September 6, 2013

Via Electronic Mail
Marilyn Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1600-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY2014; Proposed Rule (CMS-1600-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, Clinical Laboratory Fee Schedule & and Other Revisions to Part B for CY2014; Proposed Rule (CMS-1600-P), Federal Register, Vol. 78, No. 139, (Friday, July 19, 2013, p. 43282).

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 2014 PFS rule:

I. provisions of the Proposed Rule for PFS
   A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)
      i. Equipment Cost Per Minute
      ii. Changes to Direct PE Inputs for Specific Services--Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)
      iii. Using OPPS and ASC Rates in Developing PE RVUs
   B. Misvalued Codes- The Multiple Procedure Payment Reduction Policy
II. Other Provisions of the Proposed Regulations
   A. Medicare Coverage of items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage
   B. Proposals Regarding the Clinical Laboratory Fee Schedule
      i. Proposed Identification and Prioritization of the Codes to be Reviewed
      ii. Proposed Process
      iii. Payment Adjustments
      iv. Process – Personnel
   C. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System
      i. Optimizing Patient Exposure to Ionizing Radiation Measures
      ii. Vascular Measures
      iii. Qualified Clinical Data Registry Reporting Option
   D. Value-Based Payment Modifier and the Physician Feedback Reporting Program

I. Provisions of the Proposed Rule for PFS
   A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)

   The proposed CY 2014 rule includes several proposals related to CMS’s 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.

   i. Equipment Cost Per Minute

   The proposed rule addresses changes to the utilization rate assumptions associated with high-cost imaging equipment. The requirements mandating that these utilization rates be increased from 75 percent to 90 percent beginning in 2014 are a direct outgrowth of the American Taxpayer Relief Act. Failing to attach realistic utilization rates to equipment impacts the overall reimbursement for the important procedures in which these devices are utilized. As such, AdvaMed is concerned that this legislatively mandated change has the potential to negatively impact Medicare beneficiary access to needed care. High tech imaging equipment such as MRI and CT play a central role in assisting health care providers with making both diagnostic and treatment decisions. Therefore, any additional/future changes which could affect the reimbursement and utilization of this type of equipment should ideally not be made without evaluating the full range of potential impacts as they relate to the diagnosis, treatment, and care of Medicare beneficiaries.

   ii. Changes to Direct PE Inputs for Specific Services—Direct PE Inputs for Stereotactic Radiosurgery (SRS) Services (CPT Codes 77372 and 77373)

   The CY 2014 proposed OPPS rule includes a recommendation to eliminate the G-codes used to describe robotic stereotactic radiosurgery (SRS) procedures. That proposal would replace the four existing SRS G codes (G0173, G0251, G0339, and G0340) with SRS CPT codes 77372 and 77373. ¹ AdvaMed supports the OPPS proposal.

¹ 78 Fed. Reg. at 43593-94 (July 19, 2013)
G codes G0339 and G0340 are also used to describe robotic SRS procedures in the physician office setting. However, CMS is not recommending elimination of these G codes in the physician office setting for CY 2014, due to the need to send CPT codes 77372 and 77373 to the RUC for re-evaluation of the practice expense (PE) RVUs associated with the procedures. CMS would like to have the RUC ensure that the direct PE inputs for the CPT codes that would replace the G code procedures are correct. AdvaMed believes that this is an appropriate measure to ensure correct code valuation.

- **AdvaMed supports retaining G codes G0339 and G0340 in the physician office setting until CPT codes 77372 and 77373 are sent to the RUC for re-evaluation of the direct PE inputs for those codes.**

**iii. Using OPPS and ASC Rates in Developing PE RVUs**

The proposed rule proposes to use the current year’s OPPS and ASC rates to cap the nonfacility PE RVUs for certain services under the PFS. More specifically, this proposal would cap the rate of 211 procedures on the PFS using either the OPPS or ASC rates. AdvaMed is concerned by the potential negative impact that this change may have on the reimbursement for the affected codes and also has several concerns regarding the process that will be used for determining the capped rates.²

Many procedures are performed in both facility and non-facility settings. While the rationale motivating the proposal, to equalize rates among the setting might seem reasonable on its face, AdvaMed is concerned that CMS has not adequately evaluated the validity of this approach for determining payments. Our comments on the proposed changes will cover several areas including volume concerns, data lag, and the legal implications of implementing the PE RVU changes that CMS has proposed.

*Volume*—The volume with which procedures are done in one setting versus another should be factored into the decision regarding which rate is used to cap fees. In its proposal CMS creates several exemptions to limit the impact of the proposed changes. One of these exemptions covers codes with low volumes in the OPPS setting. In the proposed rule CMS indicates that it will exempt from the capping policy any procedures which are performed 5% or less of the time in the hospital outpatient setting. AdvaMed agrees that a low volume threshold would be appropriate but we consider 5% to be much too low for this purpose. Both hospitals and ASCs tend to have much higher patient volume than physician offices, and they are able to better absorb financial losses on low-volume procedures. CMS’ existing policy to limit ASC payments by physician office payments requires a service be furnished at least 50 percent of the time in the physician office setting. AdvaMed would encourage CMS to consider a similar threshold approach for this proposal.

Further, for many of the affected services, CMS is proposing to base the cap on ASC rates without examining utilization in the ASC setting. AdvaMed considers this inappropriate. If CMS intends to base the cap for a service on the ASC rate, it must ensure that the service in question is furnished in the ASC setting a significant portion of the time. An examination of the data used to develop the rates for procedures that will be capped using the ASC rate shows that 60% of the codes affected by the proposed ASC cap have little or even no utilization in that

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² AdvaMed utilized the services of Christopher Hogan, Ph.D. of Direct Research LLC to assist us in analyzing the breadth and impact of the proposed PE RVU changes, including volume concerns. Dr. Hogan noted a number of problems with CMS’s methodology in a white paper titled *A critical look at CMS’s proposal to cap 2014 physician practice expense amounts*. Dr. Hogan’s analysis is attached to our comments.
setting. Additionally, it also appears that many of the procedures have low overall volume—regardless of setting. Claims for codes that are performed in very low volume generally or in low volume in one setting do not satisfy the “market test” for adequacy. The low volume at which many of the affected procedures are performed in the ASC setting suggests payment rate inadequacy which forces providers to perform the procedures in either the OPPS or PFS settings. These factors must be considered when evaluating these procedures and as CMS considers whether to move forward with this proposal in any form.

- **AdvaMed recommends that CMS create a volume exemption threshold, for OPPS and ASC procedures, to determine the level of volume/utilization that is appropriate to trigger application of the proposed PE RVU. We further recommend that CMS study the threshold percentage issue further to determine appropriate percentages to apply to services performed in either setting.**

**Other Exemptions**—The proposed rule would exempt Codes with ASC Rates Based on PFS Payment Rates from the proposal. Codes that meet this exemption status would typically have an ASC payment indicator status of P3 (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs). An analysis of the 211 codes on the CMS list reveals that 19 of them are proposed for assignment of a P3 payment indicator in CY 2014. These same codes were assigned ASC payment indicator P2 (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight) in CY 2013 thereby causing them to be caught up in the PE RVU proposal. The 19 codes in question include:

<table>
<thead>
<tr>
<th>Codes With Reduced CY 2014 Proposed Nonfacility PE RVUs Due to Proposed OPPS/ASC Cap Policy</th>
<th>2014 Proposed ASC PI</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>SHORT DESCRIPTOR</td>
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<tr>
<td>10021</td>
<td>Fna w/o image</td>
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<tr>
<td>19105</td>
<td>Cryosurg ablate fa each</td>
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<td>20697</td>
<td>Comp ext fixate strut change</td>
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<td>31295</td>
<td>Sinus endo w/balloon dil</td>
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<td>31297</td>
<td>Sinus endo w/balloon dil</td>
</tr>
<tr>
<td>36147</td>
<td>Access av dial grt for eval</td>
</tr>
<tr>
<td>41530</td>
<td>Tongue base vol reduction</td>
</tr>
<tr>
<td>45303</td>
<td>Proctosigmoidoscopy dilate</td>
</tr>
<tr>
<td>46604</td>
<td>Anoscopy and dilation</td>
</tr>
<tr>
<td>51101</td>
<td>Drain bladder by trocar/cath</td>
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<tr>
<td>51727</td>
<td>Cystometrogram w/up</td>
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<tr>
<td>51728</td>
<td>Cystometrogram w/vp</td>
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<td>51729</td>
<td>Cystometrogram w/vp&amp;up</td>
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<tr>
<td>51748</td>
<td>Anal/urinary muscle study</td>
</tr>
<tr>
<td>53855</td>
<td>Insert prost urethral stent</td>
</tr>
<tr>
<td>67700</td>
<td>Drainage of eyelid abscess</td>
</tr>
<tr>
<td>67938</td>
<td>Remove eyelid foreign body</td>
</tr>
</tbody>
</table>
- **AdvaMed recommends that the 19 identified codes that are proposed to have a P3 payment indicator as of CY 2014 be exempted from the proposed PE RVU policy to avoid circularity.**

