September 4, 2012

Via Electronic Mail
Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1590-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY2013; Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; Proposed Rules (CMS-1590-P)

Dear Ms. Tavenner:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the Centers for Medicare & Medicaid Services’ (CMS) Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face to Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations; Proposed Rules (CMS-1590-P), Federal Register, Vol. 77, No. 146, (Monday, July 30, 2012, p. 44722).

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. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

AdvaMed supports the establishment of payment rates under the physician fee schedule that are appropriate to ensure access to advanced medical technologies by Medicare beneficiaries.
We appreciate the effort you and your staff have devoted to the development of the proposed Medicare Physician Fee Schedule rule (PFS). While we are pleased with some of the proposed changes announced in the rule we remain concerned with others and welcome the opportunity to provide several recommendations. We will comment on the following issues raised in the proposed 2013 PFS rule:

I. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)- Indirect Practice Expense Per Hour Data
   A. CY 2013 Identification and review of Potentially Misvalued Services—Review of Services With Stand Alone PE Procedure Time—Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT)
   B. Expanding the Multiple Procedure Payment Reduction Policy
   C. Proposed Cuts to CT and MRI Reimbursement

II. Payment for Molecular Pathology Services

III. Other Provisions of the Proposed Regulation
   A. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery
   B. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System
   C. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program
      i. Proposed Quality of Care and Cost Domains
      ii. Episode-Based Cost Measures in the Physician Feedback Program

I. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)-Indirect Practice Expense Per Hour Data

The proposed CY 2013 rule includes several proposals related to CMS’ consideration and review of the practice expense inputs associated with various codes. AdvaMed would like to address some of these proposals in our comments below.

A. CY 2013 Identification and Review of Potentially Misvalued Services—Review of Services With Stand Alone PE Procedure Time—Intensity Modulated Radiation Therapy (IMRT) and Stereotactic Body Radiation Therapy (SBRT)

The proposed CY 2013 rule includes cuts in the value of IMRT (77418) of 40 percent and SBRT (77373) of 28 percent to reflect changes in the practice expense times associated with these procedures. CMS cites patient literature and other information as a basis for these proposed cuts. AdvaMed has concerns regarding the proposal as it does not use traditional methods for determining the non-clinician time associated with the procedure. Additionally, in making the decision to reduce the practice expense time associated with these procedures, CMS did not fully evaluate all of the practice expense inputs for these procedures. Reviewing all of the practice expense inputs associated with a procedure, including supplies and equipment costs, is critical in determining appropriate valuation.
AdvaMed recommends that CMS evaluate all of the practice expense inputs associated with the IMRT and SBRT procedure codes, including staff time, supply costs, and equipment costs, prior to making a final determination regarding the practice expense inputs for these services in CY 2013.

B. Expanding the Multiple Procedure Payment Reduction Policy

In CY 2012 CMS made several recommendations related to application of the Multiple Procedure Payment Reduction (MPPR). For CY 2013 CMS is proceeding with their CY 2012 final rule recommendation to expand the MPPR imaging policy to services furnished in the same session by physicians in the same group practice and is proposing to apply the MPPR to the technical component of certain diagnostic tests. AdvaMed opposes the proposal to expand the use of the MPPR policy as expansion could create beneficiary access issues.

AdvaMed recommends that CMS delay expansion of the MPPR policy until additional information is provided that evaluates the impact of the proposed changes on beneficiary access to diagnostic services.

AdvaMed also disagrees with CMS’s assumption that a provider(s) performing two or more imaging services during the same session on the same patient has the same level of efficiency that is accounted for using the MPPR. The complexity of performing certain imaging and diagnostics tests requires numerous steps, many of which are directly impacted by the patient. While there are arguably some pre-service and post-service efficiencies created with regard to the technical work associated with the performance of the multiple imaging services identified in the proposed rule, CMS does not cite any information related to the actual amount of replicated physician work attributable to the performance of additional imaging procedures.

