August 26, 2011

Via Electronic Mail
Don Berwick, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1524-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program: Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012 (CMS-1524-P)

Dear Dr. Berwick:

The Advanced Medical Technology Association (AdvaMed) welcomes the opportunity to provide comments on the Centers for Medicare & Medicaid Services’ (CMS) Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012 (CMS-1524-P), Federal Register, Vol. 76, No. 138, (Tuesday, July 19, 2011, p. 42772).

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 and support a system with payment rates that include sufficient resources to account for the costs of the medical technologies associated with physician-office based procedures.

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 considerable 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 2012 PFS rule:

Bringing innovation to patient care worldwide
I. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)—Indirect Practice Expense Per Hour Data—CY 2012 and the Transition to PPIS Survey Data

II. Potentially Misvalued Codes Under the Physician Fee Schedule:
   A. Progress in Identifying and Reviewing Potentially Misvalued Codes
   B. CY 2012 Identification and Review of Potentially Misvalued Services-Specific Codes Ultrasound Equipment
   C. Expanding the Multiple Procedure Payment Reduction (MPPR)—
      i. CY 2012 Expansion of the MPPR to the Professional Component of Advance Imaging Services
      ii. Further Expansion of the MPPR Under Consideration for Future Years

III. Other Provisions of the Proposed Rule—Quality Reporting Initiatives—Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System
   A. Proposed Definition of Group Practice
   B. Proposed 2012 Physician Quality Reporting System Core Measures Available for Claims, Registry, and/or EHR-Based Reporting
   C. Proposed 2012 Physician Quality Reporting Measures
   D. PQRS Reporting Mechanisms
   E. Physician Compare Web Site
   F. The Proposed Physician Quality Reporting System - Medicare EHR Incentive Pilot
   G. Improvements to the Physician Feedback Program and Establishment of the Value-Based Payment Modifier
   H. Potential Cost Measures for Future Use in the Value Modifier - Episode Groupers

I. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)—Indirect Practice Expense Per Hour Data—CY 2012 and the Transition to PPIS Survey Data

In CY 2010, CMS adopted the use of the Physician Practice Information Survey (PPIS), a newly created American Medical Association (AMA) survey which expanded the data previously captured under the Socioeconomic Monitoring System to include non-physician practitioners (NPPs) paid under the PFS. The PPIS was administered in CY 2007 and CY 2008 and was designed to update the specialty-specific PE/HR data used to develop PE RVUs. In response to stakeholder feedback CMS implemented a four year transition (75/25, 50/50, 25/75, 0/100) to the PE RVUs developed using the new PPIS data. CY 2012 will mark the third year of this transition.

PE RVUs for Radiation Oncology and Urology procedures have been negatively impacted by phasing in of the PPIS data. Radiation Oncology procedures are proposed to decrease four percent under the year three transition, resulting in an approximate 9 percent decrease in allowed charges for Radiation Therapy Centers in CY 2012. Urology procedures are proposed to decrease approximately 3 percent in CY 2012. (These decreases do not include the application of the CY 2012 proposed conversion factor).
<table>
<thead>
<tr>
<th>Specialty</th>
<th>Full Impact of PE RVU Changes under CY 2012 Proposed Rule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Oncology</td>
<td>-8%</td>
</tr>
<tr>
<td>Radiology</td>
<td>-5%</td>
</tr>
<tr>
<td>Radiation Therapy Centers</td>
<td>-9%</td>
</tr>
<tr>
<td>Urology</td>
<td>-3%</td>
</tr>
</tbody>
</table>

Adequate reimbursement for radiation therapy and urology services are essential to the progress being made in the fight against cancer and to ensure continued access to other essential procedures that improve the quality of life for Medicare beneficiaries. Low Medicare reimbursement can impact access to care and quality of care. Inadequate reimbursement also affects patient access to the most up-to-date technology needed to diagnose and treat cancer and other conditions. **AdvaMed urges CMS to consider the impact of the PPIS changes on these procedures as they move forward with phasing in of the data.**

**II. Potentially Misvalued Services Under the Physician Fee Schedule**

AdvaMed would like to offer several recommendations related to the processes that were proposed and considered by CMS with respect to the identification and appropriate valuation of misvalued services which are paid according to the PFS.

