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August 28, 2014

Marilyn B. Tavenner, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1612-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY2015; Proposed Rule (CMS-1612-P)

Dear Ms. Tavenner:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the Proposed CY 2015 Physician Fee Schedule Rule. AdvaMed will separately submit comments regarding proposed changes to the Open Payment provisions (Reports of Payments or Other Transfers of Value to Covered Recipients) included in the rule.

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 other proposals and welcome the opportunity to provide several recommendations. We will comment on the following issues raised in the proposed 2015 PFS rule:

- I. Provisions of the Proposed Rule for PFS
 - A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs) – Using OPPS and ASC Rates in Developing PE RVUs
 - B. Potentially Misvalued Services Under the Physician Fee Schedule
 - C. Chronic Care Management

- II. Other Provisions of the Proposed Regulations
 - A. Local Coverage Termination process for Clinical Diagnostic Laboratory Tests
 - B. Physician Payment, Efficiency, and Quality Improvements– Physician Quality Reporting System
 - C. Medicare Shared Savings Programs

I. Provisions of the Proposed Rule for PFS

A. Resource-Based Practice Expense (PE) Relative Value Units (RVUs)- Using OPPS and ASC Rates in Developing PE RVUs

CMS continues to explore to the possibility of equalizing payments across care settings in the CY 2015 proposed rule. While the agency does not make any formal recommendations related to achieving site neutral payment it does ask for stakeholder feedback related to this issue. Specifically, CMS is seeking input on the use of hospital OPPS cost data in setting physician fee schedule practice expense (PE) RVUs.

AdvaMed continues to have concerns related to the use of hospital cost data to set prices in the physician office. The methods used to procure and price supplies and equipment used in the hospital outpatient setting varies significantly from those used in the physician office setting. This is generally related to the volume of supplies and equipment purchased at the physician office level, as compared to the hospital outpatient department, and physicians' inability to negotiate the same level and type of discounts as hospitals. There is no consistent method for collecting and reporting charge data from one hospital to the next. Additionally, supply and equipment cost data may not be accurately captured in hospital cost reports. Consequently, hospital charge data is no more reliable than data procured from physicians.

Ideally, PFS rates should cover the cost of the supplies and equipment required for a procedure. Documenting all of the supplies needed for a procedure is critical in determining appropriate valuation. The issue of educating hospitals on the need to accurately document all of the supplies associated with a given service or procedure has been raised many times in AdvaMed comments on the OPPS rule and continues to be an issue of critical importance. There continue to be reporting inconsistencies in cost report supply and equipment categories between hospitals. A focused education effort related to coding and reporting accuracy regarding supply and equipment use is also needed.

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. AdvaMed has had ongoing concerns that all of the codes associated with procedures are not appropriately

reported on hospital outpatient department claims and, consequently, that the supply and equipment costs associated with these codes may not be accurately reflected in hospital cost report data.

In addition to our concerns related to accurate reporting of codes and cost data, there is a lingering issue regarding a lag in the available OPDS data. The cost report data available to CMS is typically two years old meaning that, in the case of updating PE inputs, this older data would be used in lieu of more current data obtained directly from physician practices or specialty societies through the RUC and other processes. Under the PFS, payments are calculated for each service or procedure. The concerns described by CMS regarding the process for determining PFS rates do not account for systematic RUC review and re-evaluation of the practice expense inputs for physician office-based codes. 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.

CMS's proposal to use data derived from OPDS cost reports to limit equipment and supply payments for PFS procedures does not appear to adequately address the problem the agency is attempting to resolve. CMS should more thoroughly evaluate the impacts of this type of change prior to pursuing or finalizing any such policy to ensure it is not inadvertently harming patient care through potential payment cuts which could compromise beneficiary access to services and procedures in the physician office setting.

Though AdvaMed continues to have concerns regarding the various site neutral payment proposals that are under development, we would like to express our support of CMS's decision to not use APC payment amounts to determine PFS PE inputs. We are aware of the efforts by MedPAC, included in its June 2013 report to Congress, to do this. In that report MedPAC identified five criteria that could be used to determine if outpatient APC costs could be equalized to those for a PFS procedure. In the same report MedPAC identified several APCs that allegedly met their criteria and included a method for adjusting the OPDS payment rate so that it would be equal with freestanding/physician offices.

AdvaMed noted several issues when attempting to replicate the MedPAC methodology – including the inclusion of several APCs in the final analysis that do not satisfy the MedPAC established criteria. In light of this, we strongly encourage CMS to be cautious in evaluating any methodology that involves adjusting APC payment rates to those for physician office procedures to establish site neutral payment. We further recommend that CMS not use the methodology included in the June 2013 MedPAC report to Congress.