AdvaMed opposes expansion of the MPPR reduction to the professional and technical components (PC and TC) of advanced imaging procedures furnished in the same session by a physician or physicians in the same group practice.

AdvaMed also opposes the proposal to apply the MPPR to the TC of certain cardiovascular and ophthalmology procedures. In support of this recommendation CMS lists a number of clinical labor activities and assumes that these activities are not needed prior to performing a second procedure. While there may be some similarity between the clinical labor associated with these procedures, AdvaMed does not agree that the approach used by CMS adequately accounts for the time and/or value associated with performing more than one of these types of procedures. Certain steps, while not completely replicated (i.e. patient positioning and preparation; preparing the room, equipment and supplies), require additional time. The proposed method used by CMS to determine the time associated with duplicate clinical activity (i.e. retaining the higher number of minutes) is insufficient to account for the actual time needed to complete more than one diagnostic procedure. Additionally, the data provided by CMS is insufficient to determine if a service is “misvalued”. The proposed expansions to the MPPR have the potential to negatively impact patient access to diagnostic imaging services.
• AdvaMed recommends that CMS perform additional analysis to ensure that any procedures considered for the MPPR be examined more fully to evaluate the clinical labor activities that may be duplicated between services, in an effort to ensure that only adjustments for those activities are made. Furthermore, AdvaMed recommends that CMS not finalize the proposal to apply the MPPR to identified cardiovascular and ophthalmic procedures until the aforementioned analysis has been completed.

• AdvaMed also recommends that CMS refrain from any expansion of the policy until it has adequate claims data regarding the initial application of the MPPR to advanced imaging procedures. That would allow CMS to assess the impact of the policies on Medicare beneficiary access prior to expanding them to other areas of imaging and/or diagnostic tests.

• AdvaMed also recommends that CMS further explain its changes to the MPPR and provide stakeholders meaningful opportunity to comment prior to implementing the proposal.

C. Proposed Cuts to CT and MRI Reimbursement

AdvaMed is concerned that CMS is proposing to reduce reimbursement for imaging procedures. Cuts in Medicare imaging reimbursement have occurred seven times since 2006, with decreased spending in recent years.\(^1\)\(^2\) AdvaMed is concerned that continued cuts will have negative implications for patient access to diagnostic services and will inevitably impede innovation.

Dramatic cuts in payments for the technical component (TC) of computed tomography (CT) and medical resonance imaging (MRI) imaging procedures are of particular concern to AdvaMed. Cuts of 22 percent for a head or brain CT (Code 70470) and 20 percent for an MRI of the orbit, face, or neck (Code 70543) are among the most dramatic cuts proposed and do not even account for changes in the Conversion Factor. The proposed reimbursements stand to reduce access to critically important diagnostic services for Medicare patients suffering from a variety of debilitating conditions.

The rationale for the cuts to the technical component (TC) of CT and MRI procedures is not clear from the proposed rule. It appears that the reduction in the TC may be related to use of practice expense (PE) relative value units (RVUs) data from the Physician Practice Information Survey (PPIS). However, the proposed reductions for 2013 appear to be larger than would be justified from that data and process.

• Accordingly, AdvaMed recommends that CMS delay the cuts to CT and MRI to

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avoid inappropriate reductions in reimbursement for these critically important services.

- In addition, AdvaMed also recommends that CT and MRI services with significant payment cuts be exempted from application of MPPR.

The MPPR policy was implemented to realize efficiencies attributed to performing multiple procedures in a single visit. Application of the MPPR, in addition to proposed cuts of up to 22 percent, could reduce the use of vital imaging procedures leading to delayed interventions that negatively impact patient health and could increase overall Medicare costs.