**Data Lag**-- AdvaMed also has a larger concern related to the way in which the capped fees would be calculated. The OPPS and ASC rates are based on claims data that has a two year lag—the CY 2013 OPPS/ASC rates CMS proposes to use were set using 2011 OPPS claims data. The existence of a lag in the OPPS claims data creates inaccurate payment information against which to compare PFS rates (resource inputs) for CY 2014. CMS, however, has not been able to devise a way to eliminate the data lag in the OPPS system to allow the use of more recent OPPS claims data in establishing payment rates for procedures done in this setting. Though CMS has included protections to prevent circularity in the capped rate it has failed to take into account the accuracy of claims data, or the lack thereof, as it applies to the information that will be used to cap the PFS rates. The failure to account for, or correct, the data lag results in a problematic and unreasonable policy for adjusting the PFS rates.

**Differences in Payment Between Facility and Non-facility Settings**— The PFS is a service-specific payment system whereas ASC and OPPS payments are bundled. The OPPS and ASC payments are determined based on the geometric mean cost for a category of services and procedures grouped into Ambulatory Payment Classifications (APCs). The result is that some procedures in an APC will have costs below the geometric mean and some will be above the geometric mean. This averaging approach to payments works for hospitals and ASCs because they have sufficient volume across a range of procedures and are able to make up for payment shortfalls using offsets from profits for other procedures. This is not the case for the typical physician’s office.

Under the PFS, payments are calculated for each service or procedure. The concerns CMS has described regarding the process to determine the PFS rates does not take into account the fact that many of the codes performed in the physician office setting are systematically subjected to RUC review which also includes a review and re-evaluation of the practice expense RVU inputs associated with a code. These input recommendations are based on the presentation of data from physicians who perform these services and procedures on a routine basis and who are familiar with the personnel, equipment, and supplies utilized in their performance as well as the cost of these items. Though the RUC process has been the subject of some criticism, CMS’s proposal to use payment amounts derived from OPPS claims data to limit payments for specific procedures under the PFS seems to create a bigger problem than it purports to solve.

While hospitals and, to a lesser extent, ASCs are able to offset losses from underpaid services physician’s offices cannot. CMS should more thoroughly understand the implications of this policy prior to finalizing it to ensure it is not inadvertently harming patient care through implementing payment cuts which could compromise beneficiary access to services and procedures in the physician office setting.

**Inaccurate Supply Inputs**— A review of the data released with the proposed rule also suggests issues related to the reporting of all appropriate supplies for the services performed in the OPPS and ASC settings. Documenting all of the supplies needed for a procedure is critical in determining appropriate valuation. The issue of educating hospitals on the necessity of
documenting all supplies associated with a given service or procedure has been raised in AdvaMed comments on the OPPS rule and to the Advisory Panel on Hospital Outpatient Payment (and its predecessor the Advisory Panel on Ambulatory Payment Classification) for many years.

AdvaMed has ongoing concerns that all of the codes associated with procedures are not being appropriately reported on hospital outpatient department claims. The codes on claims are used by CMS to identify and estimate the resources associated with a procedure and ultimately to appropriately adjust the APC payment under OPPS. Ongoing issues with hospital reporting of codes, particularly those for high-cost devices and supplies, raises questions about the accuracy of OPPS and ASC payment rates, particularly for device intensive procedures.

The proposed PFS rates should at least cover the cost of supplies required for the procedure. CMS’s ASC rates are steeply-discounted versions of the OPPS rates. CMS does not, however, discount the estimated cost of the device in device-intensive APCs, under the theory that ASC’s have to pay market rates for the devices. In the case of procedures for which supplies comprise a significant portion of the overall costs, data provided by AdvaMed’s consultant, Direct Research, LLC, reveals proposed capped payments for several codes that fall below the supply costs associated with the service or procedure.

*Charge Compression*—Charge compression continues to be an issue in the claims used to set rates under OPPS. The markup for expensive implantable devices tends to be lower than that for routine supplies. While the establishment of the implantable devices charged to patients cost center, which was used to create device specific cost-to-charge ratios (CCRs) in 2013, is an important step towards more accurately representing device costs in OPPS, its data is new and is not yet being used by CMS to set OPPS payment rates. Due to the data lag, CCRs from this cost center are not reflected in the data used to calculate the 2013 OPPS and ASC rates, nor are they reflected in the proposed 2014 OPPS and ASC rates.

While the new cost center and associated CCRs will be valuable moving forward, AdvaMed has ongoing concerns about the quality and accuracy of hospital reporting using the new cost centers in the first several years that it is available. Given the challenges in educating hospitals about use of the new cost center, inevitable delays in hospital implementation of the cost center and errors in early years of use, that will likely reduce the accuracy of this CCR data, are likely to persist for some time. Consequently, the data used to set payment rates under OPPS will almost certainly continue to undervalue device intensive procedures for a number of years.

*Legal Implications*—The proposed policy also results in significant adjustments to the practice expense (PE) relative value units (RVUs) for the 211 codes involved. In many cases these downward adjustments in PE RVU value are significant—resulting in changes of 20% or more. Section 1848 (b)(1) of the Social Security Act (the Act) lays out the method whereby fee schedule payment amounts for physician services are established. This method entails the development of RVUs and use of the conversion and geographic adjustment factors. Section 1848(c) of the Act describes the different types of RVUs and the methodology to be used by the Secretary in developing RVUs. That process involves consideration of the practice expense resources involved in furnishing a service.

In its proposal CMS does not discuss the intersection between its capped payment policy proposal and the requirements for establishing physician fees as enumerated in the Act. Specifically, there is no mention of the process used by CMS to determine the reduced
practice expense (PE) RVUs for the 211 codes that are the subject of this proposed change or whether the proposal conforms with the Act’s requirements for determining PE RVUs as indicated in section 1848(c) of the Act.

AdvaMed questions whether CMS’s proposal conforms to the requirements specified in the Act. There are notable distinctions in the type of resources used to perform services in the physician office setting versus the OPPS or ASC settings. While OPPS claims data reflects services involved in furnishing particular procedures in the OPPS and ASC settings this data does not include the “resources” used to furnish those services in the physician office setting. The SSA defines the term “practice expense component” to mean, “the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.” The definition of practice expense that is contained in the SSA is, of course, a specific reference to the physician office setting. However, as CMS even acknowledges, there are differences in the resources required to perform a procedure in the facility setting versus the non-facility setting. Understanding this distinction Congress has already mandated methods by which CMS can cap certain PFS payments by the OPPS rate. This was the case when similar caps were applied to imaging rates pursuant to the Deficit Reduction Act.

- CMS’s proposal to use the OPPS and ASC rates to determine PE RVUs for PFS procedures needs further refinement before it can be implemented in a way that generates accurate pricing for the procedures in question. As currently constructed, the proposal fails to recognize significant payment discrepancies that could result if rates from low volume ASC procedures are used to adjust PFS rates. It also does not acknowledge the inherent discrepancies that will result if OPPS rates that were developed using older claims data are used to adjust PFS rates for CY 2014. These problems are substantial and compromise the ability of CMS to develop accurate and appropriate PE RVUs for PFS procedures until they are resolved. Given these facts AdvaMed recommends that CMS not move forward with its plan to use OPPS and ASC rates in developing PE RVUs for PFS procedures.