B. Potentially Misvalued Services Under the Physician Fee Schedule – Payment for Ocular Screening

AdvaMed recommends that the status indicator for CPT 99174 (instrument-based ocular screening) be changed from “*N – Not Covered*” to “*C – Carrier priced*.” Status indicator C is frequently used for codes when it is inappropriate to assign a payment rate in the physician fee

schedule. CPT code 99174 is not eligible for physician fee schedule payment, and is suitable for carrier pricing, because it is a pediatric service that is almost never billed to Medicare and is also a statutorily non-covered screening. Despite this, in 2014 CMS reviewed the PE values associated with this code.

AdvaMed understands that, as a general policy, CMS does not review RVUs for codes that are not covered and paid under the Medicare program. In light of this, we were troubled by CMS's decision to sharply reduce the Practice Expense (PE) RVUs for CPT 99174 in calendar year 2014. AdvaMed contends that:

- Any revaluation of Medicare non-covered services runs counter to CMS's stated aim of only devoting resources to review of covered services **and**
- Any adverse revaluations of non-covered services without a clear mechanism for stakeholder input is at odds with the rulemaking process, which seeks to be responsive to the concerns of the public.

We further contend that the issues related to payment for CPT code 99174 are best addressed through modifying the status indicator associated with the code.

- **In lieu of further reviewing RVU values for CPT 99174, AdvaMed recommends that CMS assign status indicator C to the procedure.**

C. Valuing New, Revised and Potentially Misvalued Codes

The Proposed Changes

The proposed rule contains a lengthy discussion about the process for establishing values for potentially misvalued, new, and revised CPT codes. The proposal included in this year's rule represents an effort on the part of CMS to provide an opportunity for stakeholders to comment on the proposed values for potentially misvalued, new, and revised codes prior to their being published as part of a fee schedule. While AdvaMed appreciates CMS's willingness to provide an opportunity for stakeholder feedback prior to finalization of these rates, we are very concerned with the additional delays related to use of new and revised code values and descriptor language that would be created by the proposed changes.

The proposal would require CMS to include proposed values for all potentially misvalued, new, and revised code values in the proposed rule if they receive complete RUC recommendations by January 15th of the preceding year. This same proposal would delay revaluing of codes for which data are not received by the January deadline for one additional year. In these instances stakeholders would be provided an opportunity to comment on proposed values for potentially misvalued, new, and revised codes following publication of values in the final rule. In exchange for this comment opportunity, CMS would delay use of updated code values for potentially misvalued and revised codes for one year while they evaluate stakeholder comments.

In the case of revised codes, with proposed value changes, CMS would create G-codes to

describe the predecessor to these codes and would use the values associated with those predecessor codes to price the code for an additional year. This proposed change also would delay use of revised code descriptor language. Similarly, potentially misvalued codes would continue to have the same data values applied for an additional year pending CMS review of stakeholder comments. In the case of newly developed codes CMS would work with the RUC to include value recommendations in the proposed rule. However, if this were not possible CMS would establish values for the code during its initial year.

Historic Process Concerns

Historically, CMS has published the interim final RVU values for potentially misvalued, new, and revised codes in the final rule – leaving stakeholders unable to modify them for at least one year. In response to this, stakeholders have requested that CMS publish the proposed relative values for these codes in the proposed PFS or OPFS rules. Publication of these data in the proposed rules would provide an opportunity for stakeholder input prior to finalization of the data for the upcoming year.

AdvaMed's members historically have had significant concerns regarding the ability of stakeholders to comment on the proposed values for new and revised CPT codes prior to publication of the final rule. Having an opportunity to do so is imperative in ensuring that the most accurate payment rate is set and available when a new or revised code is initially introduced. Our members also place a high priority on improving the speed with which they are able to access and use new codes and code values. Consequently, we are greatly concerned by any proposal that would add additional time to the, already lengthy, process for obtaining new and revised codes.

While AdvaMed understands CMS's concerns regarding the ability to get value data in a timely manner, we encourage CMS to continue working with the American Medical Association (AMA), stakeholders, and others to develop a process that provides an opportunity for publication of and comment on new values during the proposed rulemaking comment cycle whenever possible. Publication of the new values with release of the proposed rule provides the best opportunity for stakeholder feedback in a way that does not create potentially harmful delays in release and use of new and revised code values for services and procedures that benefit Medicare beneficiaries.