II. Payment for Molecular Pathology Services

CMS has asked stakeholders for input on how to determine payment rates for the 101 new molecular pathology test codes assigned by the AMA CPT Editorial Panel for 2012, as well as additional codes to be released for 2013. CMS has proposed that all of these codes, which include Tier 1 codes for common gene-specific and genomic procedures and Tier 2 codes that identify less common gene-specific and genomic tests, be placed on either the Clinical Laboratory Fee Schedule (CLFS) or the Physician Fee Schedule (PFS). The pricing of these codes is a complex matter, and AdvaMed recognizes the various factors that must be considered in making payment determinations. We are also aware that CMS has heard differing points of view from various stakeholder groups regarding whether these tests do or do not require interpretation by a physician and whether these tests should be assigned to the PFS or the CLFS. Although AdvaMed acknowledges that some tests may require physician interpretation to produce a patient reportable result, we also are aware of tests – especially novel test kits developed by AdvaMed members – that do not require physician interpretation.

- We strongly encourage CMS not to assign all of the new molecular diagnostic tests to the PFS or CLFS. Instead we recommend that CMS consider whether individual molecular pathology tests do or do not require physician interpretation and that the Agency, consistent with long-established policies, assign tests that require physician interpretation to the PFS and assign those tests which do not require physician interpretation to the CLFS.

The tests that are described by molecular pathology codes are complicated and involve some of the most advanced techniques currently available. Laboratories have previously described these tests using codes that specify only the steps taken to generate a result; however, the new Tier 1 codes classify the tests by analyte and the new Tier 2 codes by intensity group. Medicare has been paying for many of these tests for some time, and most have been billed and paid under the CLFS. We recognize the difficulty in determining with specificity the steps involved in performing individual tests given the substantial variability in the way laboratories have reported this information in the past. Establishing fair and accurate payment rates for these tests in a way that does not compromise their availability is a challenge, and a number of factors must be considered in making payment determinations. It is critical that CMS’ process for making these determinations results in accurate and appropriate payment for these important diagnostic tests.
AdvaMed is concerned that placing all of the molecular pathology codes on one fee schedule could negatively impact use of and access to these tests and thus, does not support this approach. Such action would be inconsistent with established regulations that determine which clinical laboratory tests fall under the CLFS and which fall under the PFS. Traditionally, CMS has placed laboratory tests that require physician interpretation to produce a reportable result on the PFS with all other laboratory tests falling under the CLFS. It is unclear how CMS would determine appropriate fee schedule placement for new laboratory tests, whether molecular or non-molecular, in the future if the Agency deviates from its current policy.

The complexity of molecular pathology tests necessitates CMS’ solicitation of input from stakeholders, including clinical and laboratory payment experts, whose technical expertise can be used to guide payment and fee schedule placement determinations related to these tests.

- **We strongly recommend that CMS use stakeholder and other data to individually evaluate each of the molecular pathology test codes for appropriate fee schedule placement, giving full consideration to the various combinations of existing CPT methodology codes that are currently used to identify the test, whether or not physician work is required to interpret and report an individual patient test result, the technical requirements associated with performing the test, and the frequency with which the test is expected to be used.**

- **CMS should also consider Medicare Administrative Contractor (MAC) data, when applicable, in informing payment and fee schedule placement decisions related to molecular pathology tests. Many local MACs have established payment rates reflecting in-depth analysis of the gap-fill factors set forth in current CMS regulations (including recognition of the substantial research and development costs required to commercialize many advanced molecular diagnostics).**

Additionally, CMS should include a process for transferring a test from the PFS to the CLFS if, for example, a test that is currently determined to require physician work and is assigned to the PFS is later determined to no longer (due to technological advances) require physician interpretation to obtain a result.

While we believe that individual review of each test is the best approach, we are sensitive to the issues identified by CMS in the preamble of the proposed rule regarding the sufficiency of the information that would be relied upon in making fee schedule placement determinations and the impact of this on CMS’ proposal to place all molecular pathology procedure codes on a single fee schedule. Nonetheless, if the single fee schedule proposal is pursued CMS will have to address its approach for handling molecular pathology codes that require physician work (i.e., interpretation and report). AdvaMed recommends that CMS consider developing a code (or codes) to acknowledge the professional component (e.g., interpretation and report of a molecular pathology test) associated with certain molecular pathology codes when furnished.
and billed by a physician.

