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AdvaMed
Advanced Medical Technology Association

March 1, 2016

Via Electronic Mail to **MACRA-MDP@hsag.com**
Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, M.D. 21244

Re: CMS Quality Measure Development Plan

Dear Acting Administrator Slavitt:

AdvaMed appreciates the opportunity to respond to the request for comments by the Centers for Medicare & Medicaid Services (CMS) regarding the "Draft Quality Measure Development Plan (MDP) for Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs)."

AdvaMed member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. Our members range from the largest to the smallest medical technology innovators and companies.

CMS seeks comments on this draft strategic framework for the future of clinician quality measure development to support MIPS and APMs. We are providing feedback on some of the issues related to operational requirements of the MDP as well as challenges in quality measure development and potential strategic approaches.

I. Operational Requirements of the Quality Measure Development Plan

A. Measure Applications Partnership (MAP)

Although the MACRA specifies that the pre-rulemaking process and review by the National Quality Forum (NQF)-convened MAP is optional for measures used for MIPS, we are pleased that the MDP specifically notes that CMS will leverage multi-stakeholder groups to identify the issues related to the development of measures that can be applied across payers and delivery systems, including the Measure Applications Partnership (MAP). **We encourage CMS to continue to leverage the MAP and its processes for gathering and providing input from**

stakeholders on measures that will meet CMS' needs and align with the needs of other payers to support multi-payer applicability of recommended measures related to implementation of the MACRA.

B. The Core Measures Collaborative

Recently, the Core Quality Measures Collaborative announced the release of its core measure sets to promote alignment among public and private use of quality measures. We support the efforts by CMS and others to create aligned core measure sets for both private and public sectors. We believe this will help streamline provider reporting as it relates to quality metrics and encourage equitable access. In releasing the initial seven measure sets, CMS noted that it intends to invite broader participation in the future (potentially through public comment opportunities) and will announce additional measure sets in the future. **While we encourage public commenting opportunities, we believe that the Collaborative should seek the direct participation of the medical technology industry as the Collaborative considers adoption and harmonization of measures in these sets. We believe that industry participation is essential in the selection and modifications of measure sets, including minimizing unintended consequences and selection of new measures, as better measures become available.**

C. Evidence Base for Non-Endorsed Measures

As noted in the MDP, MACRA authorizes CMS to include measures for MIPS that are not consensus-endorsed. While MACRA requires that measures selected for use in MIPS be "evidence-based" if not endorsed by a consensus-based entity, the law does not define evidence-based or specify how to evaluate the evidence. **We are pleased that CMS plans to use the rating criteria established by NQF to evaluate the quality, quantity, and consistency of the evidence for the development of quality measures included in this plan.[1] Examining the evidence from this perspective allows for a more transparent and robust vetting process in quality measurement evaluation**.

D. Quality Domains and Priorities – Care Coordination / Clinical Practice Improvement Activities

AdvaMed's detailed recommendations related to Care Coordination and Clinical Practice Improvement Activities including clinical practice guidelines, clinical care pathways and Telehealth Services are included in our previous Comment Letter to CMS concerning the recent *RFI on Implementation of MIPS and Development of Alternative Payment Models* **("Attachment A")**.

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[1] National Quality Forum. Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. 2015.

II. Challenges in Quality Measure Development and Potential Strategic Approaches

A. Developing Appropriate Use Measures

a) Appropriate Use of Services: Quality Measures to Address Underuse

In the MDP, CMS appropriately acknowledges the issue of potential underuse of medical imaging and diagnostic tests and requests input on creating balancing measures to prevent underuse:

> *"As providers focus on performance on overuse measures, a potential unintended consequence of quality measurement is underuse of services. As measures are developed for other quality domains, CMS will consider the development of "balancing measures" that can mitigate the potential for unintended consequences.*
>
> *CMS seeks comments from the public as to relevant topic areas for this category of measures. CMS is also aware of concern about the unintended consequence of underuse of services once overuse measures are implemented and seeks comments from the public on mitigation strategies, including the use of balancing measures and suitable exclusions."*