Alternative Recommendations

It is our understanding that the American Medical Association (AMA) provided CMS with recommendations in June of this year (see attachment) regarding ways to ensure the transmission of value data for new codes in time for publication in the proposed rule. AdvaMed is generally supportive of the AMA's recommended approach for getting data to CMS in a timely enough manner to facilitate inclusion of proposed values in the proposed rule. We fully support the AMA's recommendation to develop a data transmission schedule that coincides with the CPT and RUC meetings and which allows CMS to receive valuation data in a consistent manner that allows publication of proposed rates and temporary code descriptors in the proposed rule. We believe that the AMA's approach addresses many of the concerns that our members have traditionally had regarding their ability to comment on proposed values.

AdvaMed does not, however, support the AMA's recommendation to have the CPT Editorial Panel and the RUC limit their review of certain types of codes (especially high volume services) deliberated during the February and April CPT and RUC meeting cycles. This change would prevent all of the code change applications deliberated during the February CPT Editorial Panel meeting from being considered for inclusion in proposed rulemaking – subjecting an unknown number of proposals to an additional 23-month delay. This level of additional delay would create too much uncertainty for stakeholders and providers regarding the anticipated availability of new and/or revised codes and would unnecessarily complicate the timetable and process for obtaining codes. In lieu of this, AdvaMed instead recommends that the AMA work with stakeholders and CMS to ensure that valuation data generated for potentially misvalued, new, and revised code requests considered during the May, October, **and** February CPT Editorial Panel meetings can be transmitted to CMS in time for inclusion in the proposed rule. AdvaMed strongly encourages CMS to reconsider the proposal submitted by the AMA, bearing in mind our recommendation regarding code proposals deliberated during the February and April CPT and RUC meetings.

CMS Proposals

While AdvaMed is generally supportive of the AMA recommendations, we also wanted to provide feedback on the CMS proposals included in the rule. We believe that CMS's proposal regarding revised code descriptors that do not impact value can work effectively. We do however, have concerns that the proposals related to potentially misvalued codes, revised codes, and wholly new services may create problems for our members. It is less than ideal to wait an additional year after going through the CPT and RUC processes to update the values for a revised or misvalued code. AdvaMed strongly encourages CMS to consider other alternatives which provide the option to include value data in the proposed rules and which do not create additional delay in accessing new and revised code value data and descriptors.

We also are concerned that the process of assigning G-codes for codes that would essentially be treated and reimbursed at the same level as the previous/unrevised codes will not add much value to the process and will be confusing for payers and others. AdvaMed strongly advises against the creation of G-codes in this situation. Lastly, AdvaMed ask CMS to clarify the process that the agency would use to assign values to newly created codes for the first year. In those instances, we recommend that the agency consider the input of affected stakeholders before finalizing values for any new codes. We further recommend that CMS consider applying this same approach to all potentially misvalued and revised codes for which they lack RUC recommended values in advance of publication of the proposed rule in lieu of using inaccurate value data for an additional year.

AdvaMed Recommendations

AdvaMed and its members strongly support approaches that provide an opportunity for inclusion of the proposed values for new and revised CPT codes in the proposed rule and that allow stakeholder comment prior to finalization of these rates. Adopting these types of approaches will ensure inclusion of more accurate rates in the final rule. We further support approaches, such as those advanced by the AMA, that allow for receipt of the proposed value data in time for publication in the proposed rule. In the event that the AMA is unable to provide valuation data for potentially misvalued, new, and revised codes in time for publication of the proposed rule,

AdvaMed encourages CMS to work with stakeholders to establish appropriate valuation for the first year.

AdvaMed strongly encourages CMS to consider options for gathering and disseminating value data in ways which do not result in additional delays and that provide an opportunity for stakeholder comment prior to release of the final rule. We are confident that this can be done in a way that allows comments to be collected in conjunction with publication of the proposed rules and encourage CMS to continue to work on this effort with a CY 2016 implementation timeline in mind.

D. Chronic Care Management

CMS Should Clearly Articulate Definite Standards Regarding the Required Use of Electronic Health Information Technology (Health IT) In Furnishing CCM.

Few providers have the present capacity to provide Chronic Care Management (CCM). A provider that commits to furnishing this service most likely will need to secure new staff or assign new duties to existing staff. New processes will have to be developed and implemented to identify those patients eligible for CCM, secure patient consent to receive the services, and deliver the range of services encompassed by CCM. Providers will need to develop new or enhanced working relationships with other providers and community organizations. Also, given CMS's requirements for use of Health IT in furnishing CCM, providers will have to secure new technology or retrofit existing resources to meet these requirements. These and other changes to provide and correctly bill for CCM services will require significant upfront cost.