Although AdvaMed believes that it would be inappropriate for CMS to assign all of the codes to the PFS, should CMS decide to do so, we would encourage CMS to consider that patient co-payments under the PFS could create a new financial burden for some Medicare beneficiaries, which could potentially restrict or delay access, negatively impacting patients and ultimately patient outcomes.

III. Other Provisions of the Proposed Regulation

The CY 2013 proposed rule includes several other provisions of importance to AdvaMed. Comments and recommendations on these issues are provided below.

A. Durable Medical Equipment (DME) Face-to-Face Encounters and Written Orders Prior to Delivery

AdvaMed supports provisions in the Affordable Care Act (ACA) requiring that a physician have a documented face-to-face encounter with a Medicare beneficiary and conduct an evaluation of the patient to determine their need for any covered item of DMEPOS. These in-person evaluations are essential for ensuring that patients receive the items and equipment most appropriate for their medical conditions. They are also important for preserving the integrity of the DMEPOS benefit. As important as this provision is both for improving beneficiaries’ health and well-being and deterring fraud and abuse, CMS should not create onerous burdens for physicians in implementing the statutory requirement. AdvaMed recommends that the proposed rule be amended as follows:

Incorporating Flexibility in the Timeframe for the Face-to-Face Encounter. Rather than requiring, as the proposed rule would do, that the face-to-face encounter occur within 90 days prior to the written order and up to and including 30 days after the order is written, the final rule should incorporate flexibility that would allow the face-to-face encounter to occur during a longer period prior to the written order but within the statute’s specified timeframe of 6 months. Such flexibility would be appropriate for cases where the patient’s condition as documented by previous physician encounters (e.g. a patient with multiple chronic conditions and the onset of a decubitus ulcer) will likely lead to the need for DMEPOS (e.g. a support surface). Alternatively CMS could consider a risk-based approach where specified conditions would be designated as not requiring a face-to-face encounter within the proposed timeframe. Prior to finalizing the proposed rule, CMS should work more closely with physicians and supplier stakeholders to determine the best approach to establishing a timeframe for the face-to-face encounter. In addition, AdvaMed recommends that CMS convene a town hall meeting one year after implementation of the requirement to receive additional input from stakeholders as to whether the provision has compromised beneficiary access to DME or created unnecessary burdens for physicians.

Avoiding Duplicating Requirements. The final rule should clarify that the hospitalist physician ordering the DME for the inpatient and who has the face-to-face encounter with the
patient prior to discharge will meet the face-to-face encounter requirement. Beneficiaries in these situations should not also have to see another physician in order to fulfill the face-to-face requirement after discharge.

**Documentation Issues.** The proposed rule at §410.38(g)(3)(A) would require that a physician document and communicate to the DME supplier that the physician (or physician assistant, nurse practitioner, or clinical nurse specialist) had a face-to-face encounter with the beneficiary on the date of the written order or within the proposed timeframe. The preamble discusses four communication options and notes that CMS is reserving judgment on them until the final rule. In order to avoid creating new burdens for physicians, AdvaMed recommends that the new process for communicating documentation to suppliers resemble, as closely as possible, current processes used by physicians. We believe that this may be similar to the second option discussed in the proposed rule, and, if this is the case, we would recommend using that. The proposed rule at §410.38(g)(4)(vii) would also require that the written order from the physician include necessary and/or proper usage instructions as applicable. This could also result in an onerous burden for the physician. Therefore, the rule should clarify that the principal responsibility for meeting this requirement lies with the supplier.