Although there has been much discussion in various quality initiatives regarding the overuse of medical technologies (such as imaging) procedures and services (such as screenings for various cancers), very rarely is underuse discussed. On the road to determining "appropriate use" it is essential that underuse is evaluated simultaneously with those measures of overuse. There is some correlation that underuse is associated with older age, fewer medical visits, and increased comorbidity. These characteristics represent a large portion of the population who are also chronically ill. Many chronically ill patients and their caretakers and physicians are focused on their current primary complaint and lose track of the need for medical and ancillary services which healthier individuals receive. In addition, because of impairments to their functioning, they are a prime population to benefit from technologies to address these deficiencies and restore their quality of life. Therefore it is important that underuse, in addition to overuse, be evaluated when developing quality measures, especially for patients with chronic illness.

In May of 2015, the Centers for Disease Control issued the report, "Cancer Screening Test Use – United States, 2013" to describe progress in cancer screening relative to Healthy People 2020 goals. The authors report that the most recent data on screening use (2013) indicate no progress toward meeting Healthy People 2020 targets for cancer screening. Mammography use in women aged 50–74 years was 72.6% (target 81.1%), Pap test use in women aged 21–65 years was 80.7% (target 93.0%), and colorectal screening in persons aged 50–75 years was 58.2% (target 70.5%). Compared with 2000, mammography use was unchanged, Pap test use was lower and colorectal screening was higher, although unchanged since 2010. Taken together, these data demonstrate significant underutilization of cancer screening tests.[2]

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[2] Sabatino SA, White,MC, Thompson TD,. Klabunde, CN "Cancer Screening Test Use – United States, 2013," Morbidity and Mortality Weekly Report May 8, 2015 / Vol. 64 / No. 17 464-468.

For certain patient conditions, technologies such as imaging and diagnostic testing are especially important for determining the appropriate diagnosis and/or selecting the appropriate treatment. **CMS should identify conditions for which imaging and/or diagnostic tests are integral to determining the appropriate care pathway for patients and create quality standards to ensure appropriate use of these tests**.

b) Data Collection Issues in Determining Appropriate Utilization

Inadequate data are available to CMS to analyze and determine what constitutes appropriate utilization. For example, in the field of medical imaging or diagnostic testing, databases that are currently available only capture patients who were actually referred for these procedures, but do not provide any awareness into the patients for whom these procedures might have been appropriate, but was not ordered. Subsequently, only two conclusions can be drawn; utilization of these services has been perfectly appropriate or there has been over-utilization of these services. There is no readily available way to establish in what way, or to what extent, any service has been underutilized. Those who were candidates for imaging or testing, who might have benefited but did not because it was not ordered, are concealed in databases which are not accessible for such an analysis. Underutilization can only be detected by review of patients with presenting complaints, or a differential diagnostic dilemma, which called for imaging or testing. This gap needs to be addressed and should be a focal point of any under-utilization advocacy quality measure data collection and analysis protocols.

AdvaMed encourages CMS to implement more comprehensive data collection and analysis protocols to better understand what constitutes appropriate utilization of these services. Additionally, CMS should measure the reduction in imaging and diagnostic testing relative to the baseline established prior to creation of a bundled payment for an episode of care, in order to safeguard against inappropriate decreases in utilizations of these services.

B. Identifying and Developing Meaningful Outcome Measures

a) Developing Quality Measures for Chronic Conditions

As the MDP notes, developing quality measures for care needed by persons with one or more chronic conditions is a complicated task. These patients tend to have complex medical and social needs as well as time intensive and labor intensive management needs that may extend well-beyond others in the health care system. It is therefore important that these quality measures reflect the time needed by medical and paramedical professionals to manage the complex care of these patients. In the absence of this consideration, it is possible that measures developed for the chronically ill may be viewed by providers as a burden and thus the patient could ultimately be disadvantaged by being provided with abbreviated care unintentionally.