B. Misvalued Codes-- The Multiple Procedure Payment Reduction Policy

CMS is not currently recommending the expansion of the Multiple Procedure Payment Reductions (MPPR) to any other categories of codes for CY 2014. AdvaMed is supportive of CMS’s decision given our historic and ongoing concerns with adverse impacts created through the application of the MPPR policy.

- While AdvaMed is supportive of CMS’s decision to not further expand use of MPPR in 2014 we also recommend that the agency refrain from any future expansion of the policy until it has adequate claims data regarding the initial application of the MPPR to advanced imaging, diagnostic tests and other procedures. This information would allow CMS to assess the impact of the MPPR policies on Medicare beneficiary access prior to expansion to other areas.

II. Other Provisions of the Proposed Regulations

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3 See Social Security Act §1848(c)(1)(B)
A. Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage

CMS proposes to revise the existing regulations relating to the coverage of Category A and Category B Investigational Device Exemption (IDE) studies and trials. The Agency proposes a centralized review process to replace Medicare contractor coverage decisions. CMS further specifies additional scientific and ethical standards for covered studies and trials. The IDE regulations have a direct impact on beneficiary access to state-of-the-art medical technologies and procedures as well as on medical technology innovation.

AdvaMed consistently has supported policies that further clinical research. For nearly 20 years, the 1995 IDE regulation has provided a clear pathway for securing Medicare coverage of Category B IDE studies, and has facilitated Medicare beneficiaries’ access to the most current medical technologies. The Congress expanded this pathway in 2003 in the Medicare Modernization Act, providing the potential for Medicare coverage for the routine costs associated with Category A IDE studies—a policy that complements other Medicare policies to spur the generation of evidence and to encourage the participation of Medicare beneficiaries in clinical research. Medicare Administrative Contractors (MACs) are currently responsible for making coverage determinations regarding these IDE studies. However, local contractors’ procedures and coverage determinations can vary, and in some cases lack transparent criteria, resulting in conflicting determinations, the omission of beneficiaries from clinical studies in problematic MAC regions, and overall confusion and burden on trial investigators, clinical sites and sponsors. In addition, ongoing issues regarding internal communication at some of the MACs often result in delays and errors in communicating coverage decisions made by the policy department to the claims processing department so that claims can be appropriately paid. Despite these concerns, the local contractor-based process for determining coverage of IDE studies has generally worked well, although revisions to the process, or the provision of more uniform guidance to the MACs, might address these issues and create greater consistency across MAC jurisdictions.

The proposal to create a centralized review process for determining coverage for FDA-approved IDE clinical studies represents a significant change from the current process. For the reasons outlined below, AdvaMed believes CMS should not finalize the proposal as drafted. Instead, CMS should carry out a comprehensive review of the current coverage process to determine whether the local carrier-based process should be refined or should be replaced with a centralized process. This review should include extensive consultation with relevant stakeholders, including investigators, study sponsors, Medicare contractors and others, to fully explore the current challenges of the local process, as well as the potential challenges associated with implementing a new process. After performing this extensive review, CMS should issue a separate notice of proposed rulemaking, with a public comment period, to ensure adequate feedback on the proposal. In the interim, CMS should continue to rely on local contractors for coverage determinations regarding IDE trials.

**General Comments**

In general, we appreciate CMS interest in improving the coverage determination process for IDE trials. However, changes in this area should be approached cautiously, given the importance of this matter to Medicare beneficiaries, the physicians who treat them, and to medical innovators.

While stakeholders have raised concerns regarding the current, local contractor-based process
for determining coverage for Category A and B IDE studies, we recognize that the process has also provided, with some exceptions, flexibility and relatively rapid coverage reviews. We also recognize that CMS wants to ensure that it does not support studies that are methodologically flawed, or that do not meet quality and ethical standards, and we agree with this goal. Nevertheless, we have concerns regarding the 13 criteria CMS has identified for studies to be considered for coverage. Each of the criteria requires interpretation and could be applied in a different manner by the various individuals who will review IDE studies for compliance—regardless of whether the review is performed centrally by CMS staff or locally by Medicare contractors. Variability across contractors has been an industry concern, particularly when various local MACs have inconsistent policies and procedures, or reach inconsistent decisions. For example, AdvaMed has repeatedly raised to CMS’ attention inconsistencies in the MACs’ interpretation of “conditional approval” of IDE trials, noting some MACs have denied coverage for IDE clinical studies that have been conditionally approved by the Food and Drug Administration (FDA). AdvaMed has requested that CMS provide guidance to the MACs on this specific issue in order to provide more consistency. It is not clear, however, that the centralized approach being proposed would minimize or eliminate these inconsistencies and, in the end, the proposed process could restrict beneficiary access to innovative technologies and procedures more than current policy.

In addition to the 13 standards for IDE trial coverage described in the proposed rule, CMS identified two additional characteristics of studies that, if met, would provide “automatic” coverage for Category A and Category B IDE trials. Without further guidance, these general criteria and additional characteristics have the potential to increase uncertainty for innovators, and could potentially lead to less willingness on the part of innovators and the medical technology industry to conduct clinical research involving Medicare beneficiaries, and discourage program beneficiaries from participating in clinical trials. Our specific and more detailed comments are outlined below.

i. Coverage Process for IDE Trials

The proposal to create a centralized national coverage determination process for FDA-approved IDE clinical studies in place of local contractor determinations represents a significant departure from the process that Medicare has followed since coverage of IDE studies was initiated in 1995. CMS states in the proposed rule that variability in coverage made the conduct of national IDE studies difficult, and that inconsistent coverage determinations contributed to Medicare beneficiaries’ reluctance to enroll in IDE studies.

AdvaMed would support improvements to streamline the process and reduce the burden on study sponsors and study sites, which CMS states is a goal of this proposal. The proposal raises questions regarding the details of the centralized process CMS is contemplating, including questions about CMS’ capacity to perform these reviews in a timely and efficient manner and the resources and personnel that will be allocated to this process. We note, for example, that the proposed rule does not specify deadlines for CMS action or the usual process for deeming a submission to be approved if CMS does not act within such a timeframe. Given current constraints on hiring within the federal government, reported CMS staff vacancies that are not being filled, and other budgetary considerations, we have serious concerns that CMS will have the resources to administer a centralized review process in a responsible manner.

CMS must consider whether a centralized process will truly address the variation, inconsistencies, and inefficiencies, as discussed in more detail below, or whether refinements
to the current process, such as the provision of clear guidance to the MACs, would result in improvements in these areas. We note that the local coverage decision-making process has generally worked well over the years, though variation across contractors has led to inconsistencies in processes and in some cases, in the resulting coverage determinations. We believe that progress could be made toward more uniformity across contractors with increased CMS communication and instructions to contractors when problems become apparent, for example, with the conduct of large, multi-center IDE trials that span multiple contractor jurisdictions.

A radical change in the coverage decision-making process for IDE trials may not be needed. AdvaMed is concerned that a move to a centralized review process that introduces new criteria with which CMS and medical innovators have little or no experience, and which does not resolve the inefficiencies in the current process could result in increased uncertainty with respect to Medicare coverage, and potentially non-coverage of care in important clinical research. An abrupt shift in the criteria and loci of decision-making from Medicare contractors to CMS Central Office could pose multiple implementation obstacles that will—at least in the short term—hinder the conduct of IDE clinical research and reduce Medicare beneficiary access to IDE clinical trial participation.

CMS states that the proposed centralized review process would be more efficient. However, the proposed rule does not provide detail on the centralized procedures that CMS intends to use to make coverage determinations for IDE trials, the personnel that will be devoted to this task (or their expertise), the timelines for decision-making, or the resources that will be allocated to interact effectively with stakeholders and researchers during the process. To our knowledge, CMS has not inventoried the volume or variety of tasks that contractors currently perform in dealing with study sponsors and determining coverage for IDE trials in preparation for taking on this responsibility. Further, the CMS proposal does not quantify the savings or efficiencies that it expects from this proposed change, and does not address the resources needed to implement it.

CMS does not discuss the role that local contractors will continue to play in IDE clinical trial matters even if coverage determinations are made centrally nor the process that will support such coordination. The MACs may have to resolve local coverage policies to accommodate national CMS coverage determinations. By necessity, contractors will continue to be engaged in claims processing as IDE trials and studies are undertaken, and in providing coding advice to researchers related to covered clinical research. We do not believe that contractors’ budgets could be reduced appreciably to offset the additional cost associated with CMS Central Office staff performing the coverage decision-making task for IDE trials.