**Provider Education on Documentation Requirements.** Beneficiaries and physicians will need adequate training and education on any new face-to-face and documentation requirements before they become effective. While the proposed rule notes that CMS plans to conduct provider education and outreach in implementing the DME face-to-face requirement, AdvaMed is concerned that the time remaining in the year will be insufficient for this training. Rather than jeopardizing beneficiary access to DME because providers may not fully understand the new documentation requirements, AdvaMed recommends that the effective date of the rule be delayed until July 1, 2013, or such later date as found reasonable to provide adequate education to patients and providers about the new requirements.

**Allowing Other Health Care Professionals to Fulfill Face-to-Face Encounter Requirements.** The proposed rule would require physicians--and physician assistants, nurse practitioners, or certified nurse specialists--to have a face-to-face encounter with Medicare beneficiaries within a specified timeframe to conduct an assessment that supports the need for covered items of DME. For some beneficiaries needing products on the specified list of DME, such as TENS, it is common today for physical therapists, occupational therapists, chiropractors, and other participating Medicare health care professionals to have that face-to-face encounter and conduct a needs assessment for DME. AdvaMed recommends that other health care professionals be allowed to meet the requirement of the face-to-face encounter while physicians continue to be responsible for producing the written order and documenting that the face-to-face encounter has occurred. Together these proposals will both ensure quality of care for patients and reduce the risk of fraud and abuse in the benefit.

**A Phased Approach to Application of the Face-to-Face Encounter.** The proposed rule would apply the face-to-face encounter and documentation requirements to a specified list of DME items. AdvaMed recommends that CMS apply the new encounter and documentation requirements initially to a smaller number of HCPCS codes and first evaluate the impact of
the requirements on beneficiary access to DME and costs to providers before expanding the
list in the future. AdvaMed also recommends that CMS provide substantial notice and
comment periods and detailed explanations of the criteria that are used to determine the items
included.

B. Physician Payment, Efficiency, and Quality Improvements—Physician Quality
Reporting System

The Physician Quality Reporting System (PQRS), which began as the Physician Quality
Reporting Initiative (PQRI) in 2007, provides incentive payments to eligible professionals
who satisfactorily report data on quality measures and payment adjustments for those who do
not. AdvaMed supports the further development of the PQRS, as required by statute and
appreciates the efforts of CMS to implement the PQRS. AdvaMed appreciates the opportunity
to comment on the following aspects of the PQRS in the proposed rule:

New Proposed PQRS Quality Measures for 2013. For CY 2013, CMS is proposing only
thirteen new PQRS individual measures, which were not available for the 2012 PQRS. The
more than 200 remaining measures were previously established for reporting under the 2012
PQRS.

AdvaMed supports CMS’s goal of increasing participation in the PQRS and these minimal
changes to the PQRS seem to be aimed at enabling additional physician participation.
AdvaMed also supports the inclusion of an optional voluntary administrative claims-based
reporting mechanism for the 2015 and 2016 adjustments. AdvaMed also supports the
inclusion of a six-month reporting period (July 1, 2013 – December 31, 2013) for the 2015
payment adjustment for the reporting of measures groups via registries and a comparable six-
month reporting period for the 2016 payment adjustment.

Chronic Wound Care Measure Removal from 2013 PQRS. In the proposed rule, CMS
lists measures (Table 31) that they are not proposing to retain in the PQRS measure set for
2013 and beyond. One of these measures, Chronic Wound Care: Use of Compression System
in Patients with Venous Ulcers, was not recommended for reporting by the NQF-convened
Measure Applications Partnership (MAP) during pre-rulemaking review, as it had not been
NQF-endorsed. CMS noted in the proposed rule that they agreed with the MAP’s assessment
and proposed to remove the measure.

AdvaMed supports CMS’s decision not to retain this and other measures in the PQRS
measure set which have not been endorsed by NQF. AdvaMed fully supports the MAP’s
Measure Selection Criteria which states, among others things, that all measures recommended
by the MAP back to HHS for inclusion in public reporting and performance-based payment
programs are NQF endorsed or meet the requirements for expedited review. The NQF
endorsement process provides a robust, transparent, and criteria-based method of vetting
submitted measures developed by measure stewards.