CMS understand providers will be reluctant to make these investments if questions remain regarding exactly what is required to bill for CCM. Any ambiguity in the final rule will result in fewer providers willing to commit to CCM and, in turn, fewer beneficiaries receiving these critical services.

CMS's definition of Health IT requirements in the proposed rule leaves much room for interpretation. CMS initially characterizes these requirements as follows:

CCM services must be furnished with the use of an electronic health record or other health IT or health information exchange platform that includes an electronic care plan that is accessible to all providers within the practice, including being accessible to those who are furnishing care outside the normal business hours, and that is available to be shared electronically with the care team members outside of the practice.

CMS then goes on to identify specific Health IT certification standards that must be satisfied:

To ensure all practices have adequate capabilities to meet electronic health record requirements, the practitioner must utilize EHR technology certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-

applicable version of 45 CFR part 170. At a minimum, the practice must utilize EHR technology that meets the certification criteria adopted at 45 CFR 170.314(a)(3), 170.314(a)(4), 170.314(a)(5), 170.314(a)(6), 170.314(a)(7) and 170.314(e)(2) pertaining to the capture of demographics, problem lists, medications, and other key elements related to the ultimate creation of an electronic summary care record.

These two paragraphs appear to reflect two separate Health IT requirements – one with regard to an electronic care plan and the other concerning an electronic summary care plan. If the former interpretation reflects CMS’s intent, the agency should identify objective criteria to evaluate whether a particular Health IT product has adequate capabilities to meet this requirement. If it is the latter, CMS should clarify this language in the final rule, by indicating that CCM must be furnished using a Health IT product that has been certified as meeting certain criteria. With regard to those criteria, CMS should consider an alternative to the specific regulatory provisions cited in the proposed rule (i.e. Summary Record Exchange (SRE) capability tag).

CMS Should Revise Its CCM Eligibility Requirements by Eliminating the Reference to the Acuity Level of the Beneficiary’s Chronic Conditions

CMS’s proposed CCM eligibility requirements limit the availability of the service to those Medicare beneficiaries with two or more chronic conditions which “place the patient at significant risk of death, exacerbation/decompensation or functional decline.” To determine whether a beneficiary qualifies for CCM, a practitioner must make a subjective determination regarding the acuity level of the beneficiary’s chronic conditions.

CMS has not suggested any criteria – nor do any objective criteria exist – by which to categorize an individual’s chronic condition as a significant risk versus a moderate or low risk of death, exacerbation/decompensation or functional decline. Absent such criteria and the associated risk of providing services for a beneficiary who later may be deemed ineligible by an administrative contractor, an auditor, or an investigator, practitioners will be reluctant to make the necessary investments to provide CCM for their patients.

Additionally, imposing this risk requirement goes against the very reason CMS now proposes to pay for CCM. For many chronic conditions, the significant risk to the beneficiary’s health is associated with not properly managing the condition. Therefore, by receiving care management, and thus reducing the risk associated with the chronic condition, a beneficiary would become ineligible for future care management services. While AdvaMed does not believe that this was CMS’s intent yet it is the ultimate result of imposing the risk requirement.

We recommend that CMS adopt eligibility criteria similar to the criteria for the Medicaid health home benefit. Section 2703 of The Affordable Care Act created an optional Medicaid State Plan benefit for states to establish health homes to coordinate care for Medicaid beneficiaries with chronic conditions.

Specifically, the statutory language provides that health home services may be made available to Medicaid beneficiaries who (1) have two or more chronic conditions; (2) have one chronic condition and are at risk for a second; or (3) have one serious and persistent mental health condition. Section 2703 lists specific qualifying chronic conditions and vests the Secretary with

the authority to expand the list as he or she determines appropriate.

Similarly, CMS should define eligibility for CCM based on a beneficiary's diagnosis with specific chronic conditions as opposed to a subjective determination of the level of risk associated with a condition.

CMS Should Revise Its Regulations Defining Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Services to Include CCM

The proposed rule for CCM does not include a face-to-face encounter as a required element of the service. Under 42 CFR 405.2462, CMS only pays an RHC or FQHC under its all-inclusive rate for beneficiary visits for covered services. A "visit" is defined by 42 CFR 405.2463 as a face-to-face encounter. Thus, CCM would not qualify as a service for which CMS would reimburse an RHC or FQHC at its applicable all-inclusive rate.

The statutory definition of RHC and FQHC services found at 42 USC 1395(x)(aa)(1) and (3) does not impose any face-to-face requirement. Instead, the statutory language only requires RHC and FQHC services to be "furnished to an individual as an outpatient of" the RHC or FQHC. CMS, therefore, has the authority to expand the regulatory definition of RHC and FQHC services to include CCM, despite the fact this service does not necessarily involve a face-to-face encounter with the beneficiary.