Additionally, study sponsors will still have to work with multiple MACs in cases where a trial spans multiple jurisdictions, resolving potential coverage issues and working with individual claims processing teams.

Finally, local contractor medical directors are known to stakeholders, familiar with research centers and practitioners in their contractor jurisdictions, and are generally reachable by investigators, sponsors and study center personnel. Shifting their responsibilities regarding decisions about coverage of IDE trials to as-yet unidentified CMS staff might be intended to improve efficiency; however, the volume of clinical research that is conducted via FDA-approved IDE studies (ranging from approximately 150-250 in a given year) could pose substantial internal management and coordination issues that will slow the conduct of clinical research. In addition, the CMS proposal provides the public with no assurances that the
various tasks associated with the coverage of IDE studies that are currently performed by Medicare contractors will be continued by CMS staff.

In our experience, the coverage decision-making process for IDE trials demands a level of individual interaction and communication between the research sponsor and the Medicare medical director that does not appear to be built into the proposed new process. Questions might arise with respect to specific matters involving IRB approvals, or patient selection criteria, or the research protocol that demand timely and personal discussion. The CMS proposal describes a system that appears to assume little interaction with stakeholders, in which paper submissions relating to FDA-approved IDE studies for which coverage is desired are filed by study sponsors who must monitor web site postings or Federal Register publications to learn whether coverage has been approved.

**Coverage Process Recommendations:**

For the reasons stated above, AdvaMed recommends the following:

- **CMS should undertake a comprehensive assessment of the local contractor IDE study coverage process to determine whether the local process should be refined or whether replacing the local process with a centralized process would improve efficiency and consistency. This comprehensive assessment should include broad consultation with relevant stakeholders, including manufacturers and the MACs. CMS should continue to rely on local contractors for coverage determinations regarding IDE trials and studies while it undertakes such an assessment.**

- **CMS should refrain from implementing the proposed shift to a centralized review process while it gathers stakeholder input and performs a full analysis of the consequences and implementation challenges associated with this action. This analysis will allow for development of process improvements that continue to promote Medicare beneficiary participation in IDE clinical trials while providing efficiency and consistency.**

- **CMS could explore establishing a process for study sponsors to request a centralized coverage determination for IDE trials and studies of promising medical technologies and procedures that are non-covered by Medicare. This limited application of CMS’ centralized process proposal might permit direct discussions between CMS coverage staff and potential study sponsors apart from the timelines and procedures associated with the national coverage process, and it could serve as an adjunct to CMS evidence generation efforts through Coverage with Evidence Development.**

- **Before any change in the coverage decision-making process for IDE clinical studies is implemented, CMS would need to provide more detail on the process, the timelines associated with reviewing studies, the staff that will conduct the reviews, and the nature of the interactions with CMS staff that will be possible during the process. In particular, if CMS were to continue to pursue the notion of centralized review, we would recommend:**
  - That CMS specify a 30-day timeline for reviews;
  - That CMS establish a formal appeals process; and
- That CMS ensure appropriate and timely communications with the MACs (e.g., issuance of timely transmittals regarding coverage, claims processing and related issues).

Further, CMS should solicit comments on the details of the proposed new process and encourage stakeholder participation.

- CMS should address and clarify the logistics relating to documentation of IRB approval in a centralized review process. Typically, IRB approvals happen on a rolling basis; that is, one IRB approval may be received for the first study site in a multi-site trial and then additional approvals for other sites are received at later times. Therefore, a rolling process for submitting IRB approval documents should be incorporated, so that a coverage decision can be made based on the initial IRB approval.

ii. Coverage Criteria/Standards for IDE Trials

The proposed rule identifies 13 criteria that both Category A and Category B IDE studies must meet in order to be considered for coverage. In addition, CMS proposed two additional characteristics of studies that, if met, would lead to automatic coverage for Category A and Category B IDE trials. That is, CMS proposes to automatically cover an IDE trial when all of the 13 criteria are met and the study is: (1) a pivotal study; and (2) has a superiority study design.

AdvaMed agrees that IDE studies should meet scientific and ethical standards. The criteria that currently govern Medicare participation in clinical trials are identified in the Medicare NCD for coverage of routine costs in clinical trials. More recently, CMS included the same 13 criteria that are being proposed in this rule for clinical research studies in a Draft Guidance Document on Coverage with Evidence Development (CED). As mentioned above, we note that these criteria are general and subject to interpretation, and could therefore be applied differently by different reviewers, even within the context of a national review process. More specificity on these criteria, developed through a robust dialogue with stakeholders, would provide guidance to clinical trial sponsors and would eliminate such subjectivity.

AdvaMed has additional and significant concerns regarding the 13 criteria. The criteria duplicate, to a large extent, the responsibilities of the Food and Drug Administration which is tasked with reviewing and approving or disapproving Investigational Device Exemptions (IDEs) including determining among other things whether the study design is appropriate, whether the number of anticipated enrolled subjects is appropriate, whether the study complies with applicable federal regulations governing protection of human subjects, whether risks to subjects are outweighed by anticipated benefits to the subjects, and the importance of the knowledge to be gained by the study. We are also concerned about the deference to the International Committee of Medical Journal Editors in the CMS criteria given that ICMJE does not have transparent or open decision-making processes.

CMS also does not justify the need or value in going beyond the statutory clinical trial reporting requirements in Section 801 of the Food and Drug Administration Amendments Act of 2007, which require registration of trials on the site no later than 21 days after the first patient is enrolled in the clinical trial. It should be noted that the statute does not mandate release of medical device clinical trials results until 30 days after FDA clearance or approval of the device in order to protect confidential commercial and trade secret information. It
should also be noted that the Secretary of Health and Human Services has not yet issued a rule governing release of negative clinical trial results. CMS requirements should be consistent with the current statute governing release of clinical trial results.

We also have significant concerns regarding the two additional characteristics – (1) pivotal study and (2) superiority trial design.

(1) Regarding pivotal studies, many IDE studies for medical devices being investigated as part of the FDA Premarket Approval (PMA) process would appear to constitute “pivotal studies” because these studies are designed to collect definitive evidence of safety and effectiveness for a device for a specified intended use in a statistically justified number of subjects—the elements of a “pivotal study” set forth in the proposed rule. As such, those IDE studies would meet this characteristic. Additionally, it is duplicative of FDA’s review process.

(2) We are concerned that by automatically covering IDE trials that are pivotal studies and have superiority designs (along with the other characteristics), CMS is making prospective judgments about the quality of an IDE trial and about the evidence it will produce before the trial has been conducted. We raise this concern because we would not want this requirement to lead to a decrease in the number of approved IDE studies because they do not have superiority designs.

AdvaMed has provided comments to CMS with respect to the particular challenges associated with the evaluation of medical device technologies on a number of occasions, including recent proposed NCDs that address trial design matters. In those comments, we have emphasized a number of factors that shape the choice of a study design for medical device interventions: the wide variety of device types, their short life cycles, the incremental nature of the device innovation process, and the ethical constraints that often exist in designing studies to compare new devices with established medical therapies.

In one recent proposed NCD and in some of the language in this proposed rule relating to Category B IDEs, CMS stated its intention to require a superiority trial design for clinical research as a condition of clinical trial coverage. We objected to this for a number of reasons: First, we note that clinical trials designed to answer valuable and valid research questions have been designed without a superiority requirement after consultation with the FDA. It is not necessary to require “superiority” if the goal is to illustrate that a medical intervention is “reasonable and necessary.” Superiority requirements would also increase study sample size, overall study costs and could potentially limit access to beneficiaries. In large, cardiology-oriented studies, for example, superiority studies could raise sample size requirements significantly (i.e., 1,000 versus 8,000 patients) and add a tremendous burden.

Second, medical device innovation is unique compared with other innovative products. Significant advances are often realized through a series of incremental changes. Given the incremental nature of medical device development, it is not unusual for a new device to show only small improvements in outcomes against a comparator. Yet, such incremental improvements over an earlier generation device are beneficial, allowing for advancements in products, techniques, and treatment protocols that can optimize patient care or allow more patients to receive treatment as the health care system collectively learns. For example, a study may be designed to measure non-inferiority to conventional treatment, but the results of the study may demonstrate superiority in terms of other measures, such as reduced pain, decreased recovery time or complications, and/or shorter hospitalizations. Superiority trial
designs presume that all potential patients will weigh the pros and cons of treatment the same way; in reality, some patients, for example, may prefer medical management to surgery or vice versa, for a variety of medical and non-medical reasons relating to their own individual circumstances.