• AdvaMed strongly recommends that all measures proposed for inclusion in
current and future CMS programs be submitted for NQF endorsement.
The measure, *Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers*, was recommended by the MAP for submission to NQF for endorsement by the measure steward. It is our understanding that this measure has, unfortunately, not been submitted to NQF for endorsement.

As compression therapy is a main clinical cornerstone and essential for venous leg ulcer management and preventing their reoccurrence, AdvaMed supports the efforts of the measure stewards to fill this important performance gap and submit this measure for NQF-endorsement in the very near future.\(^3,4,5,6,7\)

**Proposed PQRS Individual Core Measures Available for Claims, Qualified Registry, and EHR-Based Reporting for 2013 and Beyond.** In the CY 2012 Medicare PFS final rule, CMS noted that the prevention of cardiovascular conditions is a top priority for CMS, and thus adopted a set of core measures for CY 2012 which focused on the prevention of cardiovascular conditions. CMS is hoping that these measures will serve to encourage eligible professionals to monitor their performance with respect to the prevention of cardiovascular conditions. In 2011, the Department of Health and Human Services (HHS) started the Million Hearts Initiative, an initiative to prevent 1 million heart attacks and strokes in five years. CMS is dedicated to this initiative and seeks to encourage eligible professionals to join in this endeavor. Based on their desire to support the Million Hearts Initiative and to maintain their focus on cardiovascular disease prevention, CMS is proposing to adopt individual PQRS core measures for 2013 and beyond. The proposed core measures are the same measures that were finalized under the 2012 PQRS in the CY 2012 PFS final rule.

As cardiovascular disease remains a major cause of mortality and morbidity, AdvaMed supports the efforts to develop and implement a core set of cardiovascular measures. To the extent that the individual proposed core cardiovascular measures are NQF-endorsed, AdvaMed supports their adoption. Seven core measures are proposed and listed in Table 29 of the proposed rule; however, two proposed core measures (Preventative Care and Screening: Screening for High Blood Pressure; and Preventative Care and Screening: Cholesterol-LDL Test Performed), which have both been developed by CMS, are not NQF endorsed.

- AdvaMed strongly recommends that CMS submit the two core cardiovascular measures (Preventative Care and Screening: Screening for High Blood Pressure; and Preventative Care and Screening: Cholesterol-LDL Test Performed) to NQF.

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\(^6\) Agency for Healthcare Research and Quality (AHRQ), Effective Health Care Program. Evidenced-Based Practice Center Systemic Review Protocol. Project Title: *Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities*. Source: www.effectivehealthcare.ahrq.gov; Published online: March 5, 2012.

for endorsement before their adoption for PQRS Individual Core Measures for 2013 and beyond.

Proposed Criteria for the PQRS-Medicare EHR Incentive Pilot. The Medicare EHR Incentive Program is a voluntary program whereby Eligible Professionals may earn an incentive payment for demonstrating meaningful use of Certified EHR Technology (CEHRT). This includes, among other requirements, the submission of clinical quality measures (CQMs). In the CY 2012 Medicare PFS final rule, CMS established the PQRS-Medicare EHR Incentive Pilot in an effort to pilot the electronic submission of CQMs for the Medicare EHR Incentive Program and move towards the alignment of quality reporting requirements between Stage 1 of the Medicare EHR Incentive Program and the PQRS. CMS is proposing to extend this Pilot for the CY 2013 payment year only, as Stage 2 of the EHR Incentive Program is expected to begin in CY 2014. Additionally, for the EHR Incentive Program, CMS is proposing to extend the use of attestation as a reporting method for the CQM component of meaningful use for the EHR Incentive Program. CMS has determined that it is not feasible to report CQM electronically and that eligible professionals may continue to report CQM as calculated by CEHRT attestation.