A. Progress in Identifying and Reviewing Potentially Misvalued Codes

In recent years both CMS and the AMA-RUC have taken significant steps to address potentially misvalued codes and have identified various methods for identifying codes for review including site of service shift, introduction and use of new technology, and other factors. CMS’s current proposal to consolidate the annual review of misvalued codes with the Five-Year review serves to continue addressing the issues of appropriate code valuation. AdvaMed has specific concerns related to the proposal to consolidate the two processes.

Elimination of the Five-Year review process would presumably lead to the discussion and review of misvalued codes on a regular basis pursuant to the RUC meeting schedule. While the proposal includes a mechanism for submission and notification of codes subject to review, AdvaMed would strongly urge CMS to further increase transparency by readily providing the public with access to the codes that will be reviewed at a particular RUC meeting. Additionally, AdvaMed would ask that if CMS moves forward with the proposal to consolidate these two processes, the review of the work and PE inputs associated with these codes should be limited to the list of codes subsequently published by CMS as being subject to RUC review during a particular annual process.

AdvaMed also continues to have concerns regarding the frequency of revisions for certain codes. AdvaMed is concerned that some codes have been reviewed multiple times within a relatively short period of time as a result of various screens that have been established and implemented by CMS and/or the RUC. **In order to ensure Medicare beneficiary access to the highest level of quality care, including access to and use of the most appropriate technologies, AdvaMed also recommends that CMS develop guidelines regarding the**
appropriate length of time between review of codes that they identify as potentially misvalued. We further recommend that in the absence of compelling evidence that the work or PE values for a code have changed, CMS should not survey a code more often than once every five years.

B. CY 2012 Identification and Review of Potentially Misvalued Services- Specific Codes Ultrasound Equipment
In the proposed rule CMS referenced issues related to the PE inputs for ultrasound equipment included in the RUC database and asks that the AMA RUC review the equipment descriptions and pricing for these technologies. Ultrasound equipment serves a variety of diagnostic purposes and as such varies in size, function, and cost. As CMS and the RUC move forward with their efforts to clarify the database information related to these sophisticated technologies, AdvaMed recommends that manufacturers and other stakeholders with clinical expertise be provided an opportunity to provide input and feedback regarding descriptive and other information related to this range of equipment.

C. Expanding the Multiple Procedure Payment Reduction (MPPR)
Several issues related to expanding the Multiple Procedure Payment Reduction (MPPR) are of interest and concern to AdvaMed. These issues are summarized below.

i. 2012 Expansion of the MPPR to the Professional Component of Advance Imaging Services--The proposed rule includes a recommendation to expand application of the MPPR to the professional component (PC) of all advanced imaging services (CT, MRI, and Ultrasound). The proposal would impose a fifty percent reduction on the PC for these procedures. AdvaMed is concerned by the breadth of this proposal and the impact of its application on beneficiary access to necessary diagnostic imaging services.

The PC of a service typically represents an estimated valuation of the time and skill associated with interpreting the results of a procedure. While there are arguably some pre-service and post-service efficiencies created with regard to the physician work associated with the performance of multiple imaging services, CMS offers very little justification for the proposed percentage reduction (focusing primarily on code pairs for certain computed tomography codes that involve contiguous, essentially overlapping body parts and the same imaging modality, making it inappropriate for CMS to generalize to all advanced imaging services). Further, CMS does not cite any information related to the amount of total physician work value attributed to pre- and post-procedure imaging services even though CMS claims that efficiencies primarily arise during the pre- and post-procedure periods. Additionally, the MedPAC recommendation cited by CMS did not include a percentage figure and only spoke to the issue of perceived efficiency gains and suggested that determining the amount of such efficiencies, which MedPAC noted could vary by type of imaging, would require careful analysis--something the proposed rule fails to demonstrate. The MedPac recommendation in
no way suggests that the CMS-proposed fifty percent reduction is appropriate to account for efficiency gains.