In addition, recent discussions in the NQF-convened MAP regarding the proposal for a chronic composite measure have continued to highlight that socio-demographic factors may have a significant impact on these types of measures for this population. Chronic care measure developers should consider addressing socio-demographic factors early-on in the development phase to avoid unsuccessful implementation of proposed measures

b) Outcome Measures: Measure Development Should Emphasize Patient-Centered Measures

Incorporating patient-centered factors, such as patient experience, quality of life, improvements in functional status, and evidence-based behavioral interventions is currently gaining increased importance in quality measure discussions. In the elderly population especially, it is important to have sufficient appropriate measures regarding patient experience and quality of life. Currently there are some quality measures in CMS quality-related programs regarding the functional status outcomes for patients, but since functional status is such an important factor for those that are elderly and have chronic conditions, we believe that there should be an emphasis on further developing measures in this area. For example, patients with chronic wounds experience pain, increased risk of complications, and amputation, as well as delayed healing. Creating patient-centered measures that capture functionality and experience for chronic wound patients will encourage use of advanced wound therapies that reduce the total cost of care and improve a patient's quality of life.

In the development of patient-centered metrics CMS should give careful consideration to performance metrics that measure processes or outcomes that are within a provider's control. Although outcomes metrics are important as these ultimately reflect what happens to patients, outcomes metrics do not tell the complete story of the process of care experienced by the patient, and outcomes metrics must be adjusted to reflect patient and environmental factors that may be beyond a provider's control.

c) Care Coordination: Measures to Ensure Proper Discharge/Transfer Planning including Wound Care and Nutritional Measures

The MDP notes that care coordination and associated measure gaps are a priority under the MACRA. AdvaMed believes that well-designed and thought-out discharge planning is a critical care coordination component of successful transitions from acute care hospitals and post-acute care (PAC) settings. This is a cornerstone of successful continuity of care for patients, especially those who are chronically ill. Recently, CMS issued a proposed rule on "Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies." The critical nature of properly documenting and providing the handoff information that will accompany the patient as they transition from one care setting to another ultimately impacts patient outcomes, including reducing complications/adverse events, reducing avoidable hospital readmissions and offers an opportunity to improve the quality and safety of patient care and reducing costs. These handoffs are particularly important for the chronically ill.

The proposed rule provided a list of "necessary medical information" that, at a minimum, is to be provided from the current treatment setting to the receiving facility or health care practitioner, regardless of whether the patient is being discharged or transferred to any post-acute care setting. These settings include home (with or without PAC services), skilled nursing facility, nursing home, long term care hospital, rehabilitation hospital or unit, assisted living center, substance abuse treatment program, hospice, or a variety of other settings. The proposed list contains

important information concerning the patients' health including course of illness/treatment, procedures, functional status, reconciliation of all discharge medications and others.

AdvaMed agrees that patients would especially benefit from a well-detailed discharge plan that is communicated properly. AdvaMed provided comments to the proposed rule with recommendations for specifically including patient wound status and nutritional status at discharge. AdvaMed recommends that quality measures be developed regarding the collection and transfer of specific information, including patient wound status and nutrition status, to ensure that appropriate information is shared when discharging or transferring a patient between care settings. Although a measure such as this could be considered a "process" measure, the resultant adherence to providing this information would very likely result in improved patient outcomes and the data from these lists could possibly be used to develop outcomes measures.

As the MDP continues to evolve and be updated annually or as otherwise appropriate, we would encourage CMS to continue to seek industry input. AdvaMed and our member companies would like to thank CMS for the opportunity to comment on the CMS Quality Measure Development Plan. Please feel free to contact me or Steve Brotman at sbrotman@advamed.org or 202-434-7207 with any questions. Thank you for your consideration.

Sincerely,

/s/

Donald May
Executive Vice President
Payment and Health Care Delivery Policy