Finally, many medical devices and technologies are developed for relatively small populations. A medical device may be developed for use with a very limited number of patients with a given medical condition, for which it would be difficult to achieve a large sample size in a clinical study, particularly if the study required a superiority design. Non-inferiority or equivalence trials are often used to demonstrate that two treatments work equally well.

We understand the CMS is proposing to provide automatic coverage of IDE trials that meet all other criteria and have a superiority design; and that CMS may cover IDE trials that do not have this characteristic. Therefore, we urge CMS to strongly consider all factors regarding the clinical trial design when reviewing requests for IDE trial coverage, and not to deny coverage for non-inferiority trials or equivalence trials solely on the basis of trial design when all other criteria are met.

**Coverage Criteria/Standards Recommendations:**

For the reasons discussed above, AdvaMed makes the following recommendations:

- **CMS should provide more specificity with respect to the meaning of the 13 criteria so that stakeholders understand their purpose, particularly in situations where an FDA-approved IDE clinical trial is not a pivotal trial and does not have a superiority study design. This specificity should result from dialogue with key stakeholders, including study sponsors.**
  - Example: The first review criterion relates to generalizability to Medicare beneficiaries. CMS should clarify this criterion (e.g., if a multi-arm trial has one arm that includes patients over the age of 65, and the other arms do not, how would this be reviewed and interpreted?)
  - Example: The third review criterion states that study results should not duplicate existing knowledge. This standard is highly subjective and should not be used to restrict coverage of IDE studies that build on an existing body of evidence or that provide confirmatory data on new devices, even if similar studies have been conducted.
  - Example: The seventh review criterion relating to the conduct of IDE studies should be revised to state that all aspects of the study are conducted “according to appropriate standards of scientific integrity established in the code of Federal Regulations.” CMS should delete any references to the International Committee of Medical Journal Editors (ICMJE).

- **CMS should recognize that many IDE studies for medical devices being investigated as part of the FDA Premarket Approval (PMA) process would be considered “pivotal studies” based on the definition of “pivotal study” in the proposed rule.**

- **CMS should understand and appreciate the value of clinical research studies that are not pivotal studies, or that have study designs other than superiority. New device entrants that demonstrate equivalency to a currently approved device may provide treatment options for diverse patient characteristics or other benefits to the
health care system. We understand that the proposal gives CMS the discretion to cover IDE trials that do not have these characteristics. However, the proposal as drafted indicates a strong preference for such studies. CMS should carefully review requests for IDE trial coverage and should not deny Medicare beneficiaries access to important medical technologies in certain trials by non-covering trials that are not pivotal trials and do not have a superiority study design, particularly when all other criteria are met. As noted above, many factors shape the choice of study design for medical device trials, and many clinical trials are designed to answer valuable and valid research questions, but do not have a superiority study design.

- CMS should clarify what it means by superiority trial design. Specifically, CMS should clarify the definition of “superiority studies or trials” set forth in the proposed rule at §405.201(b) by specifying that such studies or trials include trials with multiple study arms where one arm is designed to demonstrate superiority, non-inferiority trials with secondary endpoints designed to demonstrate the superiority of the medical intervention over an active control and non-inferiority trials with subsequent testing of superiority once non-inferiority is demonstrated.

Based on the above discussion, AdvaMed believes that CMS should not finalize this proposal in the PFS final rule for CY 2014. Instead CMS should closely examine the existing issues with the current process in order to make a fully informed decision regarding whether a centralized review process will adequately address those concerns, or whether refinements to the current process would improve efficiency and consistency. CMS should consult with the relevant stakeholders to explore all options and then issue a separate notice of proposed rulemaking, with an adequate public comment period, so that stakeholders have appropriate time and opportunity to provide meaningful input on the proposal. CMS should continue to rely on local contractors for coverage determinations regarding IDE trials in the interim.

B. Proposals Regarding the Clinical Laboratory Fee Schedule

The proposed rule includes a proposal to create a process for reconsidering payments for individual CPT codes on the Clinical Laboratory Fee Schedule (CLFS). These reconsidered payment amounts would be based on technological changes that have impacted the efficiency, personnel and supplies, and sites of service associated with tests on the CLFS. The proposal includes a definition of technological changes that includes changes in supplies, equipment, labor, skills, technique, test production, and test use among other factors. CMS would use this reconsideration process to determine whether changes in technology warrant an adjustment to current CLFS payment amounts. CMS anticipates that most payment adjustments will be reductions.

While AdvaMed has long acknowledged that the CLFS is in need of reform, we have significant concerns with this proposed rule. The CLFS, though subject by law to inflation adjustments, has been adjusted for inflation only 5 times in the past 23 years. Instead of realizing increases, in most years Congressional action has resulted in fee schedule amounts being held at prior levels or reduced. As a result, the actual payments for many tests are lower today (when inflation is taken into account) than they were in 1984 when the CLFS was established. The Medicare statute further requires the annual application of a productivity adjustment\(^5\) for clinical laboratory tests in addition to all other required fee schedule

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\(^5\) The productivity adjustment is defined in the Social Security Act §1836(b)(3)(B)(x)(II) as the “10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).
adjustments, resulting in further payment reductions. The Bureau of Labor Statistics, which calculates the productivity adjustment each year, describes it as reflecting the effects of a number of factors on productivity, including changes in technology. Therefore, the current proposal to re-evaluate codes on the CLFS for technological changes and recommend payment adjustments would appear to be unnecessary and redundant in light of all of the statutory fee schedule adjustments currently available.

We strongly urge CMS not to finalize this proposal as drafted. CMS should delay the implementation of this proposal, and should further develop the details of its intended approach, and consult with all relevant stakeholders. CMS should consider holding a public meeting or other forum as part of this process to gather input from interested stakeholders with experience, expertise and knowledge regarding the clinical, scientific and technical aspects of the tests CMS intends to review.

If CMS proceeds with this proposal, we strongly encourage the agency to ensure that any savings achieved are retained in the clinical laboratory fee schedule payment structure, enabling newer tests that may embody advanced techniques or require extensive development to receive higher payments. CMS generally relies on section 1833(h)(2)(A)(i) of the Social Security Act to make payment adjustments for particular tests as “justified by technological changes.” It appears that the language in the Act would allow this recommendation to be implemented.

This approach is similar to the budget neutrality adjustments in the physician fee schedule and hospital inpatient and prospective payment systems. Overall payments would still change due to annual updates and as new tests are introduced, just as they do in the physician and hospital payment systems. This approach would provide necessary stability to the CLFS, particularly given the negative annual changes to Medicare’s payments for lab tests over the last 23 years, as discussed above.

Many other aspects of the technological change proposal raise questions and concerns. AdvaMed’s specific comments on these issues are detailed below.

i. Proposed Identification and Prioritization of the Codes to be Reviewed

CMS proposes to review all codes currently on the CLFS, beginning with codes that have been on the CLFS the longest and working forward to the present. CMS states that payment amounts for these older codes are more likely to have experienced technological changes because technology tends to be more expensive earlier in a test’s life cycle – with costs tending to decrease as a technology matures and diffuses. CMS acknowledges that tests that are less than five years old are still likely in their “technological infancy” and that not enough time would have passed to adequately assess any change in technology for those services.

AdvaMed supports the proposal not to review codes that have been on the CLFS for less than five years. AdvaMed does, however, have some other specific concerns regarding the overall proposal.

Throughout the discussion in the rule, CMS uses the terms “codes” and “tests” interchangeably. The agency proposes to undertake a review and evaluation of CLFS codes. CMS should be mindful, however, that multiple tests (produced by different manufacturers or by different laboratories) may be described by a single CPT code. The various tests, while testing for a specific condition or trait, may utilize different technological approaches that are not accounted for in CPT code descriptors, which generally describe only what is being measured by the test.

