November 17, 2015

Via Electronic Mail to file code CMS–3321–NC
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Request for Information (RFI) 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 Acting Administrator Slavitt:

AdvaMed appreciates the opportunity to respond to the Centers for Medicare & Medicaid Services’ (CMS) request for information that was published in the October 1, 2015 Federal Register. 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 several provisions of MACRA including establishment of various aspects of the Merit-based Incentive Payment System (MIPS) and development of Alternative Payment Models (APMs). Our comments highlight specific areas where the use medical technologies should be considered more specifically and on the appropriate use of telemedicine and remote monitoring services.

I. Merit-based Incentive Payment System (MIPS)

A. Clinical Practice Improvement Activities Performance Category

a) General Comments

The RFI asks a series of questions related to Clinical Practice Improvement Activities, one of the four weighted performance categories upon which eligible professionals will be assessed under the new Merit-Based Incentive Payment System (MIPS). CMS specifically seeks comment on what activities could be classified as clinical practice improvement activities according to this
definition. MACRA specifies clinical practice improvement activities as one of the performance categories used in determining the composite performance score under the MIPS. These are defined as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, are likely to result in improved outcomes. The following subcategories of clinical practice improvement must be included:

1. Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.
2. Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.
3. Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.
4. Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.
5. Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.
6. Participation in an alternative payment model.

AdvaMed recommends that in regard to Subcategory (1) (Expanded Practice Access), this definition should include same-day access to medical technologies, when needed on an emergent basis, as well as expedited access to medical technologies for urgent clinical situations. In this regard patients who are acutely and chronically ill will not be needlessly contributing to the burden of Emergency Department over-crowding and allow for appropriate access of those patients in most need of access to emergency services. Relatedly, CMS should consider improved ways to remove unnecessary barriers that contribute to the delay in patient care, such as preauthorization, so that care can be expedited for patients truly in need of these services.

AdvaMed also recommends that in regard to Subcategory (5), relevant clinical or surgical checklists should include the consideration of utilizing medical technologies – such as planning for the use of specific wound care therapy and using advanced diagnostic imaging and treatment options when appropriate – in order to ensure patient safety, enable more timely access by patients and avoid unnecessary care. Additionally, development of care plans that would incorporate these concepts should be encouraged which would help to reduce the time to vet and implement proper clinical treatment and alert all eligible professionals involved in the patient’s care of the proposed treatment.

b) Clinical Practice Improvement Activities Performance Category – Telehealth Services

The authorizing statute for this category requires that the overarching category – Clinical Practice Improvement Activities – include a number of different subcategory activities, among them
subcategory 3 includes care coordination for “timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth” [emphasis added]. While the authorizing statute does not mention remote monitoring or telehealth for several of the other specified subcategory activities, these technologies would be as useful in achieving the purposes of other subcategories as they are for care coordination. For example, remote monitoring and telehealth can play critical roles in expanded practice access, population management for monitoring health conditions to provide timely health care interventions, and beneficiary engagement through care plan development for persons with complex care needs—all of which are subcategory activities included in the authorizing statute for MIPS. We also note that remote monitoring and telehealth technologies could play critical roles in several of the potential additional subcategories of clinical improvement activities that CMS seeks comments on. These include subcategories on promoting health equity and continuity, social and community involvement, achieving health equity, and integration of primary and behavioral health.

AdvaMed recommends that the proposed rule incorporate telehealth and FDA approved remote monitoring technologies as essential dimensions of each of the subcategory activities related to overall clinical improvement activities, to the extent that they are relevant for required subcategories that define clinical practice improvement. In addition, we note that CMS has not yet indicated how scoring will be structured and points awarded for the Clinical Practice Improvement Activities category. To the extent that CMS constructs the Clinical Practice Improvement Activities category as a series of requirements as opposed to a menu of options, then one of the requirements should pertain to telehealth and remote monitoring.

c) Clinical Practice Improvement Activities Performance Category –
Subcategory Recommendations