CMS has not explained its rationale related to the pre- and post-service clinical efficiencies which form the basis of its recommendation. The only constant in the case of doing more than one imaging procedure using different imaging modalities is the patient. Therefore, while a provider might save some time on chart review and determining referral services, this time savings does not necessarily amount to fifty percent of the overall PC resource inputs. In particular, few if any efficiencies are achieved when two imaging services involving different imaging modalities and/or non-contiguous areas are provided during the same session. Furthermore, it is reasonable to assume that a provider rendering a different imaging service on the same patient using a different imaging modality might face additional challenges when it comes to professional work associated with the procedures’ interpretation.

AdvaMed disagrees with CMS’s assumption that a provider 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. Consequently, AdvaMed opposes expansion of the MPPR reduction to the PC of advanced imaging procedures. AdvaMed urges CMS to reconsider this proposal and to not move forward with its implementation in CY 2012.

ii. Further Expansion of the MPPR Under Consideration for Future Years—
AdvaMed is similarly concerned with the three proposals that CMS is considering for future years. For many of the reasons cited above and for others cited in our letter on last year’s rule, related to patient repositioning and performance of imaging studies on non-contiguous areas, we do not support application of the MPPR to the Technical Component (TC) of all imaging services, the PC of all imaging services, or the TC of all diagnostic tests.1

The breadth of services that would be covered under these proposals is enormous. As such AdvaMed is concerned that any policy aimed at reducing the subsequent service(s) rendered in a session could create beneficiary access issues. CMS should bear in mind that the complexity of performing certain imaging and diagnostics tests requires numerous steps, many of which are directly impacted by the patient. AdvaMed recommends that CMS wait until it has adequate claims data regarding initial application of the MPPR to advanced imaging procedures and assesses the impact of those policies on Medicare beneficiary access prior to expanding these policies to other areas of imaging and/or

1 We disagree with CMS’s statement that a provider performing imaging services on the same day on the same patient using different modalities has the same level of efficiency that is already accounted for using the MPPR. It stands to reason that a provider rendering a different imaging service on the same patient using a different imaging modality would have to repeat a number of steps involving set up, positioning, and calibration of the machine prior to performing the subsequent imaging procedure. The patient would also have to be repositioned for each subsequent procedure.
diagnostic tests. Further, CMS should not propose expansions to the MPPR policy unless there is sufficient evidence to justify such expansion, nor should the agency automatically assume application of an MPPR policy which results in a fifty percent payment reduction.

III. Other Provisions of the Proposed Rule--Physician Payment, Efficiency, and Quality Improvements – Physician Quality Reporting System (PQRS)

The Physician Quality Reporting System (PQRS), which began as the Physician Reporting Quality Initiative (PQRI) in 2007, provides incentive payments and payment adjustments to eligible professionals who satisfactorily report data on quality measures. AdvaMed supports the further development of the PQRS, as required by statute and appreciates the efforts of CMS to implement the PQRS. AdvaMed appreciate the opportunity to comment on the following aspects of the PQRS in the proposed rule:

A. Proposed Definition of Group Practice
CMS has identified two ways an eligible professional can participate in the PQRS: (1) as an individual; or (2) as part of a group practice under the PQRS Group Practice Reporting Option (GPRO). Regarding the GPRO, CMS notes that many practices with fewer than 25 physicians that self-nominated to participate in GPRO II for 2011 subsequently elected to opt out. Therefore, in the proposed rule, CMS proposes to change the definition of “group practice” from the current “two or more eligible professionals” to “25 or more individual eligible professionals.” AdvaMed supports the decision to re-evaluate and re-define the definition of “group practice”, as the GPRO mechanism continues to evolve and as experience is gained over time.

B. Proposed 2012 Physician Quality Reporting System Core Measures Available for Claims, Registry, and/or EHR-Based Reporting
In the proposed rule, CMS notes that the prevention of cardiovascular conditions is a top priority for CMS, and thus is proposing to adopt a set of core measures for CY 2012 which focuses 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. 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 (Proportion of adults 18 years and older who have had their BP measured within the preceding 2 years; and Preventative care: cholesterol-LDL test performed), which have both been developed by CMS are not NQF endorsed. AdvaMed strongly recommends that CMS submit these two core cardiovascular measures to NQF for endorsement before their adoption into the PQRS.

C. Proposed 2012 Physician Quality Reporting Measures
For CY 2012, CMS is proposing to retain all measures currently used in the 2011 PQRS and
to add 26 new individual quality measures, only two of which are NQF-endorsed. CMS notes that the remaining measures are either pending NQF endorsement or would have to be adopted under the statutory exception to NQF-endorsement. **AdvaMed strongly urges CMS to submit all proposed measures for NQF endorsement prior to adoption and implementation.**

CMS also proposes to add the following 10 new measures groups for 2012: (1) chronic obstructive pulmonary disease (COPD); (2) inflammatory bowel disease; (3) sleep apnea; (4) epilepsy; (5) dementia; (6) Parkinson's; (7) elevated blood pressure; (8) radiology; (9) cardiovascular prevention, which contains individual measures from the proposed PQRS core measure set previously discussed; and (10) cataracts. Again, the majority of these proposed measures have not been NQF-endorsed, as indicated in Tables 46–55. In fact, only one complete proposed measure group – the COPD Measure Group – appears to have NQF endorsement. CMS notes that the remaining measure groups would be adopted under the statutory exception to NQF-endorsement. **AdvaMed strongly urges CMS to submit all proposed measures -- whether individual measures or measure groups -- for NQF endorsement prior to adoption and implementation.**

**D. PQRS Reporting Mechanisms**

For CY 2012 and subsequent years, CMS is proposing to retain the 6-month reporting period option for the reporting of PQRS measure groups via registry, but specifies a 12-month reporting period for all other reporting options, including claims-based reporting, registry reporting of individual measures, EHR-based reporting and reporting via the GPRO. In doing so, CMS is proposing to eliminate the 6-month reporting period for claims and certain registry reporting (individual measures via registry) previously available under the PQRS. **AdvaMed agrees that the elimination of the 6-month reporting period for claims and registry reporting will further align the reporting period of these mechanisms with the EHR mechanisms and help to streamline and simplify the reporting requirements for the PQRS without substantial burden to eligible professionals who may still satisfactorily report using the 12-month reporting period.**

**E. Physician Compare Web Site**

In the proposed rule, CMS is proposing to develop aspects of the Physician Compare Web Site in stages. In the first stage (completed in 2011), the names of those Eligible Professionals (EPs) who satisfactorily participated in the 2009 PQRS were posted. The second phase of the plan, which would occur during CYs 2011 through 2012, would include the posting of the names of EPs who are successful e-prescribers under the 2009 eRx Incentive Program, as well as EPs who participate in the EHR Incentive Program. Finally, in 2012, CMS proposes to make public the performance rates of the quality measures that group practices submit under the 2012 GPRO and to report the performance rates of the quality measures that the group practices participating in the Physician Group Practice Demonstration collected. In order to eliminate the risk of calculating performance on a small denominator, CMS has set a minimum threshold sample size of 25 patients, which will have to be met in order to have a group practice's measures performance rate reported. In determining the minimal patient sample size, CMS reviewed other Compare Web Sites that publically report measure performance data. **AdvaMed supports these staged efforts to develop various**
aspects of the Physician Compare Website. We also support efforts to ensure that the sample size is large enough to accurately measure performance, but not so large as to limit the number of groups for which measure performance could be reported. AdvaMed further believes that additional refinement of the Physician Compare Website may be necessary in the future and urges CMS to remain flexible in instituting additional improvements as needed.

F. The Proposed Physician Quality Reporting System - Medicare EHR Incentive Pilot
The Medicare EHR Incentive Program is a voluntary program whereby EPs may earn an incentive payment for demonstrating meaningful use of certified EHR technology. This includes, among other requirements, the submission of clinical quality measures (CQMs). For the 2011 payment year, EPs attest that CQM results are calculated by certified EHR technology. For 2012, CMS has again concluded that it is not feasible to report CQM electronically. Therefore, EPs may continue to report CQM as calculated by certified EHR technology by attestation. In addition to attestation, for the 2012 payment year CMS proposes to establish a pilot mechanism (the PQRS-Medicare EHR Incentive Pilot) by which EPs participating in the Medicare EHR Incentive Program may report CQM information electronically using certified EHR technology. Participation in this pilot only applies to the method of reporting for meeting the meaningful use CQM objective in the EHR Incentive Program. The Pilot would require EPs to electronically report the CQMs using certified EHR technology via one of two possible options, which are based on the existing reporting platforms of the PQRS. One option would be based on the infrastructure used for the PQRS EHR data submission vendor reporting mechanism. The second option would be based on the infrastructure used for the PQRS EHR reporting mechanism. As the pilot will rely on the infrastructure used for the PQRS, EPs must also participate in that program. EPs in the pilot would need to submit the same information required for the Medicare EHR Incentive Program. AdvaMed supports use of Pilot programs, and specifically CMS’ proposal for the PQRS-Medicare EHR Incentive Pilot, which could be instrumental in shaping and facilitating the mechanisms for electronic reporting by eligible professionals in the near future.