Therefore, CMS will have to review and assess multiple tests, some of which may only have been developed in recent years, even though the CPT code has existed on the CLFS for a much longer period of time. Any assessment of a given CPT code will have to address this issue, i.e., the array of individual tests assigned to a CPT code and the improvements in test characteristics over time (including improved sensitivity and specificity).

Any determination regarding the extent of technological change associated with a code must also consider the range of technologies used to perform the variety of tests that fall within the code. Moreover, savings associated with technological change should be considered only if the specific technology is widely adopted as common practice. Specifically, we would argue that a technological change that results in savings should be considered if it is used routinely (for example, more than 50 percent of the time).

For example, in the proposed rule, CMS describes point-of-care (POC) testing as a technological advance that reduces costs. We have significant concerns regarding this assertion as there is no empirical data demonstrating that the costs associated with POC tests are less than those associated with using a central lab. While POC testing has become more flexible due to the portable nature of the platforms utilized by these tests, and they may be easier to use in various formats (e.g., lower volume or single tests formats), the POC version of a test may not be routinely used and the costs are not necessarily lower. In fact, supply costs of POC testing may actually be higher in the laboratory setting, though labor costs may be lower than in other settings. Additionally, manufacturers invest significant resources in POC testing, including research and development, clinical trials, and regulatory compliance. Data should be gathered to measure the cost and resources of both POC and laboratory-based tests for comparison prior to concluding that one is less costly than the other. In general, we urge CMS to carefully consider both current and potential patterns of test use in evaluating the level of technological change.

**ii. Proposed Process**

The proposed rule provides insufficient detail regarding the proposed reconsideration process, other than noting that CMS will (1) identify test codes for which it believes payment should be adjusted due to technological changes, (2) discuss in a future proposed rule how that code has been impacted by technological changes, and (3) propose an associated adjustment to the payment amount “as appropriate” to reflect that impact. CMS would solicit comment on the technology used to perform any tests reviewed for potential payment changes, as well as any relevant cost information.

In order for the public to provide meaningful feedback regarding technological changes, and the associated costs of delivering test services, CMS must be open and transparent in sharing the detailed information the Agency has reviewed including all of the factors described in the proposed rule (changes in tools/machines, supplies, labor, instruments, skills, techniques and devices) and relevant cost data. In most circumstances, the costs of laboratory equipment and
materials, particularly machines and supplies, have increased as a result of technological change. Therefore, it is often the case that while laboratories have become more efficient, the increased costs of new machinery, supplies, instruments, etc., results in a scenario in which the overall cost to perform a test has not decreased over time and a payment adjustment is not warranted.

AdvaMed is deeply concerned that the proposed reconsideration methodology has not been fully fleshed out. CMS must be more explicit regarding its plans for sharing the information on which its decisions will be based. Given that this proposal involves a substantial change in CMS’ current procedures we request that CMS provide details of its intended approach before proceeding and that the agency consult with interested stakeholders. The agency should also execute its approach for gathering and using this data in a systematic and predictable way.

iii. Process – Personnel

The performance of reviews and assessments regarding technological changes and associated payment adjustments will require significant effort and advanced technical expertise. CMS should explain its capacity to handle the increased and highly specialized workload that this proposal would create. AdvaMed recommends that CMS form and utilize the services of an expert panel that can review technical, clinical, and quality information regarding the tests under review. We further recommend that the panel include individuals with experience and expertise with clinical/diagnostic laboratory tests, including individuals with expertise with the technical characteristics of the tests being reviewed, as well as the requirements to develop, validate and perform diagnostic tests.

iv. Payment Adjustments

The proposal describes potential criteria for determining technological changes, but does not provide any level of detail regarding how payment rate adjustments will be determined. CMS states only that the agency will propose a payment amount for reconsidered test codes “as appropriate.” The technical processes, equipment, and supplies used to generate the results for the different tests that are covered by a single CPT code vary. In the context of the Physician Fee Schedule, these changes are evaluated using survey data and a panel of clinicians that evaluate the overall value of technological and other changes in order to determine an appropriate value for the procedures. It is unclear from the proposal what mechanism CMS will use to determine the actual dollar impact attributable to technological changes for a particular CLFS code.

Payments for the majority of tests on the CLFS are based on cross-walks to comparable tests with technical, clinical, and economic similarities. In the proposal CMS does not make clear whether it intends to propose new cross-walks for a test/code that has experienced a meaningful technological change, or whether another methodology will be used (e.g., contractor pricing, gapfilling). AdvaMed believes it would be inappropriate to adjust the payment of every code that is cross-walked to a revalued code and that CMS should be required to individually evaluate each code on the CLFS.

We are further concerned by language in the proposed rule which states, “if, during the course of reviewing these individual codes, [CMS finds] that there are additional, newer codes that are clinically and/or technologically similar, we are proposing to consider them for review at the same time as we review the older codes because we expect we would have the same or
similar justifications for making payment adjustments to those codes." If CMS were to review additional codes, AdvaMed believes it is important to review and assess each of those codes individually, in order to avoid improper or incorrect payment adjustments.

Multiple factors and processes must be considered before CMS undertakes such a significant reevaluation of the CLFS codes. All interested stakeholders, including test manufacturers, must be given adequate opportunity to provide meaningful feedback on proposed determinations regarding the technological changes applicable to tests within a CPT code, and the associated potential payment rate adjustments. If CMS is fully transparent in providing the detailed inputs, formulae and justification for price adjustments, a 60-day comment period on a proposed rule may not provide adequate time for stakeholders to review and consider proposed changes for a large number of codes and tests.

Recommendations

Based on the above, AdvaMed makes the following recommendations:

- **CMS should not finalize this proposal as drafted. Instead, CMS should provide additional details of its intended approach before proceeding and consult with interested stakeholders. Further, CMS should enlist a panel of experts consisting of individuals who have expertise with clinical/diagnostic laboratory tests to review technical, clinical, and quality information regarding the tests that will be reviewed.**

- **CMS should hold a public meeting or other forum as part of this process to gather input from interested stakeholders with experience, expertise and knowledge regarding the clinical, scientific and technical aspects of the tests CMS intends to review.**

- **CMS should issue its proposals regarding the codes that will be reviewed and the methodology it plans to use in a manner that provides sufficient time for stakeholder interaction and comment, before proceeding to notice and comment rulemaking with its limited comment periods. For example, CMS could announce in year one the codes it intends to review and the methodology it plans to use and solicit feedback. In year two, CMS could publish its findings and proposed adjustments. This would allow stakeholders an opportunity to develop resource data on the relevant codes over a full year period and provide meaningful input regarding the proposed adjustments.**

At a minimum, CMS should publish the list of the codes it intends to consider well in advance of each proposed rule. Pre-rulemaking publication of such a list would provide a more reasonable time period for interested parties to undertake their evaluations of the codes that will be subject to review, and to respond to CMS in a thoughtful manner. CMS should also consider holding a public meeting to discuss the codes in question, or perhaps expand the annual CLFS public meeting to include such discussion.

- **Should CMS proceed with the re-evaluation process, the agency should phase in over a four-year period any new payment rates for codes whose payments decrease as a result of reconsideration. For example, the year one payment amount would equal a blend of 75 percent of the previous payment amount and 25 percent of the**
new payment amount; in year two, the payment amount would equal a blend of 50 percent of each of the previous payment amounts and the new payment amount; in year three, the payment amount would equal a blend of 25 percent of the previous payment amount and 75 percent of the new payment amount; the new payment would be fully implemented in year four. This approach would mitigate the financial impact of rate changes on all stakeholders, and would allow the Agency to track and refine its approach over this four-year period.

- Over the longer term, CMS should explore the development of new methodologies for measuring the effects of clinical diagnostic tests in the Medicare program, particularly where such tests provide measurable savings, for example, in Medicare Parts A, B and D. Many of the diagnostic tests on the CLFS enable prevention or early detection of disease, and enable beneficiaries to avoid unnecessary complications, surgery and hospitalizations. These tests may also be used to tailor or “personalize” treatment so that a beneficiary only receives treatments determined to be effective for his or her specific health condition or disease. In these and other ways, diagnostic tests are different from other Medicare expenditures and the value they deliver to the Medicare program as a whole must be better understood and documented.