CMS also requests comments on the following Clinical Practice Improvement Subcategories:

1. Promoting Health Equity & Continuity
2. Social and Community Involvement
3. Achieving Health Equity
4. Emergency Preparedness and Response
5. Integration of Primary Care and Behavioral Health

AdvaMed believes that timely access to medical technology is a key component to the success of any Clinical Practice Improvement Activity within many of these subcategories. We are pleased that CMS points out in the RFI that the subcategory of “Promoting Health Equity and Continuity” should incorporate maintaining equipment and other accommodations (for example, wheelchair access, accessible exam tables, lifts, scales, etc.) which are necessary to provide comprehensive care for patients with disabilities. Likewise, AdvaMed recommends that there should be similar emphasis on providing timely access to medical technologies – such as those dealing with chronic conditions, imaging, diagnostic testing/screening, wound care and nutrition/malnutrition – especially for those that are in need of social services including disabled patients and underserved populations. Advanced medical technologies should also be an inherent part of the subcategory dealing with “Emergency Preparedness and Response.”
B. Quality Performance Category

a) Quality Performance Category: Scores – Domains and Weights

For the quality and resource use performance categories, CMS is requesting comments on whether they should use a methodology – for example, equal weighting of quality and resource use measures across National Quality Strategy domains – similar to what is currently used for the value-based payment modifier.

In other value-based purchasing programs such as the Medicare Shared Savings Program, CMS uses the six priorities established in the National Quality Strategy to classify measures into quality domains. The quality domains are: patient safety, patient experience, care coordination, clinical care, population/community health, and efficiency. In developing the value-based payment modifier previously, CMS proposed to classify each of the quality measures proposed for the value-based payment modifier into one of these six domains and to weight each domain equally to form a quality of care composite. Within each domain, CMS proposed to weight each measure equally so that groups have equal incentive to improve care delivery on all measures. If a domain does not contain quality measures, the remaining domains would be equally weighted to form the quality of care composite.

AdvaMed continues to strongly disagree with the approach of assigning equal weights to each domain in the calculation of the Quality of Care Composite for use in the MIPS without regard to the characteristics of the patient population served by an individual physician or physician group. Implementation of this approach would have the effect of diluting: (1) the importance of delivering effective care and treatment practices for patients (clinical care domain), and (2) the significance of efforts to make care safer by reducing harms caused in the delivery of care (patient safety domain). In addition, individual or small physician groups – which would likely have fewer resources than larger group practices – will be less likely to devote equal attention to all domains, and thus may potentially perform substantially below larger practices.

AdvaMed believes that CMS should assign varying weights for each domain in the MIPS, as they have previously done with the Hospital Value-Based Purchasing Program. This would best reflect overall performance, concerning the direct role of physicians, with proper emphasis on their most important roles as the MIPS is implemented.

C. Resource Use Performance Category

a) Resource Use Performance Category – Resource Use and Episode-Based Care Measures

AdvaMed believes that it is fundamentally important that measures of cost, or resource use, be considered only when accompanied by measures of quality related to the same health care. If providers are to be recognized for the value of care that they deliver, that value should be assessed by the outcomes of care, the resources used to create those outcomes, and the patient’s experiences with the care. AdvaMed believes that efficiency, and measures dealing with efficiency and resource use, should be defined to include the overall value of the service, including efficiency gains to the care delivery system, quality and composite cost. Ideally, the
best care means delivering the right treatment to the right patient in the right setting at the right time, regardless of financial incentives. Previously utilized resource use definitions by CMS have conveyed information about estimated costs of treatment and have been devoid of any information concerning the quality of care provided as it relates to those costs. Gross measures of costs not more directly tied to quality measures are likely to give misleading or unhelpful information to consumers and others.