- AdvaMed supports use of Pilot programs, and specifically CMS’s proposal to extend the PQRS-Medicare EHR Incentive Pilot for the 2013 payment year only. AdvaMed recognizes that this Pilot could be instrumental in shaping and facilitating the potential mechanisms for reporting by eligible professionals in the near future.

C. Physician Value-Based Payment Modifier and the Physician Feedback Reporting Program

Beginning January 1, 2015, the Secretary is required to apply a value-based payment modifier to claims from specific physicians and groups of physicians that the Secretary determines are appropriate. Not later than January 1, 2017, the Secretary is required to apply the payment modifier to all physicians and groups of physicians. The Secretary is also required to provide physicians with confidential Physician Feedback reports that measure the resources used to provide care to Medicare beneficiaries; the Secretary is also authorized to include information on the quality of care furnished to these Medicare beneficiaries in these reports. AdvaMed wishes to make the following comments in relation to the Physician Value-Based Payment Modifier and the Physician Feedback Program.

i. Proposed Quality of Care and Cost Domains. In 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. CMS is proposing 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 proposes 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 strongly disagrees with the approach of assigning equal weights to each
domain in the calculation of the Quality of Care Composite. 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). While other domains, such as care
coordination and population/community health, are strategically important for the
overall success in Medicare’s shared savings and bundling programs, they
typically play less of a role for physicians. By contrast, physicians directly
participate – on a day-to-day and patient-to-patient basis – on the clinical care that
patients receive and in identifying/preventing harms caused in the delivery of care.
Additionally, 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
these larger practices.

For the reasons stated above, AdvaMed believes that CMS should re-assess their
proposal to weigh each domain of the Quality of Care composite equally.
AdvaMed believes that CMS should assign varying weights for each domain, 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 Physician
Value-Based Payment Modifier is implemented.

ii. Episode-Based Cost Measures in the Physician Feedback Program.
Beginning in 2013, CMS plans to include episode-based cost measures for several
conditions in the Physician Feedback reports. Several comments on the CY 2012
PFS final rule recommended that CMS use episode-based cost measures in the
value-based payment modifier, rather than total per capita costs. CMS plans to
provide this information in the Physician Feedback reports before proposing them
for the value-based payment modifier in future rulemaking. The per episode
method measures the resource use associated with treating the specific episode of
an illness in a beneficiary (e.g., stroke or hip fracture). Episode of care generally
refers to all services related to a health condition with a given diagnosis, including
post-acute services such as home health, skilled nursing, and rehabilitation. Per
episode costs can be determined using "episode groupers," which are essentially
software programs that use diagnosis codes and various rules to assign claims to
clinically distinct episodes of care. AdvaMed is very much aware that a Medicare-
specific episode grouper is likely to have important implications in developing and
maintaining episode-based payments in the future.

AdvaMed believes that it is very important for efficiency — and measures dealing
with efficiency — to be defined to include the overall value of the service,
including both quality and cost. However, episode grouper limitations make it very unlikely that these groupers would adequately take into account the true costs and value of services provided in many circumstances. 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 insufficient to assess the value of many new technologies to patients and/or the health care system overall.

- In developing efficiency measures and episode groupers, AdvaMed strongly recommends that CMS determine estimated resource use over an appropriate episode of care, which includes a sufficient period of time to assess the overall value of the services provided. Appropriate sensitivity to this consideration may allow CMS to avoid adopting measures or policies relating to public disclosure of performance data that provide incentives for providers to adopt practices that have negative consequences for patients over the long term.

Conclusion

AdvaMed urges CMS to carefully consider our comments as well as those submitted by our member companies, as they provide a unique source of information in developing appropriate PFS payment rates. We appreciate the opportunity to submit comments on the proposed CY 2013 PFS rule, and look forward to working with CMS to address our concerns.

We would be pleased to answer any questions regarding these comments. Please contact DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can be of further assistance.

Sincerely,

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy