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Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: CMS-1612-P; 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 CY 2015.

Dear Ms. Tavenner:

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the Medicare proposed physician fee schedule (MPFS) rule for CY 2015 published by the Centers for Medicare & Medicaid Services (CMS).¹ PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

Our comments on the proposed rule are set out below.

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I. REVIEWING POTENTIALLY MISVALUED CODES

In the 2015 MPFS proposed rule, CMS proposes to prioritize the review of “approximately 65” codes it identified as “high expenditure” across various specialties.² We note that CMS proposes to “[i]ncrease efforts to make available more information about the specific issues being considered in the course of developing values for new, revised and potentially misvalued codes to increase transparency,” including suggesting a new timeline for making changes to facilitate this transparency.³

¹ 79 Fed. Reg. 40318 (July 11, 2014).

² 79 Fed. Reg. at 40337–38 and Table 10.

³ 79 Fed. Reg at 40361.

We appreciate CMS' acknowledgement of the importance of making the coding review process more transparent in order to give stakeholders a fair and meaningful opportunity to participate in this process, which will benefit Medicare and its patients. Accordingly, we urge CMS to delay proposing any changes related to potentially misvalued codes until after it completes the implementation of its transparency initiative and is able to publish revised Relative Value Units (RVUs) for misvalued services in the MPFS proposed rule.

II. COMPLEX CHRONIC CARE MANAGEMENT SERVICES

In the 2014 MPFS rule, CMS discussed a policy to pay separately for care management services furnished to Medicare beneficiaries with two or more chronic conditions, beginning in 2015.⁴ CMS established the Complex Chronic Care Management (CCM) code for reporting this service, "GXXX1 Chronic care management services furnished to patients with multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; 20 minutes or more; per 30 days."⁵ Now, CMS proposes to finalize this code.

PhRMA appreciates CMS' recognition of the value of CCM services, and we support the creation of the CCM code. We also hope CMS will provide greater clarity about what is included in CCM and how this code should be used. In particular, we encourage CMS to require comprehensive medication management as part of the scope of services for CCM. Comprehensive medication management is a standard of care that ensures each patient's medications are individually assessed to ensure that the medication is: 1) appropriate, 2) effective for the medical condition, 3) safe given the comorbidities and other medications being taken, and 4) willing and able to be taken by the patient as intended. CCM is more comprehensive than medication reconciliation because it includes the development of a care plan with individualized therapy goals, follow-up evaluation of the patient, and timely communication with other providers on the care team, all of which are essential for effective management of chronic disease.

We support incentives for adoption of electronic health records and believe services in support of complex chronic care management should be integrated with EHRs in a way that is feasible, not overly burdensome to providers, and has the effect of expanding and not restricting the use of CCM services. We are concerned that CMS' proposal to limit covered CCM services only to those that are "furnished with the use of an electronic health record [(EHR)] or other health IT or health information exchange platform," and to require that all practices billing CCM "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 identifiable in the then-applicable version of the [CFR]"⁶ would have the effect of limiting access to CCM services.

⁴ 79 Fed. Reg. at 40365.

⁵ 79 Fed. Reg. at 40365.

⁶ 79 Fed. Reg. at 40367.

CMS recognizes chronic care management “as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth.”⁷ PhRMA appreciates CMS’ interest in using electronic data exchanges of patient records to facilitate effective care coordination. Given the importance of this service to the delivery of efficient, high-quality patient care, all patients should have access to CCM services, regardless of whether their providers have certified EHR capabilities. Patients that reside in rural areas or are otherwise limited in their choice of providers may not have the option of selecting providers using certified EHRs, particularly if EHRs must be certified to the version currently applicable in the CFR. Challenges faced this year by EHR vendors and health care providers in completing upgrades to the 2014 Edition certification criteria under the rapid timelines established in the CFR illustrate this problem. Many of CMS’ recent initiatives have been aimed at promoting consumer choice in healthcare.⁸ Patients should not be penalized and their access to needed services limited because their providers choose not to or cannot comply with the rigorous certification standards required of EHRs. We strongly encourage CMS to implement its CCM program in ways that do not restrict the availability of these important services to patients whose providers are using certified EHRs.

III. DEFINITION OF COLORECTAL CANCER SCREENING TESTS

CMS proposes to revise the applicable definition of “colorectal cancer screening tests” at 42 C.F.R. § 410.37(a)(1) to include anesthesia that is separately furnished in conjunction with screening colonoscopies, as this has become a prevalent practice in the United States. PhRMA supports this proposal as a means to ensure that beneficiaries will not be charged cost-sharing for medically appropriate anesthesia services that are furnished in conjunction with screening colonoscopies. As CMS notes, section 4104 of the Affordable Care Act (ACA), waives the deductible and coinsurance for preventive services with robust clinical evidence such as screening colonoscopies. Without the proposed change to the regulations, however, beneficiaries who receive medically appropriate covered anesthesia services from a different professional than the one furnishing the colonoscopy would incur costs for any coinsurance and unmet deductible for this component of the service. As CMS notes, if adopted, this proposal “will encourage more beneficiaries to obtain a screening colonoscopy, which is consistent with the intent of the statutory provision to waive Medicare cost-sharing for certain recommended preventive services, and is consistent with the authority delegated to the Secretary in section 1861(pp)(1)(D) of the Act.”⁹

IV. CMMI ACCESS TO INDIVIDUALLY IDENTIFIABLE DATA

⁷ 79 Fed. Reg. at 40364 (emphases added).

⁸ E.g., 79 Fed. Reg. at 40368 (requiring that to participate in CCM, practitioners must, inter alia, create “a patient-centered care plan document to assure that care is provided in a way that is congruent with patient choices and values”); see also 79 Fed. Reg. at 40385 (“Under section 10331(f) of the Affordable Care Act, we are required to submit a report to Congress . . . on Physician Compare development, and include information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice . . .”).

⁹ 79 Fed. Reg. at 40369

The proposed rule cites the need for CMMI to receive individually identifiable data to conduct research authorized by the ACA. Specifically, CMMI believes that it requires access to patient health information that would not generally be available to CMS to evaluate its models using control groups. Accordingly, CMS proposes to require that all participants in CMMI models submit individually identifiable health data to CMS. To the extent that the CMMI engages private payers, this data would include individually identifiable information on patients in commercial health plans in addition to Medicare and Medicaid patients.¹⁰ It is not clear from the discussion in the proposed rule whether CMS believes that the proposed requirement for CMMI to have access to “identifiable health and utilization information” from model participants comes under HIPAA’s “required by law” disclosure exception or some other exception. We ask that CMS clarify under what authority it is proposing this new disclosure requirement and if there are limits to such disclosures or any specific privacy protections that would apply.

Although we appreciate CMS’ interest in obtaining data to conduct robust evaluations of CMMI demonstration programs, we are concerned that patients may not be aware that CMMI may be accessing protected health information not generally available to the agency. In the proposed rule, CMS does not discuss how patients — in particular, patients in private, commercial health plans — will be notified that CMS is receiving their personal data and using it for research and evaluation purposes. At a minimum, any providers who plan to share individually-identifiable patient information under this proposed regulation should be required to provide notice of the disclosure to impacted patients. Ideally, patient authorization should be obtained for data disclosures made to CMS. Accordingly, we are concerned that the proposal, if adopted, would undermine important protections for patients’ individually identifiable health information under HIPAA.

V. CHANGES TO THE LOCAL COVERAGE DETERMINATION (LCD) PROCESS FOR CLINICAL DIAGNOSTIC LABORATORY TESTING

CMS “proposes an expedited LCD process for clinical diagnostic laboratory testing” to manage the growing number of clinical diagnostic tests available.¹¹ Currently, at least 45 days are provided for public comment after a Medicare Administrative Contractor (MAC) publishes a draft LCD. Under the proposed expedited process, only 30 days would be allowed for public comment.¹² CMS notes that although “it takes time for the provider community and the claims processing systems to adapt to changes in coverage, a notice period delays the date when coverage may become effective.”¹³ We appreciate CMS’ concern for expediency and its effort to promote efficient LCD development. We disagree, however, that “30 days is . . . adequate to allow for robust public comment.”¹⁴

¹⁰ 79 Fed. Reg. at 40376.

¹¹ 79 Fed. Reg. at 40378.

¹² 79 Fed. Reg. at 40379.

¹³ 79 Fed. Reg. at 40379.

¹⁴ 79 Fed. Reg. at 40378.

As CMS suggests, electronic comment submission has made the process easier in many ways. However, electronic comment submission does not reduce the time necessary to understand and analyze the implications of proposed LCDs and prepare thoughtful comments — not to mention the time it may take for a commenter to learn that a proposed LCD has been released and is available for comment. Although meetings in advance of LCD publication may help stakeholders prepare for drafting comments, stakeholders cannot truly begin to respond to a proposed LCD until it has been published. Accordingly, shortening the comment period would have the effect of reducing important public involvement in coverage policymaking.

CMS recognizes the potential for this problem and states, “in the event that stakeholders and/or members of the public are not able to submit comments within the 30 calendar day window, the MAC would have discretion to extend the comment period.”¹⁵ CMS provides no details about how stakeholders can request an extension and how a MAC would determine whether to grant them. Consequently, we believe this unspecified extension process would not be an adequate vehicle to ensure appropriate stakeholder input.

We are particularly concerned about how this LCD proposal would undermine public involvement in light of the Protecting Access to Medicare Act of 2014 (PAMA) provision that permits CMS to designate up to four MACs to establish coverage policies for laboratory tests.¹⁶ This PAMA provision effectively allows for the development of de facto national coverage determinations (NCDs) but without the protections built into the established process for developing NCDs. As CMS recognizes in the preamble, these processes have serious implications for the fairness, transparency, and soundness of coverage determinations processes. At the same time, elements of CMS proposed process, such as establishing a defined timeline for publication of a comment/response document and final LCD, serve to increase efficiency without limiting stakeholder input. Accordingly, we strongly encourage CMS to implement an LCD process for clinical diagnostic laboratory tests that more appropriately balances the need for efficiency and stakeholder input by retaining the 45 day comment and seeking efficiencies that do not disrupt the process for stakeholder input.

VI. PROPOSED ELIMINATION OF SUNSHINE ACT EXCLUSION FOR PAYMENTS ASSOCIATED WITH CERTAIN CONTINUING MEDICAL EDUCATION EVENTS

In its July 11, 2014, Federal Register notice, CMS proposes to eliminate the exclusion in the Sunshine Act final rule for certain qualifying continuing medical education (CME) programs. PhRMA is concerned that the proposed rule will link applicable manufacturers and speakers at independent CME in a manner that is antithetical to the notion of “independent” CME and inconsistent with current guidance from FDA and accrediting organizations regarding the conduct of these programs. PhRMA is concerned that this proposal will harm independent CME programs by diminishing speaker and attendee participation at

¹⁵ 79 Fed. Reg. at 40378.

¹⁶ Social Security Act § 1834A(g)(2), as amended by PAMA § 216(a).

independent CME and by chilling manufacturer funding of these programs. Accordingly, PhRMA respectfully submits that CMS should retain the CME exclusion with modifications, as set forth below.

A. THE CME EXCLUSION

In February 2013, CMS published the final rule implementing section 6002 of the ACA, "Transparency reports and reporting of physician ownership or investment interests" (the "Sunshine Act").¹⁷ The Sunshine Act final rule provides that a payment or transfer of value provided as compensation for speaking at a CME program is not reportable if all of the following conditions are met: (1) the event meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association's Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association; (2) the covered recipient is not paid directly by the applicable manufacturer; and (3) the covered recipient speaker is not selected by the applicable manufacturer and the applicable manufacturer does not provide the third party a set of individuals for consideration as speakers.¹⁸ Subsequently, in a "Frequently Asked Question" (FAQ) posted to CMS's website, CMS explained that, to qualify for this exclusion, the CME program must be accredited by one of the five accreditation bodies identified in the final rule.¹⁹

In providing the exclusion for accredited CME, CMS recognized the vital role that CME programs play in educating healthcare professionals about medical developments. In the preamble to the final rule, CMS described industry support for accredited or certified continuing education as a "unique relationship."²⁰ CMS recognized that accrediting and certifying bodies and industry standards for support "create important and necessary safeguards prohibiting the involvement of the sponsor in the educational content."²¹ These safeguards are set forth in FDA's guidance on industry support for independent medical education programs, *Guidance for Industry, Industry-Supported Scientific and Educational Activities*,²² and the Accreditation Council for Continuing Medication Education's *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*.²³ The hallmark of these standards is the requirement that the content and substance of these programs, as well as control over speakers and attendees, be independent of the manufacturers that provide funding for these programs.

¹⁷ 42 Fed. Reg. 9458 (Feb. 8, 2013).

¹⁸ 42 C.F.R. § 403.904(g)(1).

¹⁹ FAQ No. 8398 ("[T]he list of accrediting or certifying bodies in the final rule at 42 CFR § 403.904(g)(1)(i) is exhaustive; in order to qualify for the exclusion . . . CME events must be run by CME providers that are accredited or certified by one of the accreditation or certification entities in § 403.904(g)(1)(i) and, accordingly, meet the accreditation or certification requirements and standards of any of those specific entities. Payments to speakers at CME events that are not run by CME providers accredited or certified by one of the entities in § 403.904(g)(1) . . . are reportable payments or other transfers of value for Open Payments."

²⁰ 78 Fed. Reg. at 9492.

²¹ *Id.*

²² *Guidance for Industry, Industry-Supported Scientific and Educational Activities*, 62 Fed. Reg. 64093 (Dec. 3, 1997).

²³ *Standards for Commercial Support: Standards to Ensure Independence in CME Activities*, available at <http://www.accme.org/requirements/accreditation-requirements-cme-providers/standards-for-commercial-support>. Similar standards have been adopted by other accrediting organizations.

Based on these safeguards, CMS distinguished accredited and certified CME from “unaccredited and non-certified education,” because “this type of education program does not require the same safeguards.”²⁴ Accordingly, CMS specified that industry support of CME programs that meet the three criteria specified in the final rule would “not be considered indirect payments or other transfers of value for purposes of reporting [and] the awareness standards for indirect payments are not applicable to such support.”²⁵

CMS now proposes to eliminate the exclusion found in § 403.904(g)(1). The proposed rule states that doing so will remove a redundancy with the separate exclusion for certain indirect payments (42 C.F.R. § 403.904(i)(1)) and is responsive to comments from stakeholders that CMS’s current position appears to endorse certain organizations that accredit CME events. CMS explains that, if the CME exclusion is removed, an applicable manufacturer’s grant to a CME provider still would not be reportable as an indirect payment if (1) the covered recipient is not selected or paid directly by the applicable manufacturer and (2) the applicable manufacturer does not provide the CME provider a distinct, identifiable set of covered recipients for selection as speakers.²⁶

B. PhRMA’S CONCERNS REGARDING CMS’S PROPOSED ELIMINATION OF THE CME EXCLUSION

PhRMA does not agree that the current exclusions for accredited CME (at 42 C.F.R. § 403.904(g)) and certain indirect payments (at 42 C.F.R. § 403.904(i)(1)) are redundant. The latter provides an exclusion “where the applicable manufacturer is unaware of the identity of the covered recipient”—*i.e.*, when the manufacturer “does not know . . . the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.”²⁷ “Knowledge” means that an applicable manufacturer has actual knowledge of the identity of the covered recipient or acts in deliberate ignorance or reckless regard of the identity of the covered recipient.²⁸ The current exclusion for accredited CME does not include this “awareness” standard.

PhRMA appreciates that the preamble comments to the proposed rule provide that payments associated with medical education programs will not be reportable if certain criteria are met. However, CMS has not proposed to codify these criteria in the regulation itself, and CMS does not reconcile its proposal with the existing “awareness” standard for indirect payments. Applicable manufacturers that provide grants to independent medical education providers for CME will almost always meet the “awareness” threshold as schedules of events and speaker lists are typically published in CME course materials and through other means. Importantly, however, a company may not know how much, if any, of

²⁴ 78 Fed. Reg. at 9492.

²⁵ *Id.*

²⁶ 79 Fed. Reg. 40318, 40384 (July 11, 2014).

²⁷ 42 C.F.R. § 403.904(i)(1).

²⁸ 42 C.F.R. § 403.902.

the grant funding that it provided to support the CME program was ultimately used to compensate a physician speaker.²⁹ For these reasons, the CME exclusion is not redundant of the “certain indirect payments” exclusion provided in 42 C.F.R. § 403.904(i)(1).

Effectively eliminating the exclusion for grants to accredited CME is tantamount to challenging the independence of such programming, as provided for by FDA guidance and the standards of many accrediting organizations. Moreover, PhRMA is concerned that eliminating this exclusion could chill industry funding of CME, thus impacting the ability of medical societies and other organizations to provide important educational programs. Currently, in response to the existing Sunshine Act regulations, a number of applicable manufacturers fund only certain accredited CME. By extension, if the CME exclusion is eliminated, this change could prompt manufacturers to place additional constraints on their support for CME. Such a result would be contrary to the identified goal of the proposed rule, which is to expand the CME programs covered by the exclusion.

Finally, PhRMA notes that CMS's proposal does not address how, if at all, eliminating the exclusion for CME speakers will affect the reporting of registration fees for physician attendees. In the preamble to the final rule, CMS states that it does “not intend to capture the attendees at accredited or certified continuing education events whose fees have been subsidized through the CME organization by an applicable manufacturer.”³⁰ CMS has similarly stated in presentations, webinars, and other stakeholder outreach that CME tuition and educational materials included in CME tuition fees are not reportable for attendees of accredited or certified CME.³¹ Required reporting of registration fee off-sets as a transfer of value to CME attendees would impose a heavy burden on CME providers and applicable manufacturers. In addition, physicians may be deterred from attending CME events if their attendance will be reported and a dollar value assigned to their participation.

C. PROPOSED SOLUTIONS

PhRMA respectfully submits that CMS should retain the CME exclusion currently in the final rule in § 403.904(g). To avoid the appearance of endorsing particular accrediting organizations, CMS could eliminate the requirement in § 403.904(g)(1)(i) that the accredited CME program be accredited by one of the listed organizations and, instead, require in that the CME event be recognized by a state or the federal government as accredited or certified.³²

²⁹ Indeed, the independence of accredited CME from manufacturer involvement (i.e., with respect to content, speakers, attendees) interrupts the causal chain such that the transfers of value no longer flow “from” an applicable manufacturer “to” a covered recipient. This independence is what distinguishes manufacturer support for such programming from other indirect transfers of value.

³⁰ 78 Fed. Reg. at 9481 (emphasis omitted).

³¹ See Appendix A.

³² This approach would require CMS to revoke FAQ 8398, which requires that the CME event be accredited by one of the five listed organizations.

A second, albeit less preferable, option would be for CMS to adopt the substance of its proposal but retain an exclusion at § 403.904(g) for CME programs that explicitly states that the “awareness” prong of the indirect payment exclusion does not apply when the payment or transfer of value is for speaking at a CME event. The language of the revised § 403.904(g) should also include the criteria discussed by CMS in the preamble to the proposed rule—*i.e.*, that CME programs would not be reportable if (1) the speakers are not selected or paid directly by the applicable manufacturer; and (2) the applicable manufacturer does not suggest a distinct, identifiable set of covered recipients for selection as speakers. CMS should make clear that this revised CME exclusion applies to payments to speakers as well as registration fees for attendees at events that meet these criteria.

PhRMA remains committed to the success of the Sunshine Act in providing transparency regarding interactions between biopharmaceutical companies and health care providers. By continuing to recognize that industry support of independent CME programs does not constitute a reportable transfer of value, CMS will continue to advance this goal. We would be pleased to provide CMS with any additional information on these subjects and other matters relating to Sunshine Act implementation.

VII. COMMENTS REGARDING PROPOSED CHANGES TO THE PHYSICIAN QUALITY REPORTING SYSTEM

A. MEASURE SELECTION

CMS proposes the addition of 29 new measures to the Physician Quality Reporting System (PQRS). PhRMA appreciates that CMS continues to refine the measure set for the program, adding new measures to fill existing gaps, including new measures evaluating care of patients with lung cancer, melanoma, and ALS. We appreciate that some of these new measures include shared decision-making, which is important in the aim to engage the patient and his or her family in care. We also appreciate the inclusion of two patient-reported outcomes performance measures; we believe that this type of patient-centered measure provides invaluable information. However, we note that of the 29 proposed new measures, only four of them have achieved endorsement by the National Quality Forum (NQF). CMS should continue to rely on measures supported by multi-stakeholder consensus agreement as reflecting essential elements of high-quality care, reflecting all treatment modalities within the current standard of care, and having ability to improve overall health outcomes. Measures that have attained NQF endorsement have successfully undergone the rigor of careful testing, validation, and scrutiny to ensure that they provide accurate, reliable, and meaningful results; have been subjected to external review; and are published for public review and comment. Accordingly, we encourage CMS to rely on measures that have been through this type of intensive, transparent development and evaluation process and have achieved endorsement by the time these regulations are implemented. In the rare instance that NQF-endorsed measures are not available to evaluate a gap in quality care causing CMS to use non-NQF-endorsed measures, we believe that they should have gone through a rigorous, transparent evaluation process like the one described. Multi-stakeholder consensus endorsement processes, like NQF's, provide a validation of the rigor of the measure.

CMS proposes a new set of cross-cutting measures for 2015 and beyond, of which eligible professionals would be required to report on at least two. One of these measures is the CAHPS survey and includes a survey question, Stewardship of Patient Resources, which specifically asks a patient if his provider discussed his prescription medication costs with him. However, the survey does not capture discussion of other health care costs between a patient and his provider, which are also relevant to a conversation about patient resources. We believe that it is more appropriate to include those other aspects of health care costs in this type of discussion, particularly when a patient's benefit design influences the costs for which he is responsible. Further, this survey question seems to be disconnected from any conversation about treatment options and shared decision-making about treatment selection. If CMS wishes to include a survey question about health care costs, we believe that it should be a more comprehensive question, rather than singling out a particular aspect of treatment. Even taking these issues into account, we question whether this is the appropriate line of questioning to include in a patient experience survey that is classified as evaluating non-clinical quality-related outcomes, and will likely be linked with cost incentives either in a value-based payment program or other payment models.

B. MEASURE REMOVAL

CMS proposes to remove 73 measures from the PQRS measure set for a variety of reasons. CMS has previously outlined reasons for removing measures from the program, including a measure no longer had room for improvement (otherwise known as "topped out"), was no longer being maintained, or no longer reflected current evidence-based guidelines, among others. In this proposal, CMS suggests removal of 7 measures because they evaluate a practice that is "substantially adopted," "common practice," "currently accepted," "commonly utilized," or "commonly provided." While we agree that many of these measures seem to be "low-bar" process measures, the reasons given for removal are not consistent with those CMS has outlined in the past, nor does CMS state that these measures are topped out. If there is legitimate reason to remove these measures from the set, either CMS should indicate one of its currently articulated policies or adjust the policy to reflect an additional reason. Furthermore, we believe that these examples of low-bar measures demonstrate the need to continue to drive toward inclusion of outcome measures.

Additionally, we are concerned that removal of some of the measures without proposed replacements will create gaps in the measure set. These measures are being removed for valid reasons: the measure steward will no longer maintain the measure, the measure is topped out, or the evidence-based guidelines have changed. However, CMS is not proposing new measures that would advance quality in these areas, and we are concerned that these removals could result in gaps in the measure sets for prevalent chronic conditions. Therefore, we urge CMS to identify appropriate measures to continue to evaluate the quality of care in these chronic conditions.

CMS also proposes to remove Medication Reconciliation (PQRS 46) from the Group Practicing Reporting Option Web Interface and replace it with Documentation of Current Medications in the Medical Record (NQF 0419). We believe that these measures are complementary. Errors often occur at transitions of care, which makes reconciliation of discharge medicines with other medications a necessary activity to ensure that patients are not taking duplicate therapies or inappropriate medications. Thus, we believe that

continuing to report on Medication Reconciliation is an important evaluation of care provided post-discharge. We also believe that documenting an accurate medication list at each encounter between a clinician and patient is an important ongoing activity to ensure that the clinician always has an up-to-date medication list, including both those medications he has prescribed plus those prescribed by other clinicians and any over-the-counter medications. These two measures work well together because reconciliation and documenting are two different activities, and as described in these measures, completed at different times; we urge CMS to use both to evaluate care coordination.

C. MEASURES INCORPORATED IN THE QUALIFIED CLINICAL DATA REGISTRY

CMS identified Qualified Clinical Data Registries (QCDR) based on criteria set forth in the Calendar Year 2014 rule. While we appreciate the experience these QCDRs have with clinical measure reporting, we are concerned that the measures reported by QCDRs are not required to be developed and evaluated in the same transparent manner as the measures included in the other PQRS reporting options. We believe that because of the impact these measures could have on the clinician's treatment behavior through the Quality Resource and Utilization Reports and the application of the Value-Based Payment Modifier, these measures should also be subject to review and endorsement consideration by a consensus-based standards organization, such as NQF, just as those being reported through other means for PQRS.

VIII. COMMENTS REGARDING PROPOSED CHANGES TO THE VALUE-BASED PAYMENT MODIFIER

A. COST MEASURES

Last year CMS finalized inclusion of a claims-based measure, Medicare Spending per Beneficiary, within the cost domain for all attributed beneficiaries, in addition to the Total per Capita Costs measure and Total per Capita Costs for beneficiaries with four conditions: Chronic Obstructive Pulmonary Disease, Coronary Artery Disease, Heart Failure, and Diabetes. While resource use measures, like these, report information about costs of treatment, they do not provide any information about the quality of care provided relative to those costs, and therefore do not represent efficiency or accurately demonstrate value. It is important to report appropriate quality data alongside any cost data and ensure that the quality data have a meaningful relationship to the cost data, as a framework for interpretation so that the cost data are not misused or misunderstood. The quality component of the value-based payment modifier (VM) consists of quality measures reported by an eligible professional through PQRS, yet the quality of care evaluated may not relate to the costs calculated. In other words, an eligible professional will report on 9 measures of his choosing that relate to his practice. The provider may choose to report on care he or she provides relative to a particular disease state; however, the calculated cost measures account for all care and may include costs not evaluated by the reported quality measures. In this case, the quality component and cost component likely do not directly relate.

Well-designed quality measures, preferably outcomes measures, can help to balance cost measures and ensure that patients are receiving the right types of treatment to achieve desired health outcomes, if those quality measures relate to the cost measures. We are concerned that application of

unbalanced cost measures could result in reduced provision of needed care and decreased beneficiary access to medically beneficial treatments in an effort to stem costs, especially when applied in an incentive program. Therefore, we encourage CMS to investigate alternative frameworks for true efficiency measurement that would allow for the proper tandem evaluation of cost and quality.

Additionally, the Medicare Spending per Beneficiary measure is specified at the hospital/facility care setting level, instead of the physician group or individual physician level. PhRMA encourages CMS to only apply measures to care settings in which those measures were tested, validated, and endorsed. Application of a measure in a care setting or at a care level for which it was not tested and validated could result in inappropriate conclusions to be drawn from the results.

Further, we note that the Total per Capita Costs measures are not NQF-endorsed, and the Medicare Spending per Beneficiary measure is not endorsed at the physician or group level. Many concerns were raised by the members of the NQF Cost and Resource Use Steering Committee charged with reviewing these measures. The reliability and validity of these measures was questioned and challenged. For the purpose of the VM program, we understand that, by statute, CMS is required to incorporate cost measures. In meeting this statutory requirement but recognizing the validity and reliability issues with these measures, we suggest that CMS weight more heavily the quality measures used in the VM so that the quality tiering of physician groups is defined more based upon the quality of care being rendered.

B. COMPARISONS OF PHYSICIANS

CMS aims to include all physicians in the VM program by 2017, as required. However, some specialties and subspecialties do not have measures that address the care they provide. In order to participate, or else be penalized, these specialists will likely be judged on quality measures that may be beyond their scope of care. Further, these specialists may be compared to other physicians whose practice is different, making the comparison not meaningful and unreasonable. Further, if their care is then found to be more costly or of lesser quality based on measures that do not truly reflect their scope, they could be penalized. PhRMA suggests that CMS should re-evaluate the implementation plans, the methodology for comparing physicians and groups, and the measures included to ensure that optimal care is not hindered but promoted.

C. COST/ QUALITY ADJUSTMENTS

CMS proposes to increase the at-risk percentage for 2017 to 4%. CMS proposes that eligible professionals who provide high quality, low cost care could receive a +4% payment adjustment, while those who provide low quality, high cost care could receive a -4% payment adjustment. However, those eligible professionals who provide low quality, low cost care would receive no adjustment, either negative or positive. The VM program is designed to encourage quality improvement. Not penalizing low quality, regardless of cost expended, is not consistent with the goal of the program. PhRMA suggests that this proposal sends the wrong message about the goal of the program and we encourage CMS to reconsider this aspect of the payment adjustment proposal, whereby low quality is penalized.

D. PHYSICIAN FEEDBACK PROGRAM

CMS continues to disseminate Quality and Resource Use Reports (QRURs) to eligible professionals, making them available to all physicians this year, with the intention that these reports provide actionable information to physicians to aid them in improving quality of care. However, we are concerned about unintended consequences and the impact these reports may have based on how performance comparisons between physicians are made if the comparators are not truly similar. Making incorrect comparisons could potentially lead physicians to not provide appropriate care, in an effort to appear to be less resource-intensive.

CMS also describes the development and dissemination of Supplemental QRURs using episodes of care. We are concerned about the lack of transparency in the development of episodes of care and multiple potential uses of them. These reports show information about costs of care for as many as 26 episodes without any quality of care context. Providing these types of comparison reports with a hint that measures based on these episodes may be included in the VM in future years could have detrimental effects on the quality of care provided. We urge CMS to include relevant clinical outcome measure results with these reports as an appropriate context for interpretation and action.

IX. COMMENTS REGARDING PROPOSED CHANGES TO MEDICARE SHARED SAVINGS PROGRAM (MSSP)

A. MEASURE REMOVALS

CMS proposes to remove Medication Reconciliation after Discharge from an Inpatient Facility (ACO 12) and replace it with Documentation of Current Medications in the Medical Record (NQF 0419). As mentioned above in relation to PQRS, we believe that these measures are complementary. Errors often occur at transitions of care, which makes reconciliation of discharge medicines with other medications a necessary activity to ensure that patients are not taking duplicate therapies or inappropriate medications. Thus, we believe that continuing to report on Medication Reconciliation is an important evaluation of care provided post-discharge. We also believe that documenting an accurate medication list at each encounter between a clinician and patient is an important ongoing activity to ensure that the clinician always has an up-to-date medication list, including both those medications he has prescribed plus those prescribed by other clinicians and any over-the-counter medications. These two measures work well together because reconciliation and documenting are two different activities, and as described in these measures, completed at different times; we urge CMS to use both to evaluate care coordination in ACOs.

CMS also proposes to remove four components of the Diabetes Composite: Hemoglobin A1c control (<8%); Blood Pressure (<140/90); Tobacco Non-use; and Low Density Lipoprotein (<100). CMS proposes that the new Composite will consist of the following: Daily Aspirin or Antiplatelet Medication Use for Patients with Diabetes Mellitus and Ischemic Vascular Disease; Hemoglobin A1c Poor Control; Foot Exam; and Eye Exam. In making these changes, CMS is proposing to remove three outcome measure components (hemoglobin A1c control, blood pressure control, and LDL control) of the composite and replace them with two process measure components (foot exam and eye exam). PhRMA supports use of a