Definitions by CMS regarding resource use and efficiency place emphasis on accountability and are likely to pressure providers to avoid patients who will incur the highest costs, such as the elderly and those with numerous illnesses. AdvaMed is concerned that application of such a cost-associated definition when used in registries/measures could result in reduced provision of needed care – and reduced access to appropriate care – in an effort to limit costs, especially when applied in an incentive program. Well-designed quality measures can help to ensure that patients are receiving the right types of treatment to achieve desired health outcomes. It is also essential that the costs and quality outcome be appropriately attributed to the physician providing the specific care being measured (see comments below). AdvaMed continues to encourage CMS to develop more appropriate definitions and value models for resource use and efficiency measures that consider the costs in conjunction with quality across varied episodes of care. Failure to incorporate these concepts together in the proposed definitions will likely have important unintended consequences.

Additionally, AdvaMed emphasizes that resource use must be determined over an appropriate episode of care, which includes a sufficient period of time to assess the overall value of the services provided. One could easily draw erroneous conclusions about the relative value of care if an inappropriate time period is used. For example, a provider may have a choice between a lower-cost medical device which is expected to need replacement within a few years, necessitating another hospitalization, and a higher-cost device which will last many more years. If resource use, or costs, are measured based on an episode of care that only considers the hospitalization and perhaps a 90-day period post-discharge, the “total” cost of the episode may appear on its face to be a better value because the initial cost of the device was lower. However, this assessment would be inaccurate as it would not consider the additional costs associated with a subsequent readmission, surgical costs and device replacement costs that could have been delayed or avoided if the higher-cost, longer lasting device was initially chosen. Even a one-year period might be an insufficient to assess the value of many new technologies to patients and/or the health care system overall.

b) Resource Use Performance Category - Attribution

AdvaMed also recommends that CMS remain flexible in the implementation of quality measures that relate in part to attribution. Attribution has become increasingly important in ever-changing environment of public reporting, pay for performance, and penalties, where improvements in outcomes may not be ascribed directly to a single provider. There is general agreement among interested stakeholders that guidance is needed concerning the assignment of attribution of patients and care episodes, as lack of clarity in attribution approaches continues to be major limitation in the use of outcome and cost measures. To this end, beginning in 2016 the National Quality Forum (NQF) will conduct an environmental scan using a multi-stakeholder Standing
Committee, to examine the strengths and weaknesses of the attribution models identified in the environmental scan. The environmental scan will be used as a foundation for establishing a set of principles and recommendations for applying the models within a complex healthcare delivery system. AdvaMed recommends that CMS closely track the findings and recommendations of the “NQF Attribution Principles and Approaches Project.” AdvaMed is also concerned about episode-based measures being incorporated into the MIPS that do not take into account all the complex factors that contribute to the cost of care. Not considering these factors may have the unintended consequence of putting providers at risk solely based on their selection of patients.

II. Alternative Payment Models

A. Alternative Payment Models – Payment Incentives and Quality Measures

The RFI asks questions regarding calculation of payment incentives that should be incorporated into incentive payment for APMs and other questions regarding quality measures that should be applied to APMs.

AdvaMed has supported alternative delivery reform models, such as ACOs and bundled payment programs, and their goals to achieve lower cost and higher quality health care, and we believe that our members’ technologies play a critical role in assisting providers to achieve these goals.

At the same time, we are concerned that the financial incentives in these delivery reform models can have the inadvertent effect of discouraging providers from (1) considering the full array of treatment options, especially if they may increase costs above “benchmark” thresholds—we refer to this as stinting, or (2) using innovative treatments, technologies, and diagnostics that may bring value to the health care system over the longer term, but are more costly in the short run. The potential negative impact of the financial incentives of these models is magnified by the short payment windows used in the programs to compare actual spending against benchmarks in order to determine the level of savings that may be shared among providers. Many medical devices and technologies provide benefits over a long period of time spanning multiple years.