Because RHCs and FQHCs serve as primary care providers for patient populations with a high percentage of beneficiaries eligible for CCM, CMS should encourage and enable these providers to develop necessary capabilities to provide CCM.

Alternatively, CMS should clarify that CCM furnished by an RHC or FQHC constitutes a non-RHC or non-FQHC service for which the RHC or FQHC may bill separately. CMS should also permit CCM and TCM furnished by an RHC or FQHC to be furnished "incident to" under general supervision.

CMS Should Provide a Model Agreement for Beneficiaries to Consent to the Provision of CCM

In a number of instances, HHS has provided forms or model agreements to assist health care providers in complying with complex regulatory requirements. These forms and model agreements facilitate compliance with regulatory requirements, which in turn helps to assure that beneficiaries receive the information and services that the applicable regulations are intended to facilitate. The forms and model agreements also reduce the cost of compliance for health care providers, allowing scarce resources to be used for care rather than expended on administrative overhead.

We propose that CMS publish a model agreement for beneficiaries to consent to the provision of CCM. This model agreement would assure that beneficiaries are notified of: the availability of CCM; the beneficiary's rights with respect to CCM; and the practitioner's obligations associated with such services.

CMS Should Establish an Additional Separate Code for CCM Incorporating Electronic Remote Patient Monitoring to Which a Higher Practice Expense RVU Is Assigned

The real-time information and response achieved with electronic remote patient monitoring enables early identification of changes in a patient's condition and early intervention to address the change before it develops into an acute episode. CMS should encourage providers to use electronic remote patient monitoring by establishing a separate code for "CMM with electronic remote patient monitoring" that compensates providers for the added practice expense associated with acquiring, maintaining, and upgrading the technology for electronic remote patient monitoring and installing and educating the patient and caregivers regarding the use of the technology.

II. Other Provisions of the Proposed Regulations

A. Local Coverage Termination process for Clinical Diagnostic Laboratory Tests

CMS proposes to revise the Medicare Local Coverage Determination (LCD) process when used for clinical diagnostic laboratory tests. Citing section 216 of the "Protecting Access to Medicare Act of 2014" (PAMA) and the desire to expedite and streamline the process and address certain limitations within the existing LCD process, CMS proposes a revised process that would apply only to clinical diagnostic laboratory tests, including molecular diagnostic tests. In its proposal, CMS also encourages the Medicare Administrative Contractors (MACs) to collaborate across jurisdictions on policies contained in LCDs.

AdvaMed supports the local coverage process because it provides flexibility to respond to local and patient-specific circumstances that can result in more timely beneficiary access to state-of-the-art medical care. Local contractor medical directors can respond to individual patient needs by developing formal policies (LCDs) or by making claim-by-claim determinations with respect to a particular technology or medical procedure, without relying on or waiting for a national coverage decision, with its associated processes and time constraints. Since the enactment of Medicare, this feature of the program has served beneficiaries well.

In response to this proposed regulation, AdvaMed commends CMS for considering ways to streamline the local decision-making process to allow for more timely local coverage decisions for clinical diagnostic laboratory tests. However, we have several suggestions for improving the proposal, as discussed in more detail below.

Notification of the Draft LCD and Proposed 30-Day Comment Period

CMS proposes to post draft LCDs in the Medicare Coverage Database, thereby making them "publicly available." Stakeholders would then have 30 calendar days to comment on a draft LCD.

AdvaMed is not convinced that this action provides the necessary transparency and notice needed to generate a robust comment period. In fact, navigating the Coverage Database, as

currently organized, presents difficulties that need to be addressed if CMS's intent is to use the posting process as the initiation of a public comment period. In addition, the coverage matters that arise for public discussion in LCDs are often quite technical. We believe that a 30-day comment period is too short a time for stakeholders to review a comment solicitation/draft coverage policy and generate the data and evidence necessary to inform a substantive public comment.

To make this aspect of the revised process useful for stakeholders, AdvaMed recommends that CMS revise the Medicare Coverage Database in order to make the search function more user-friendly with respect to finding new information that is posted to the site. Specifically, we recommend including a method for searching by date of publication so that database users can determine when new draft LCDs are published (e.g., in the last week, or in the last month). At the present time, the search engine is adequate for locating draft LCDs *by keyword or by relevant HCPCS codes, but not by date*, making it difficult to locate newly published LCDs, particularly when covering multiple jurisdictions. Often, stakeholders learn about the existence of a proposed LCD days or even weeks after it has been posted, leaving less than adequate time to respond.