measure that can evaluate each component of appropriate diabetes care. CMS states that it is proposing removal of the hemoglobin A1c control (<8%) component because the level is considered too low for the frail elderly. However, evidence suggests that levels of control of hemoglobin A1c <8% are in fact appropriate in certain subpopulations. We note that guidelines issued by the American Diabetes Association support the clinical rationale for less stringent A1c goals in patients with “a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, and extensive comorbid conditions and in those with long-standing diabetes in whom the general goal is difficult to attain despite diabetes self management education (DSME), appropriate glucose monitoring, and effective doses of multiple glucose lowering agents including insulin.”³³ There is also a small proportion of patients in the elderly group for whom ADA Guidelines recommend an HbA1c goal of <8.5%.³⁴ This population includes very complex/poor health (long-term care or end stage chronic illnesses or moderate-to-severe cognitive impairment or 2 or more ADL dependencies). Because the ADA guidelines recognize that some elderly populations could benefit from tighter glucose control, we suggest that this component not be removed. Alternatively, we suggest applying age stratification that could demonstrate lower percentages in those patients who would be better managed through tighter blood glucose control and more appropriate results in patients who may be at risk of hypoglycemic events if lower percentages were attained. CMS states that it is proposing removal of the blood pressure control component in favor of a general population blood pressure control measure already included in the measure set. We recognize that patients with diabetes often have hypertension as a comorbid condition and evaluating blood pressure control as a component of a composite measure provides a more comprehensive picture of care being rendered; we do not believe this component should be removed. CMS states that it is proposing removal of the LDL control component because of recently updated evidence-based guidelines. PhRMA agrees that measures should reflect current evidence-based guidelines and standards of care; however, the recently released 2013 American College of Cardiology/American Heart Association (ACC/AHA) Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults has been the subject of debate and dissent amongst the medical community, including the American Academy of Clinical Endocrinologists who did not endorse the guidelines. While we agree it is important to keep measures current with standards of medical care as reflected in clinical practice guidelines, we also believe measure maintenance should occur through a robust, clinically-driven process, and we urge CMS to proceed in a more deliberate process in deciding how to respond to this change in ACC/AHA guidelines. Complete removal of these three outcome components seems counterproductive and harmful to patients. While the addition of the two process measures for foot and eye exams are important to ensure micro- and macro-vascular consequences of poor control do not manifest unnoticed, they are not outcome measures that evaluate overall blood glucose control or occurrence of diabetes-related complications. We believe that these changes are not driving toward better quality, but instead are relaxing quality expectations. We encourage CMS to build upon the successes achieved in diabetes care and evaluate clinical outcomes. Further, we note that appropriate testing of any new composite created by removal or addition of components is necessary to ensure that the composite measure continues to be valid and reliable.

³³ American Diabetes Association. “Standards of Medical Care in Diabetes – 2014” *Diabetes Care*. Volume 37, Supplement 1, January 2014.

³⁴ *Ibid.*

B. MEASURE ADDITIONS

PhRMA commends CMS for the proposed additions of four new readmission and unplanned admissions measures. We believe these types of measures demonstrate the ability of an accountable care organization (ACO) to effectively coordinate care and work together across care settings. Prior to implementation of these measures, we encourage CMS to ensure that these measures have achieved endorsement by a multi-stakeholder consensus-agreement organization, such as NQF.

As in PQRS, CMS also proposes to add a new CAHPS measure: Stewardship of Patient Resources. This survey question specifically asks a patient if his provider discussed his prescription medication costs with him. Again, the survey does not capture discussion of other health care costs between a patient and his provider, though they are relevant to the conversation too. We believe that it is more appropriate to include those other aspects of health care costs in this type of discussion, particularly when a patient's benefit design influences the costs for which he is responsible. Further, this survey question seems to be disconnected from any conversation about treatment options and shared decision-making about treatment selection. If CMS wishes to include a survey question about health care costs, we believe that it should be a more comprehensive question, rather than singling out a particular aspect of treatment. Even taking these issues into account, we question whether this is the appropriate line of questioning to include in a patient experience survey that is classified as evaluating non-clinical quality-related outcomes, and will likely be linked with cost incentives either in a value-based payment program or other payment models.

C. FUTURE MEASURES

CMS requests comments about measures to be considered for inclusion in the future. We appreciate the agency's continued work to strengthen its measure sets and openness to stakeholder input in support of this. We believe that end-of-life care and preferences about end-of-life care are not represented in the current measure set; to that end, CMS may consider adding a measure about advance care directives as a means of capturing the patient's wishes on if/when/how care should be provided (for example, NQF 0326 Advance Care Plan).

As previously stated, we believe that in general CMS should continue advancing the goal of shifting from clinical process measures to clinical outcome measures. This is particularly important as the agency administers a growing number of programs that provide financial incentives to providers for cost containment. PhRMA believes there are a number of areas that are important to improved clinical and other patient-focused outcomes (e.g., patient-reported outcome performance measures) that are not adequately captured in the existing measure sets applied to accountable care organizations. For example, the Institute of Medicine has identified several significant gaps in the existing quality measure sets for oncology care, including outcomes measures, post-treatment follow-up, palliative, and end of life care.³⁵ We also

³⁵ Institute of Medicine, *Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis*. September 10, 2013.

appreciate the challenge, as noted in MedPAC's 2014 report, of comprehensively and adequately measuring quality and incentivizing improved outcomes in ways that are administratively feasible for providers. To that end, we recommend an initial subset of NQF-endorsed measures for CMS to consider adding to its ACO programs.

Below, PhRMA has identified NQF-endorsed outcome measures that evaluate the conditions currently targeted by the ACO measures. We found a number of additional measures that CMS could consider adding to the current measure set. We acknowledge that these measures do not reflect the range of measures that would comprehensively evaluate the care provided by an ACO to all patients; however, these measures do expand upon the current set and continue to advance the set toward evaluating outcomes. Also, we note that for some conditions, NQF-endorsed outcome measures do not exist; therefore, we have identified process measures that could build upon the current measure set.