Data analysis by one of our member companies points to the potential impact the financial incentives in the ACO model and the relatively short timeframes for measuring savings can have on care received by Medicare beneficiaries in these models. The specific data analysis done by our member focused on utilization rates for several interventional treatment options for arterial procedures and utilization rates of these options for Medicare beneficiaries served by ACOs. The analysis showed an increase in utilization of a lower cost procedure option and a decrease in utilization of a higher cost alternative procedure for patients served by ACOs. The increase in utilization of the lower cost option could mean more frequent re-interventions for patients in the future, with the result that higher savings for ACOs in the short-term could also mean higher long-term spending for the Medicare program in subsequent years.

In addition, we have discussed with the Center for Medicare & Medicaid Innovation (CMMI) findings of some of our orthopedic company members that certain providers participating in the
Innovation Center’s Bundled Payments for Care Improvement (BPCI) initiative have radically changed the type of hip and knee implants that they buy and implant in patients. In the past, these hospitals had purchased a range of device implants—including some implants that are more basic, without newer features, and others with higher levels of performance characteristics that improve range of motion or impact durability. Providers made implant selection decisions that corresponded to the particular lifestyle needs of patients, including life expectancy, level of activity, and medical conditions. Now these providers are ordering almost exclusively low utility devices. We believe that they are responding to the financial incentives in BPCI to generate gainsharing rewards by ordering lower utility devices which are less expensive than the higher utility devices, leading to potentially higher internal savings that can be shared in the short term. The longer term impact of using almost exclusively lower utility devices, when they may not be appropriate for the lifestyle and medical needs of individual patients, may not be known for several years, when active beneficiaries may require earlier than expected revision procedures or experience other negative outcomes. If the choice of a hip or knee device were made solely on the basis of patients’ relative health, lifestyle and life expectancy, patients would be provided a device that appropriately matched their unique needs with cost not being a leading driver of this decision so as to ensure the best possible outcomes and longevity.

AdvaMed notes that CMS has recently acknowledged the impact a higher cost innovative technology can have on providers’ ability or interest in using that technology in patient care when they participate in delivery reform models, specifically in CMMI’s Bundled Payments for Care Improvement (BPCI) Initiative. In this instance, CMMI has decided to exclude IPPS new technology add-on payments (NTAPs) from both the actual historical episode expenditure data used to set target prices and from the hospital’s actual episode spending that is reconciled to the target price. CMS has also excluded IPPS new technology add-on payments, OPPS transitional pass-through payments for medical devices, and hemophilia clotting factors from the Comprehensive Care for Joint Replacement (CJR) model episode definition. In the final rule on the CJR, CMS noted that it would not be appropriate for the CJR model to potentially hamper beneficiaries’ access to new technologies that receive NTAPs or to burden hospitals who choose to use these new technologies with concern about these payments counting toward episode actual expenditures. **AdvaMed recommends that the proposed rule for the MACRA APM program should, at a minimum, incorporate the BPCI and CJR policy for removing IPPS NTAPs and OPPS pass-through payments from an APM’s actual expenditure total that is compared to its benchmark for calculating financial incentives for APMs.**

AdvaMed believes that additional innovative technologies, beyond NTAPs, should qualify for a similar adjustment as that being made for NTAP approvals, and that CMS should establish a review process for these technologies to determine whether their cost should be removed from actual spending totals for APMs for a limited period of time until providers decide whether the innovation should be included as an alternative standard of care. AdvaMed recommends that the review process for these technologies/treatments be similar to the one now used by CMS for NTAPs. Manufacturers and developers would provide CMS the estimated incremental increase in spending that would result from each use of an approved treatment. They would also provide CMS the data and methodology for such estimates as part of the application process to assist CMS in determining whether a treatment or technology warrants special accommodation and
what adjustments would be made. If approved by CMS, the adjustments would apply to use of the technology across all APMs, and other relevant delivery reform models. In addition, the adjustment process should allow individual providers to request an adjustment if they were to adopt breakthrough/ high cost treatments in advance of other hospitals. In this case, the adjustment could be applied to the individual provider or all providers using the technology/treatment.