In addition, we recommend that CMS provide stakeholders with notification regarding newly published LCDs (or for given topic areas) via email, similar to how CMS sends Coverage Update emails when National Coverage Determinations (NCDs) and other updates are posted to the Medicare Coverage web pages. Interested parties could sign up to receive timely updates directing them to the new information.

Timely notification of these developments is particularly important, given the proposal to reduce the opportunities to meet directly in open meetings, and the proposed reduction in the timeframe for commenting on a draft LCD from 45 to 30 days. We are especially concerned that a 30-day time frame is insufficient time to identify a solicitation for comments and prepare a response. We recommend retaining the current 45-day comment period because providing input on draft coverage policies requires a clinical and technical review, gathering and analysis of data, review of the evidence, and obtaining the input of clinical and scientific experts. Securing timely input on a proposed LCD can be challenging. Reducing the comment period will increase this challenge and may interfere with the ability of stakeholders to provide well-informed and thoughtful comments to the contractor.

- **CMS should improve the transparency of the LCD process by improving the search capability of the Medicare Coverage Database and by providing notification to stakeholders via email updates when new draft LCDs are published in the Medicare Coverage Database, similar to the notification process for NCDs.**
- **CMS should retain the current 45-day comment period on draft LCDs.**

Carrier Advisory Committee (CAC) Meetings

CMS proposes to give MACs the discretion to determine whether a Carrier Advisory Committee (CAC) meeting should be held in relation to a proposed LCD. CMS proposes that a MAC may involve the CAC if the MAC determines that a CAC meeting would contribute to the quality of the final policy; and CMS further proposes that the public comment period should be extended

when the CAC is involved, to allow for the meeting to be held before the final policy is issued.

AdvaMed agrees that a CAC meeting may not be required for every draft LCD, and that contractor discretion with respect to convening a CAC may be appropriate in cases where proposed policies are expected to expand or add new coverage. We recommend that MACs be *required* to convene a CAC meeting in cases where the MAC is proposing to limit coverage of, or to non-cover, a diagnostic test.

AdvaMed also recommends that CMS consider opening CAC meetings to public view via webinar or teleconference, to provide greater opportunity for stakeholder participation. AdvaMed also believes that CMS should encourage MACs to make use of webinars and teleconferences to gather stakeholder views on coverage matters that may be controversial, particularly if open public meetings are no longer required.

We agree that the public comment period should be extended when CAC meetings are convened, in order to allow interested stakeholders the opportunity to participate and still have time to develop appropriate comments.

- **CMS should require MACs to convene a CAC meeting in cases where the MAC is proposing to limit coverage of, or to non-cover, a diagnostic test.**
- **CMS should consider opening CAC meetings to public view via webinar or teleconference, to provide greater opportunity for stakeholder participation.**
- **CMS should provide an extended comment period when CAC meetings are convened.**

Open Public Meetings

CMS proposes to eliminate the need for open, public meetings to discuss draft LCDs as part of the proposed new local coverage determination process for clinical diagnostic laboratory testing.

AdvaMed is sensitive to the lessons that CMS has drawn from its experience in national coverage decision-making as it considers ways to adjust the local process. While we agree with CMS that robust public comment can take place through public postings and informed stakeholder submissions, we also recognize that the elimination of required open meetings to discuss LCDs could mean that stakeholders may not be permitted to exchange views face-to-face with Medicare contractors who will make coverage determinations.

This seems to undermine the flexibility and local sensitivities that are the purpose of local coverage decision-making. In addition, we are struck by the fact that, at the national level a relatively small national coverage staff at CMS will meet directly with stakeholders and interested parties regarding new technologies and medical procedures being reviewed for national coverage, while local determinations are relegated to formal comment submissions and filings without personal interactions.

Opportunities for personal interaction should be available at the local level as they are at the national level. The current requirement for an open, public meeting during the course of

developing an LCD serves this purpose. While we understand the need for expeditious action in coverage matters, we do not think it should be at the expense of stakeholders who seek a face-to-face interaction on important matters that have the potential to affect beneficiary access to new clinical diagnostic tests. In our view, transparency is required in the coverage decision-making process for it to be considered to be legitimate. The right of a face-to-face meeting should not be denied locally – especially when it is available in the NCD process.

- **CMS should require MACs to convene an open, public meeting to consider an LCD coverage matter under review when requested by stakeholders. This meeting, when conducted, is held in addition to other opportunities afforded to the public for participation (e.g., public comment period, CAC meeting).**
- **CMS should provide an extended comment period when open, public meetings are convened as part of the LCD process for clinical diagnostic laboratory tests.**

Final LCDs Effective Upon Publication

The CMS proposal would allow final LCDs to become effective immediately upon publication, consistent with the current NCD process. The current LCD process includes a notice period of at least 45 days before a final LCD is effective.

AdvaMed appreciates CMS's desire to make tests available to beneficiaries quickly by removing the 45-day notice period. As noted above under "Carrier Advisory Committee Meetings," we believe that such a change will be positive in instances where coverage is being added or expanded. We are concerned, however, that in cases where a final LCD may limit or restrict coverage, providers will require time to make the appropriate changes necessary to ensure appropriate billing, and that the current 45-day notice period should be retained in these instances.

- **CMS should permit final LCDs that provide expansions of coverage to become effective immediately upon publication.**
- **CMS should retain the current 45-day notice period prior to the effective date of an LCD when the LCD limits or restricts coverage.**

MAC Collaboration

CMS proposes to encourage MACs to collaborate on local coverage policies across MAC jurisdictions, but does not explain how this collaboration among MACs will take place. AdvaMed has serious concerns in this area. AdvaMed does not believe that an individual MAC should defer to another MAC, but rather each MAC should conduct its own analysis with respect to a proposed coverage policy.

The revised LCD process, as proposed, would require a MAC in a given jurisdiction to issue a draft LCD, allow for a public comment period, convene a CAC meeting if it chooses to do so, and publish a comment/response document and final LCD within 45 calendar days of the close of the comment period. CMS states that each MAC must "review, analyze and take under consideration all public comments on the draft LCD" and must then "respond to all public comments in writing and post their responses on a public web site." This discussion suggests but

does not make fully clear that each MAC must perform its own analysis, rather than merely adopting the analysis and findings of another MAC. Therefore, we recommend that CMS clarify its use of the term “collaboration” across MAC jurisdictions in the final rule and how collaboration would work under the revised process.

- **CMS should clarify its expectations regarding “collaboration” across MAC jurisdictions in the final rule. Specifically, CMS should clarify that each MAC is responsible for conducting its own review and analysis of a proposed LCD, and should not simply adopt the findings of another MAC.**

Cases Where Streamlined LCD Process Will Not Apply

CMS states that the proposed LCD process will not apply to clinical diagnostic laboratory testing LCDs that are being revised for a number of specific reasons, including when LCDs are “being issued for a compelling reason.”

CMS does not discuss nor provide any detail to explain what the Agency would consider to be a compelling reason. Furthermore, CMS does not specify or explain what process would be used if the proposed, streamlined process is not used in the instances that are described in the proposed rule.

It seems reasonable to require a MAC to justify any determination of “compelling reason” if the MAC determines that the streamlined process should not be used in a given instance. Further, CMS should clarify what process will apply in that instance. For example, would the MAC default to the existing LCD process (45-day comment period, CAC and open stakeholder meetings, publication of a comment/response document and final LCD issued at any time after the close of the comment period and the notice period of 45 days prior to the LCD becoming effective)?

- **CMS should describe or provide examples of those “compelling reason” situations where use of the streamlined process would not apply.**
- **Further, CMS should clarify what LCD review process would be followed for these “compelling reason” situations.**

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

a. Requirements for the PQRS Reporting Mechanisms

CMS is proposing the following definitions in the Qualified Clinical Data Registries (QCDRs) for resource use, patient experience of care, and efficiency/appropriate use measures:

- **A resource use measure** “is a measure that is a comparable measure of actual dollars or standardized units of resources applied to the care given to a specific population or event, such as a specific diagnosis, procedure, or type of medical encounter.”

- A **patient experience of care measure** “is a measure of person- or family-reported experiences (outcomes) of being engaged as active members of the health care team and in collaborative partnerships with providers and provider organizations.”
- An **efficiency/appropriate use measure** “is a measure of the appropriate use of health care services (such as diagnostics or therapeutics) based upon evidence-based guidelines of care, or for which the potential for harm exceeds the possible benefits of care.”

AdvaMed believes that efficiency, and measures dealing with efficiency and resource use, should be defined to include the overall value of the service, including both quality and cost. Ideally, the best care means delivering the right treatment to the right patient in the right setting at the right time, regardless of financial incentives. The proposed resource use definition above, 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.

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

C. Medicare Shared Savings Program

a. **Future Measures Recommended for Medicare Shared Savings Program: Gap Measurement Areas and Measures Addressing Care in the Frail Elderly Population**

AdvaMed appreciates the opportunity to provide comment on measure gaps and additional measures that might be used to assess an accountable care organization’s (ACO’s) performance with respect to care coordination in post-acute care and other settings, and measures that address the quality of care in the various different settings that may be a part of an ACO.

