measures of overuse.

Clinical Care

Clinical care measures reflect care processes closely linked to outcomes or can be measures of patient-centered outcomes of disease conditions. CMS has stated its interest in prioritizing outcomes measures and patient-reported outcomes measures (PROMs). While the Society understands that in order to make measurable change in the quality of care provided, we feel strongly that outcomes measures and PROMs must be implemented only with a strong risk adjustment model. As previously mentioned, providers can take important steps to ensure that the patient is engaged with developing their care plan and feels that it reflects their priorities, but in most cases a patient's condition will only improve if the patient optimally manages their disease. There are often sociodemographic factors that impact a patient's ability to meet their care plan, and factors that are outside of the control of the provider or health plan must not impair their quality scores.



Care Coordination

Measures assigned to the care coordination domain focus on appropriate and timely sharing of information with patients, caregivers, and families and coordination of services among health professionals. As previously mentioned, the Society urges CMS to incorporate more measures of care coordination to ensure that there is active and appropriate communication between members of the care team and the patient, and shared accountability for the outcomes of their care. However, the measures must be designed with appropriate attribution mechanisms so that members of the care team are not penalized for failures in care that are outside of their control, or choose to limit the number of these patients that they treat in order to reduce their risk.

Population Health and Prevention

Measures in this domain reflect the use of clinical and preventive services and the achievement of improvements in the health of the population served. Included in this domain are outcome measures that reflect the health of a population or community, as well as process measures that focus on the primary prevention of disease or screening for early detection of disease. The Society is supportive of further exploring the development of population health measures, because encouraging and measuring prevention efforts for diabetes and obesity at the population level can help reduce the prevalence of both of these diseases. As population health measures have yet to be widely applied to an individual or practice, the Society encourages CMS to provide greater clarity around how these measures would be used, and allow for stakeholder involvement in the development and integration of the measures into MACRA.

Efficiency and Cost Reduction

CMS has stated an interest in utilizing the recommendations developed by specialty organizations through the Choosing Wisely program as areas for measures of appropriate use. While the Society developed a list of recommendations for Choosing Wisely and still supports the goals of the program, any measures developed based on these recommendations should encourage appropriate care rather than discourage a specific test, procedure, or treatment. For instance, one of the Society's recommendations states that providers should not routinely order a thyroid ultrasound in patients with abnormal thyroid function tests if there is no palpable abnormality of the thyroid gland. Rather than developing a measure that is focused on the use of thyroid ultrasound in these cases, a measure should focus on encouraging the most widely-accepted method of treatment.

Measure Development Plan Timeline

The Society supports CMS' decision to allow inclusion of evidence-based measures in MACRA that are not endorsed by NQF or other endorsing organizations. Testing and endorsement of measures is a time- and resource-intensive process, and requiring that all measures be endorsed prior to inclusion will limit the number of measures that many specialties have in the MACRA program for the foreseeable future. This will particularly benefit smaller specialties with limited resources.



V. Challenges in Quality Measure Development and Potential Strategic Approaches

Engaging Patients in the Measure Development Process

The development of patient-centric measures is dependent on incorporation of the patient and caregiver voice during the measure development process. The Society strongly supports the inclusion of patients in the development process, but encourages CMS to provide best-practices learned by other measure developers who have successfully integrated patients into the process. Specifically, what should the patient be expected to contribute to the discussion, and how do you ensure that one patient is representative of the entire patient population with that condition? The Society has been addressing this issue with regards to incorporation of the patient perspective into our Clinical Practice Guidelines, and has considered including a small number of representatives who are active in a patient advocacy group. This will ideally mean that they are aware of the experiences of others with the same disease, and can apply that broader perspective to the discussion.

Shortening the Time Frame for Measure Development

The Society publishes the preeminent clinical journal in the field of endocrinology, the *Journal of Clinical Endocrinology & Metabolism* (JCEM), and CMS should consider JCEM as a source for publication of endocrine-related measures. Working closely with the Editor-in-Chief of JCEM, the Society recently implemented a new review process for clinical practice guidelines with the goal of decreasing time-to-publication. This process could serve as a model for publication of measures. Rather than start the peer review process after the guideline has been fully developed and approved by the Society, the journal editors now perform a review of the guideline prior to finalization. As a result, the journal peer review has been completed prior to approval, and the guideline will be ready for publication upon approval by the Society. This change to the review process has reduced the time-to-publication after Society approval from an average of five months to a few weeks.

A similar process could be applied to the publication of measures. While this process is simple to implement when the measure developers are the specialty organization and the measures will be submitted to their in-house journal, many measure developers will not have such a close link to a journal. The Society suggests that CMS add a requirement to its technical development principles that the measure developer contact the journal early in the process to express their interest in publishing the measures, as well as provide the journal editors with the opportunity to review the measures prior to finalization.

The Society appreciates the opportunity to provide comments to CMS on the Draft Quality Measure Development Plan. Please do not hesitate to contact Stephanie Kutler, Director, Quality Improvement at skutler@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