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

i. Optimizing Patient Exposure to Ionizing Radiation Measures

In Table 29 and Table 54 of the proposed rule, CMS lists the proposed Optimizing Patient Exposure to Ionizing Radiation Measures Group for 2014 and beyond. This measures group represents a new clinical theme for eligible professionals to report and addresses a significant clinical gap. Namely, the measure set includes measures collecting data for standardized nomenclature, count of high dose radiation, reporting to a radiation dose index registry, availability of CT images for follow-up/comparison, and search of CT images through a secure, authorized, media-free, shared archive, and CT follow-up for incidental pulmonary nodules. This would represent a measures group that specialty Radiologists and other eligible professionals within this scope of practice could report.

AdvaMed strongly supports the Agency’s proposal to add the measures group titled “Optimizing Patient Exposure to Ionizing Radiation” and agrees that tracking radiation exposure is currently a clinical gap that must be addressed. Given the importance of tracking potential exposure, AdvaMed urges CMS to provide flexibility for measures group reporting to ensure that providers can collect and report this information with as little difficulty as possible. For example, AdvaMed suggests that CMS specify that providers may use a variety of technologies—for example, medical informatics technologies such as commercially available dose tracking software—to track and report these measures. Also, while AdvaMed fully supports these vital measures, we believe that it is important that the Optimizing Patient Exposure to Ionizing Radiation Measures Group is submitted by the measure steward (AMA-PCPI) for NQF-endorsement.

Additionally, AdvaMed wishes to comment on potential gaps remaining in the Physician Quality Reporting System (PQRS) related to radiation dose metrics. These are focused on the development of new measures needed to capture information on effective dose management
and operating protocols for imaging modalities with ionizing radiation. Specific gaps in the PQRS metrics and some potential suggestions for addressing these gaps are as follows:

- **Gap 1: Effective Dose Management Through Appropriate Usage** -- A crucial element of effective radiation dose management is the use of appropriateness criteria when ordering medical scans. Potential metrics may include: (1) a report on mean, median, and spread (standard deviation and interquartile range) for both the distribution of scanner output parameters (i.e. technique factors) and generally accepted dose metrics; and (2) a report on the dose indices and dosimetry parameters as a function of imaging protocol.

- **Gap 2: Establishment of Specified Operating Protocols Using Dose Indices and Dosimetry Reporting** -- This second gap addresses the need to establish metrics or frequency that promote the establishment of processes and methods to optimize imaging protocols. Potential metrics to fill this gap may include: (1) the number of protocols used in imaging modalities that have been approved by a protocol committee; (2) the number of exams conducted that result in scanner output values and dosimetry estimates that exceed site determined thresholds as determined by a protocol committee, etc.; (3) the establishment of a dose committee within the institution; and (4) the establishment of a quality system or procedure that formally and frequently reviews protocols and data to drive improvement.

### ii. Vascular Measures

AdvaMed supports the CMS proposal to include two outcome measures in PQRS for Vascular Surgical Eligible Professionals to report through the registry in 2014:

- **NQF #1540 “Rate of postoperative stroke or death in asymptomatic patients undergoing Carotid Endarterectomy (CEA)”**; and

- **NQF #1543 “Percent of postoperative stroke or death in asymptomatic patients undergoing Carotid Artery Stenting (CAS)”**.

AdvaMed recommends that CMS consider expanding registry reporting on these measures to other relevant physician specialties that provide care for patients undergoing CAS and/or CEA procedures, for example, the National Cardiovascular Data Registry for Carotid Artery Revascularization and Endarterectomy Procedures (NCDR-CARE registry; American College of Cardiology). AdvaMed also recommends that CMS consider expanding these measures beyond registry reporting so that other relevant physician specialties that provide care for patients undergoing CAS and/or CEA procedures can use these measures.

CMS has also proposed inclusion in PQRS of, “Rate of Major Complications (Discharged to Home by Post-Operative Day #2) Carotid Artery Stenting (CAS) for Asymptomatic patients without Major Complications (Discharged to Home by Post-Operative Day #2)”. While this provides another outcome measure for Vascular Surgeons, the measure is not NQF endorsed or supported for inclusion by the MAP. AdvaMed strongly urges CMS to work with the measure steward, the MAP and the NQF to refine this measure and to develop/consider alternate measures that can be supported by the MAP and meet the standards for NQF endorsement. AdvaMed also recommends that CMS consider working with relevant Vascular Surgery, Cardiovascular and Neurological Specialty societies to include a NQF-endorsed
measure in the future for percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.

iii. Qualified Clinical Data Registry Reporting Option

Section 601(b) of the American Taxpayer Relief Act (ATRA) of 2012 provides a new standard for individual eligible professionals to satisfy PQRS beginning in 2014, based on satisfactory participation in a qualified clinical data registry\(^8\) (which differs from the existing qualified registry reporting mechanism under PQRS in important ways). AdvaMed supports this provision of the ATRA. Allowing doctors to substitute participation in an approved registry for other quality-reporting requirements will encourage doctors and other providers to participate in registry data gathering. In addition, numerous medical specialty groups, providers and industry already utilize or plan to develop clinical-data registries; and the PQRS itself has evolved to offer multiple reporting mechanisms, including registries for purposes of reporting PQRS quality measures data. The number of eligible professionals that participate in PQRS via registry reporting has continued to increase over the past several years. This is especially important since eligible professionals using the registry-based reporting mechanism, historically have been more successful at meeting the criteria for satisfactory reporting of the PQRS data than through the claims-based reporting mechanism.

The CY 2014 PFS proposed rule includes CMS' proposals for implementing this provision. AdvaMed wishes to provide comments on the following specific issues:

a. Definition of Qualified Clinical Data Registry

CMS proposes to define a “qualified clinical data registry” for purposes of the PQRS as a CMS-approved entity (such as a registry, certification board, collaborative, etc.) that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patients. AdvaMed agrees with the approach proposed by CMS to move gradually and slowly in designating any qualified clinical registries that would serve as a substitute for reporting of quality measures for CMS national programs. Additional factors that CMS should consider in designating registries as qualified under Section 601(b) should include, but not be limited to: sponsorship by national medical board registries or specialty society registries, or by not-for-profit entities that are committed to serving the health and well-being of the public, or by independent entities with device industry participation. In addition to sponsorship, CMS should consider the purpose of registries to be designated as qualified. Such registries should have as their focus the collection of national data on specific health care conditions and health care outcomes and assist in the development of quality measures that will improve health outcomes. As the goal should be to provide extensive national data, state registries — which would be extremely restricted in the extent of the data being captured — should be precluded from being designated as qualified entities.

b. Requirements to Ensure High Quality Data

Ensuring the capture of high quality accurate data is essential to the success of reporting clinical quality data via registries. Registries must comply with all research ethics, applicable laws and regulatory requirements including those governing data privacy and informed

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\(^8\) A “qualified clinical data registry” as established by the Secretary must provide mechanisms for transparency of data, risk models, and measures; requires submission of data with respect to multiple payers; provides timely performance reports to participants at the individual level; and supports quality improvement initiatives.
 consenting. It is essential that patient privacy be protected by this process which includes linking of databases.

All confidential manufacturer, physician, and hospital data must be safeguarded. To this end, beyond the suggested requirements to ensure high quality data by CMS specified in the proposed rule, AdvaMed recommends that each entity have a “data governance committee” that is responsible for all details concerning data submission, validation of data and data integrity and security. In addition, CMS should encourage standardization of data elements and definitions for the registries by providing a framework of certain elements to be included, leaving some of the more disease-specific detailed data elements up to the individual registries. CMS can also review the criteria of their registry qualification process on a periodic basis to account for changes, recommendations and future feedback. These recommendations will help to ensure that that registries and electronic health records can function in harmony.