NQF Number	Measure Title	Measure Description
709	Proportion of patients with a chronic condition that have a potentially avoidable complication during a calendar year	Percent of adults aged 18-65 years who were identified as having at least one of the following six chronic conditions: Diabetes Mellitus, Congestive Heart Failure, Coronary Artery Disease, Hypertension, Chronic Obstructive Pulmonary Disease, or Asthma, were followed for one-year, and had one or more potentially avoidable complications.
468	Hospital 30-day, all-cause, risk-standardized mortality rate following pneumonia hospitalization	Death for any cause within 30 days of the admission date for the index hospitalization for patients discharged from the hospital with a principal diagnosis of pneumonia
223	Adjuvant chemotherapy is considered or administered within 4 months of diagnosis to patients under the age of 80 with AJCC III (lymph node positive) colon cancer	Percentage of patients under the age of 80 with AJCC III (lymph node positive) colon cancer for whom adjuvant chemotherapy is considered or administered within 4 months of diagnosis.
385	Oncology: Chemotherapy for AJCC stage III colon cancer patients	Percentage of patients aged 18 years through 80 years with AJCC III colon cancer who are referred for adjuvant chemotherapy or have previously received adjuvant chemotherapy within the 12 month reporting period
220	Adjuvant hormonal therapy	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage I, II, III, whose primary tumor is progesterone or estrogen receptor positive recommended for tamoxifen or third generation aromatase inhibitor

		(considered or administered) within 1 year (365 days) of diagnosis
559	Combination chemotherapy is considered or administered within 4 months of diagnosis for women under 70 with AJCC T1c, or Stage II or III hormone receptor negative breast cancer	Percentage of female patients, age >18 at diagnosis, who have their first diagnosis of breast cancer (epithelial malignancy), at AJCC stage T1c, or Stage II, or III, whose primary tumor is progesterone or estrogen receptor negative recommended for multiagent chemotherapy (considered or administered) within 4 months of diagnosis
387	Oncology: hormonal therapy for Stage IC through IIIC, ER/PR positive breast cancer	Percentage of female patients aged 18 years and older with Stage IC through IIIC, estrogen receptor (ER) or progesterone receptor (PR) positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12 month reporting period

CMS also requests feedback on whether utilization measures should be included in the ACO measure set, in addition to the utilization data CMS already includes in the quarterly aggregate reports provided to ACOs. The MSSP aims to strike a balance between improved quality and cost savings. We believe ACOs hold promise in achieving this goal and that quality and efficiency can and should go hand-in-hand. The financial incentives in the program structure could discourage delivery of some needed care and adoption of new treatments. We believe that well-designed quality measures help to reduce the risks associated with financial incentives tied to reduced spending and ensure that patients are receiving the right types of treatment to achieve desired health outcomes. Many patients will present with conditions for which quality measures are not available or not included in the proposed rule. For these patients, cost reduction incentives may not be adequately balanced by countervailing quality measures.

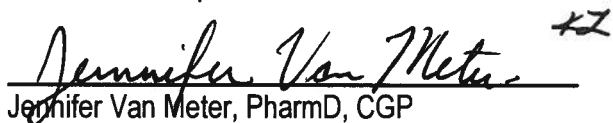
Given the cost reduction incentives in ACOs, it is critical that care be taken not to create structures or incentives that discourage use of new, innovative treatments. Adding utilization measures could increase the risk of ACOs stinting on patient care by adding to the cost reduction incentives inherent in shared savings an extra incentive to reduce utilization to achieve a better quality score. As noted by CMS, ACOs have an intrinsic incentive to contain costs in order to achieve shared savings. In light of this, we oppose inclusion of cost or utilization measures as an additional performance measure as unnecessary and potentially undermining care quality and individual patient access to optimal medical care. Instead, we think that quality measures that span the range of conditions and care continuum are appropriate to ensure that utilization is not reduced through lack of care or underutilization.

PhRMA appreciates the opportunity to comment on this proposed rule, and we hope our comments will be useful to CMS as it develops the final physician fee schedule rule for 2015. Please feel free to contact us if there is any further information we can provide or if you have any questions about the topics discussed in our comments.

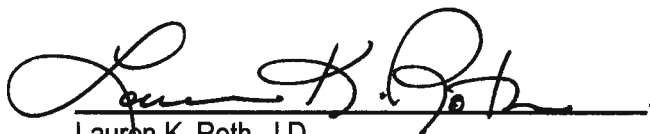
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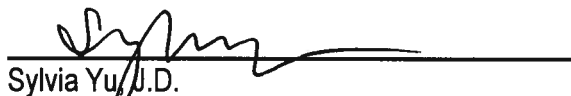
Randy Burkholder
Vice President, Policy & Research



Jennifer Van Meter, PharmD, CGP
Senior Clinical Director, Policy & Research



Lauren K. Roth, J.D.
Assistant General Counsel



Sylvia Yu, J.D.
Assistant General Counsel

Appendix A

Source: <http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2013-08-07NPC-OpenPayments.pdf>

**CONTINUING MEDICAL EDUCATION
Physician-Attendees and Physician Faculty/speakers**

Indirect payments associated with CME activities:	Physician-Attendees	Physician-Faculty/Speakers	Physician-Attendees	Physician-Faculty/Speakers
	Accredited or certified *		Non-accredited or non-certified	
Meals**	✓	X	✓	✓
Travel and Lodging	✓	X	✓	✓
Tuition Fees	X	X	✓	✓
Educational Materials included in CME Tuition Fees	X	X	✓	✓
Educational Materials not included in CME Tuition Fees	✓	X	✓	✓

* Must meet all of the conditions in accordance with § 403.904(g)(1)

** Special rules apply in accordance with § 403.904(h)