G. Improvements to the Physician Feedback Program and Establishment of the Value-Based Payment Modifier
The Affordable Care Act establishes time frames for the development of the value modifier that would apply to payment adjustments for 2015 (at least for some physicians) under the Physician Fee Schedule. Not later than January 1, 2012 CMS is required to publish three items related to the establishment of the value modifier: (1) the quality of care and cost measures; (2) the dates for implementation of the value modifier; and (3) the initial performance period for application of the value modifier in 2015. Starting in 2015, some physicians’ Medicare payments will be affected by application of the value-based Payment Modifier and by 2017 the value-based payment modifier will apply to all Medicare claims submitted by physicians paid under the PFS.

These programs were addressed in a recent GAO Report titled, Medicare Physician Feedback Program; CMS Faces Challenges with Methodology and Distribution of Physician Reports.” The report describes the various problems CMS continues to face with incorporating resource
use and quality measures for physician feedback that are meaningful and reliable. The report notes that CMS had difficulty measuring resources which were used by physicians to treat specific episodes of an illness (e.g., stroke or hip fracture) and that the quality measures used by CMS applied to a limited number of physicians. The GAO highlighted that CMS must decide how to:

- Adequately address other methodological challenges with developing feedback reports.
- Account for differences in beneficiary health status
- Attribute beneficiaries to physicians
- Determine the minimum number of beneficiaries a physician needs to treat to receive a report; and
- Select physicians’ peer groups for purposes of comparison.

The GAO report noted that CMS’s plans for improvement may not entirely address the challenges they face concerning distribution of feedback reports to physicians. AdvaMed understands that the statutory timelines for implementation of these programs is extremely challenging and advises CMS to proceed with caution, as many of the issues are very complex and may not be easily solved. As the feedback program may ultimately contribute to the designing of future value modifiers, AdvaMed believes that these are serious questions that need to be addressed and fully vetted in a transparent manner via notice and comment rulemaking.

H. Potential Cost Measures for Future Use in the Value Modifier - Episode Groupers

Resource use can be generally measured using two methods: (1) the per capita method; and (2) the per episode method. The per capita method measures the resources used by physicians in order to treat their Medicare beneficiaries over a fixed period of time. 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 to assign claims to clinically distinct episodes of care. During 2012, CMS will test and plan how to use a Medicare-specific “episode grouper”.

In developing efficiency measures and episode groupers, CMS should keep in mind 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. As episode groupers utilize diagnosis codes to assign claims, it is very unlikely that these groupers would

---

adequately take into account the true costs (and value) of services provided in many circumstances.

We believe that it only makes sense for efficiency — and measures dealing with efficiency — to be defined to include the overall value of the service, including both quality and cost. 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.

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. Therefore, in light of the comments in the recent GAO Report — and apparent lack of general information disseminated concerning the physician feedback program, value-based modifier, and episode groupers — AdvaMed has serious concerns regarding the appropriate development of the program and transparency by CMS. AdvaMed recommends that CMS provide additional information sessions, such as Town Hall meetings or similar opportunities, through which stakeholders can learn more about the status and features of the Medicare-specific episode grouper, various aspects of the feedback program, and CMS’s initial views about methodological issues relating to the value-based modifier. This would also provide a forum for all interested parties to provide valuable—and early—feedback to CMS regarding these matters.

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 2012 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
Don Berwick, M.D.
August 26, 2011
Page 11

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