AdvaMed believes that it is important to have standards and transparency in terms of methodology for data statistical analysis and reporting. Furthermore the follow-up compliance rate and completeness should be taken into consideration to produce meaningful reports. AdvaMed also recommends that all qualified clinical data registries, which collect data on the same clinical procedures, use the same risk-adjustment model to the maximum extent practicable, but still allow eligible registries to employ varying risk-adjustment methods to glean the most meaningful data from the registry. Also, AdvaMed believes that entities need to ensure that the risk-adjustment of registry data is appropriate and validated prior to public reporting.

c. Disqualification of Clinical Data Registry

CMS proposes that should the agency find, pursuant to an audit, that a qualified clinical data registry has submitted inaccurate data, it proposes to disqualify the clinical data registry. Regarding the CMS disqualification process, AdvaMed believes that it is important for registries to submit correct data once it is qualified to submit data on behalf of its eligible professionals. However, we do not believe that immediate disqualification is always warranted if an error occurs. AdvaMed believes that developing a Quality Control (QC) and Quality Assurance (QA) process may be more productive than simply disqualifying registries. It is important that CMS recognize that registries are dependent on the data they receive from eligible professionals. In cases where a registry has submitted inaccurate data, CMS should allow the registry an opportunity to correct their mistakes and rectify any processes leading to data submission errors. In addition, alternative processes such as placing a registry on probationary status may be useful for CMS to consider. AdvaMed recommends that CMS consider carefully the negative consequences of disqualifying a previously qualified registry and use this authority with caution.

d. Oversight

CMS also proposes to require a signed, written attestation statement be sent via e-mail stating that the quality measure results and any and all data provided to CMS are accurate and complete. It is our understanding that currently CMS requires only an attestation in lieu of requiring auditing of data. AdvaMed recommends that each entity submitting data institute a detailed auditing process as part of their standard operating procedures and these auditing processes be consistent across entities. Additionally, if eligible physicians find errors as a
result of auditing, they should have the opportunity to correct these errors. Entities should consider employing a review process prior to final publication consisting of input provided by statisticians and methodologists to be reviewed by a committee of EPs for face validity or commentary prior to distribution of reports. This type of mechanism may help hasten the acceptance and subsequent positive practice changes by EPs.

e. NQF Endorsement and Measurement of Outcomes

In February 2013, CMS issued a “Request for Information (RFI) on the Use of Clinical Quality Measures Reported Under the Physician Quality Reporting System (PQRS), the Electronic Health Record (HER) Incentive Programs and Other Reporting Programs”9 In the RFI, CMIO posed a number of questions, including one specifically regarding using NQF- endorsed measures and outcome-based measures for these registries. The proposed rule, however, does not appear to address that question in the context of the qualified clinical registry option or more generally for registries discussed in the RFI. AdvaMed encourages the use of NQF-endorsed quality measures. NQF has long recognized that measurement and reporting are key to improving health and health care. The NQF endorsement process provides for rigorous vetting of submitted measures that examine in detail the following measure considerations: (1) impact of the measure including addressing disparities and gaps that the measure addresses; (2) the quality, quantity and consistency of the evidence supporting the development of the measure; (3) reliability and validity testing of the measure; and (4) feasibility and usability of implementing measures and subsequent reporting with considerations of unintended consequences.

Currently, long-term clinical outcomes are often not captured with NQF-endorsed measures. Both process and outcomes measures are important, but outcome measures capture the consequence of treatment protocols and are crucial to medical decision making. Qualified registries should have the objective/goal of collecting data that can be used for developing appropriate outcome measures. Tracking quality improvement over time and understanding the appropriate length of an episode of care are essential in providing accurate information for patients and providers. To date, most quality measures are “process” measures, rather than “outcomes” measures. They are necessary, but not sufficient in many cases to capture the full benefits of advances in medical technologies. For patients who receive the benefits of an advanced medical technology, a higher quality outcome may be realized over a multi-year period. For example, an implantable device that needs to be replaced or adjusted every 10 years — rather than every 5 years — would provide higher quality for the patient, but would not be captured by existing quality measures. Quality organizations such as the NQF, PCPI and others are quickly moving to emphasize the importance of including quality outcome measures in their portfolios for all medical specialties.

f. Transparency

AdvaMed is pleased that CMS raises various aspects of public reporting and access to data in the context of clinical data registries. We nevertheless have concerns regarding yet undefined policies in relation to public reporting and access to these data. AdvaMed believes that transparency initiatives should strive to provide consumers and other purchasers of health services with tools to make informed decisions. However, it should be understood that transparency is not an end in itself, but a mechanism to achieve specific goals that will require different tools for different health sectors, processes, and transactions. While the information

9 78 Fed. Reg. at 9057-60.
contained in publicly reported clinical data registries may convey a substantial amount of clinical information that may be useful to consumers, providers and others, it is likely that this information will need to be further scrutinized in its proper context. For example, in the instance regarding the use of a medical device in a patient, even clinical risk-adjusted data will not likely capture critical information such as the skill of the surgeon/operator, patient co-morbidities or types and quality of ancillary nursing or physical therapy care. Patient outcomes — regardless of the quality of the device utilized and how well that device performs — are all too dependent upon these additional factors, which may not be acquired by these registries. The unintended consequences would be that the quality of devices and medical technologies used in patient care — and the resulting associated patient outcomes — may potentially be inaccurately portrayed by those interpreting the data reported in these registries.

- **AdvaMed strongly recommends that each approved entity provide a disclaimer notice on each publicly reported data registry document which clarifies that the information contained in the registry should be viewed in the context of the individual patient/hospital setting and the care that they received.**

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

In CY 2012, CMS disseminated both group and individual Quality Resource and Use Reports (QRURs), based on CY 2011 performance. In May 2013, CMS provided supplemental QRURs to the group report recipients that featured episode-based costs for care of pneumonia and several acute and chronic conditions. The proposed rule summarizes the findings from both the physician group and individual feedback reports. CMS plans to disseminate QRURs based on CY 2013 data to all physicians in late summer of 2014. These reports will contain performance on the quality and cost measures used to score the composites of the value-based payment modifier.

The per episode method measures the resource use associated with treating the specific episode of an illness in a beneficiary (e.g., acute pneumonia or acute myocardial infarction). 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. CMS derived per episode-based costs using the newly developed CMS Episode Grouper software — that uses 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.*

Beginning with the CY 2016 payment modifier, CMS proposes to expand the cost composite to include an additional measure, the Medicare Spending per Beneficiary (MSPB). CMS plans to base the MSPB measure used in the value-based payment modifier on the MSPB measure used for hospitals. CMS notes that on January 31, 2013 they submitted the MSPB measure and the total per capita cost for all attributed beneficiaries measure to the NQF for endorsement.

- *AdvaMed urges CMS to withdraw the proposed Medicare Spending per Beneficiary measure from the value-based payment modifier cost composite until such time that it is reviewed and endorsed by NQF for use in this context.*

As noted earlier, the NQF endorsement process provides for rigorous vetting of submitted measures that examine in detail the following measure considerations: (1) impact of the measure including addressing disparities and gaps that the measure addresses; (2) the quality, quantity and consistency of the evidence supporting the development of the measure; (3) reliability and validity testing of the measure; and (4) feasibility and usability of implementing measures and subsequent reporting with considerations of unintended consequences.

The proposed resource use measure conveys information about estimated costs of treatment and is 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. AdvaMed is also concerned that application of such a cost measure 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.

- *AdvaMed encourages CMS to develop more appropriate efficiency measures that consider the costs in conjunction with quality across varied episodes of care.*

Additionally, AdvaMed recognizes the importance of considering risk adjustment factors in the development and implementation of the proposed MSPB measure. However, we have concerns regarding the risk-adjustment methodologies for this measure. Risk adjustment is a key element that must be valid, reproducible, sensitive and specific. Any flaws that may be
present in the risk-adjustment methodology can potentially lead to flawed conclusions and therefore, compromise the validity of the resultant conclusions.

Thus it is important to consider as many relevant variables as possible in developing these models. Age, sex, race, severity of illness and clinical covariates, socioeconomic status, other concurrent treatments/interventions and their associated intensity/complexity and sources of co-morbidity should be considered factors in risk adjustors. The potential patient-specific side effects and adverse reactions associated with the different therapies and interventions may also need to be considered. Notably absent from many discussions on determination of risk stratification factors are individual patient measures such as nutritional status — including malnutrition — and functional status, including the ability to ambulate and measurements of range of motion. AdvaMed strongly believes that these patient-specific factors should be included in the risk stratification for these measures, as they vary from patient to patient and can play a very significant role in contributing to outcome measurements, potential readmissions and estimated costs, especially in the post-surgical setting.

**Conclusion**

AdvaMed appreciates the opportunity to submit comments on the proposed CY 2014 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 further assist you.

Sincerely,

Richard J. Price
Senior Vice President
Payment and Health Care Delivery Policy

Enclosures