In addition to our concerns that financial incentives in alternative payment programs could lead to stinting and compromised patient access to innovative technologies, quality standards used for these programs could discourage early adoption of new and better alternative treatments simply because the quality measures do not reflect breakthrough and innovative treatments. If a new approach to care is developed that may be superior to legacy practice methods, and no special exception is provided for the new alternative treatment, physicians or hospitals may avoid adopting it because it will lower the APM’s quality score and, in turn, reduce shared savings.

We learned recently from CMMI about a relevant example of Medicare beneficiaries being denied access to an innovative technology. Physicians in Pioneer ACOs had asked to be able to use a new and more effective pneumococcal pneumonia vaccine instead of an older vaccine that is specified in a process quality measure used for both the MSSP and Pioneer programs. The problem that physicians in these ACOs faced is a reduction in their quality scores if they do choose to use the new vaccine, simply because this particular measure does not yet reflect a new standard of care and because no special exception is allowed for physicians to use the innovation. Patients may not be harmed by the old vaccine but they are not, at the same time, provided the benefits of the new product. This is another good example of how a technical adjustment in APMs can provide Medicare beneficiaries the benefits of innovations in health care without undermining the overarching goals of the program.

AdvaMed recommends that an adjustment process similar to that recommended above for the cost of certain new technologies be established for quality measure scores where an innovation would affect an APM’s quality score for process measures. In this case, the process quality measure would be removed from the calculation of the APM’s score for a limited period of time, while the measure was revised to reflect the new standard of care.

B. Alternative Payment Models—Payment Incentives for the Provision of Telehealth Services

Telehealth and remote patient monitoring technologies are generally recognized as fundamental tools for improving the efficiency and quality of health care. APMs with their emphasis on care coordination and improving the efficiency and quality of care delivery are ideal settings for realizing the benefits telehealth and related technologies.

Currently, Medicare’s telehealth benefit severely restricts coverage and payment for these services through limitations on the type of technologies that may be covered, the site of service where beneficiaries may receive care, and the geographic area where they reside. MedPAC estimates that only 68,000 beneficiaries, or 0.2 percent of total Part B beneficiaries, used telehealth services in 2014 in large part because of these coverage restrictions. A similar problem
exists for remote monitoring services, with only limited reimbursement for these services, such as for cardiac trans-telephonic monitoring of pacemakers, or remote monitoring of patient physiological data as part of new billable chronic care management services for beneficiaries with multiple chronic conditions.

To the extent that telehealth and remote monitoring services are not covered by Medicare, APM benchmarks will never be able to reflect spending for the services because Medicare does not recognize them for payment. As a result, an APM participant deciding to provide expanded telehealth or remote monitoring services will have to weigh these new costs not recognized in a benchmark against the promise of savings in other areas, or to cover the costs through their shared savings. This creates a disincentive to use these technologies. Coverage and payment restrictions also result in a missed opportunity for APMs to address the complex needs of the 5 percent of Medicare beneficiaries with multiple chronic conditions who account for as much as 50 percent of total Medicare spending.

Under current law, the only way that APMs can realize telehealth’s benefits for improving efficiency and quality of care delivery is through waivers of the restrictions in Medicare’s fee-for-service telehealth benefit. CMS should use its waiver authority to expand the scope of coverage and payment of telehealth services provided by APMs, and should do so for all APMs regardless of the level of risk they assume. Key to the success of APMs being able to realize telehealth’s potential for improving the efficiency of care delivery are waivers to allow the beneficiary’s home to be an originating site of care, generally the lowest cost setting for delivering care. This is especially the case for serving Medicare beneficiaries with multiple chronic conditions. By prohibiting the home from serving as an originating site for care, current law restrictions will limit the ability of APMs to efficiently assess the health status of this population on a regular basis, to identify problems early when they can be easily treated, and to track compliance with their care plans. AdvaMed recommends that, at a minimum, CMS provide waivers to provide APMs the flexibility for using telehealth and remote monitoring technologies for the provision of care in the home.

AdvaMed and our member companies would like to thank CMS for the opportunity to comment on this Request for Information. 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