AdvaMed recommends that CMS consider the following gap areas for future measure development and application to ACO programs: (1) Malnutrition; and (2) Wounds.

Although evidence shows that the decline in nutritional status and wounds across all care settings impacts patient outcomes, resource use and costs, *there are currently no quality measures to address gaps in management of malnutrition and wounds through screening, assessment, nutritional intervention, execution of nutritional /wound care (treatment) plan, and care coordination in any CMS program.* Malnutrition and wound care quality are benchmarks of an effective integrated care delivery system. In addition to focusing on gap areas, these types of cross-cutting measures have particular application in addressing care in the frail elderly population.

AdvaMed recommends that CMS include a malnutrition care quality measure and additional wound care quality measures in the Medicare Shared Savings Program as soon as feasible.

Wound care measures are relevant across numerous populations, including adult and pediatric surgical, medical, and especially the geriatric population. Wound care measures would be an essential tool in containing and preventing infections and would significantly contribute to the reduction of hospital readmissions, emergency department visits, and repeat visits in other settings for evaluation by health professionals.

Malnutrition is a leading cause of morbidity and mortality, especially among older adults. Malnutrition is commonly reported among the elderly frail population. The protein intake in frail elderly has been shown to be lower, thus increasing the risk of muscle loss. As a result, muscle function, mobility, and independence may be affected, leading to an impaired quality of life.

Studies estimate that 20-50% of hospital inpatients are either malnourished or at risk for malnutrition upon admission¹, depending on the particular patient population and the criteria used to assess the patients. As many as 31% of malnourished patients and 38% of well-nourished patients will experience nutritional decline² during their hospital stay due to multiple factors. In addition, many patients continue to lose weight after discharge³, and patients with weight loss are at increased risk for readmission⁴. Additionally, hospitalized patients at risk of malnutrition are more likely to be discharged to another facility or require ongoing healthcare services after being discharged from the hospital than patients who are not at risk for malnutrition.^{5,6} Hospitalized malnourished patients, patients at risk for malnutrition, and patients who experience declines in their nutritional status while hospitalized have higher health care costs than well-nourished patients, patients not at risk for malnutrition, and patients who remain properly nourished during their hospitalizations, respectively.^{7,8,9}

While CMS has acknowledged the impact of undernutrition (and obesity) on patient outcomes

¹ Barker LA, et al. *Int J Environ Res Public Health*. 2011;8:514-527.

² Braunschweig C et al. *J Am Diet Assoc* 2000; 100 (11): 1316-1322.

³ Beattie AH, et al. *Gut* 2000;46:813-818.

⁴ Allaudeen N, et al. *J Hosp Med*. 2011;6:54-60.

⁵ Chima CS, Barco K, Dewitt ML, et al. *J Am Diet Assoc*. 1997;97:975-978.

⁶ Thomas DR, Zdrowski CD, Wilson MM, et al *Am J Clin Nutr*. 2002;75:308-313.

⁷ Chima CS, Barco K, Dewitt ML, et al. *J Am Diet Assoc*. 1997;97:975-978.

⁸ Correia MI, Waitzberg DL. *Clin Nutr*. 2003;22:235-239.

⁹ Braunschweig C, Gomez S, Sheean PM. *J Am Diet Assoc*. 2000;100:1316-1322.

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with the implementation of a body mass index (BMI) quality measure in the Medicare Shared Savings Program, patients may be malnourished regardless of BMI as they may be deficient in the macro- and micro-nutrients needed to help promote healing and reduce medical complications.

We recommend that CMS focus on malnutrition as a future measure since it is both a patient-safety risk and an underlying risk factor for multiple other CMS priorities (e.g., preventing avoidable readmissions, patient falls, pressure ulcer development, and healthcare acquired infections). In addition, addressing malnutrition directly aligns with National Quality Strategy aims and priorities related to patient safety, care coordination, patient- and family-centered care, population health, and affordability. Because malnutrition impacts patient care in multiple care settings, there is an opportunity to improve patient outcomes and decrease costs by coordinating malnutrition care and aligning provider incentives across the various care settings that may be a part of an ACO, including acute care, outpatient, and post-acute care; e.g., skilled nursing facilities and home health.

Conclusion

AdvaMed appreciates the opportunity to submit comments on the proposed CY 2015 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 me or DeChane L. Dorsey, Esq., Vice President, Payment and Health Care Delivery Policy, at (202) 434-7218, if we can further assist you.

Sincerely,

/s/

Donald May
Executive Vice President
Payment and Health Care Delivery Policy

Enclosures