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Association**

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Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1600-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Proposed Rule (Vol. 78, No. 139), July 19, 2013

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) physician fee schedule (PFS) proposed rule for calendar year (CY) 2014.

We support the agency's proposals to expand telehealth services to rural areas located within Metropolitan Statistical Areas (MSAs) and to pay physicians for complex chronic care management services. **However, we strongly oppose full application of the therapy cap to critical access hospitals (CAHs). This proposal would limit access to outpatient therapies for rural Medicare beneficiaries and is not required by existing statute.** In addition, we are deeply concerned that physician payments will decline by an estimated 24 percent on Jan. 1, 2014 due to the flawed sustainable growth rate formula. Cuts of this magnitude are unsustainable. **We urge CMS to work with Congress to fix the flawed physician payment formula, and to do so in a manner that does not result in reduced payments to hospitals and other providers.** Our detailed comments follow.

APPLICATION OF THERAPY CAPS TO CAHS

While Section 1833(g)(1) of the *Social Security Act* exempts outpatient therapy services delivered in a hospital from the cap on outpatient therapy services, Congress has temporarily suspended the exemption. *The Middle Class Tax Relief and Job Creation Act of 2012* (MCTRJCA) suspended the exemption from Oct. 1 through Dec. 31, 2012, and the *American Taxpayer Relief Act of 2012*



(ATRA) further extended it to Dec. 31, 2013. Beginning Jan. 1, 2014, outpatient therapy services delivered in a hospital will no longer be subject to the therapy cap, unless Congress acts to extend the provision.

CMS has long interpreted the exemption for hospital outpatient therapy services to include therapy services delivered in CAHs. The MCTRJCA provision that suspended the exemption specifically applied to hospitals paid under the outpatient prospective patient system (PPS); therefore, CMS continued to exempt CAHs from the cap. However, the ATRA instructed CMS to apply the cost of outpatient therapies provided by CAHs to the therapy cap using the amount that would be payable if those services had been paid under the outpatient PPS. As a result, CMS reassessed and now proposes to reverse its longstanding interpretation of existing statute by subjecting CAHs to the therapy cap beginning Jan. 1, 2014. **The AHA strongly opposes application of the therapy cap to CAHs.**

We urge CMS to rescind its proposal and continue to exclude CAHs from the outpatient therapy cap, consistent with its longstanding interpretation of existing statute. The law does not require CMS to interpret the exemption in the manner it proposes. Although the ATRA provided CMS with a proxy to use in applying the cost of outpatient therapies provided by CAHs to the therapy cap, it only directed CMS to use the proxy for outpatient therapy services furnished after Jan. 1, 2013 and before Jan. 1, 2014. There is *no clear* indication that Congress intended CMS to apply the cost of outpatient therapies provided by CAHs to the therapy cap beyond Jan. 1, 2014. Further, it is clear from this ATRA provision that Congress was aware that CMS has historically exempted CAHs from the therapy cap. If Congress did not agree, it could have expressly stated that CAHs should be subject to the cap. Congress did not do so, which indicates that it agreed with CMS's longstanding exemption of CAHs from the therapy cap.

The result of CMS's proposal would be limited access to outpatient therapies for rural Medicare beneficiaries – the direct opposite of what Congress intended when it created the CAH designation. CAHs provide health care services to Medicare beneficiaries in rural areas who would otherwise be unable to access hospital services. If CMS subjects CAHs to the therapy cap, once Medicare beneficiaries who rely on CAHs for outpatient therapies reach the cap (currently \$1,900), they would be forced to pay for additional therapies out-of-pocket or travel potentially long distances to a PPS hospital to obtain these critical services. This would impose an undue burden on the sickest Medicare beneficiaries and may result in their inability to access needed care.

Additionally, it is unlikely that CMS's proposal would result in significant cost savings or reduce unnecessary care. CAHs receive less than 5 percent of total payments to acute care hospitals, which indicates that expenditures on outpatient therapies provided by CAHs are relatively low. Further, CAHs already have in place regulations that control the utilization of therapy services. For example, under § 409.17, a physician must order outpatient therapy services performed in a CAH; without the physician order, therapists and other eligible providers are unable to initiate a plan of care. In contrast, physician orders are not required for therapy services performed in other settings, such as in nursing homes or therapists' private practices. The physician's order requirement helps guarantee that CAHs are providing medically necessary therapy services, and

therefore imposing the therapy cap on CAHs would simply limit access to those medically necessary services.

Finally, as CMS itself recognizes, effective Jan. 1, 2014, therapy services furnished in CAHs would be treated differently than therapy services furnished in other outpatient hospital settings. This differential treatment seems arbitrary given that CAHs are subject to the same regulations regarding provision of outpatient therapies as hospitals paid under the PPS and provide essentially the same service.

POTENTIALLY MISVALUED CODES: OPPTS/ASC CAP

As part of its misvalued codes initiative, CMS identified services for which Medicare's payment when the service is furnished in the physician office exceeds the total Medicare payment when the service is furnished in a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC). The agency proposes to cap payments for nearly 200 identified services when provided in a physician office to the total payment made when the service is delivered in a HOPD or an ASC.

The AHA is pleased that CMS recognizes that hospitals and ASCs typically incur higher overhead costs in delivering services than physician offices. As CMS stated in the proposed rule, hospitals and ASCs must "maintain the capability to furnish services 24 hours a day and 7 days per week, furnish services to higher acuity patients than those who receive services in physician offices, and have additional legal obligations such as complying with the *Emergency Medical Treatment and Active Labor Act* (EMTALA). Additionally, hospitals and ASCs must meet Medicare conditions of participation and conditions for coverage, respectively."

CMS estimates that most specialties would experience a limited impact under this proposed policy. However, some specialties would see a decrease in total allowed charges of 5 percent or more. **The AHA is concerned about the potential impact that cuts of this magnitude could have on affected specialties.** For example, CMS estimates that pathology and independent laboratories would experience decreases in total allowed charges of 8 percent and 27 percent, respectively. Reductions of this magnitude could have a devastating impact on the ability of independent laboratories to provide pathology services. This would, in turn, negatively impact small and rural hospitals that rely on these laboratories for pathology services so that they may provide surgical services to beneficiaries within their communities. **The AHA recommends that CMS further examine how these potential cuts could impact affected providers' ability to deliver quality care to Medicare beneficiaries before moving forward with this proposal.**

COLLECTING DATA ON SERVICES FURNISHED IN OFF-CAMPUS PROVIDER-BASED DEPARTMENTS

In nearly identical sections in the outpatient PPS and the PFS proposed rules, CMS cites recent reports of increasing trends of hospitals acquiring physician practices and integrating those

practices as HOPDs. The agency also notes concerns of the Medicare Payment Advisory Commission (MedPAC) about increasing Medicare program payments and beneficiary cost-sharing that could result from such acquisitions. Consequently, CMS requests comment regarding which of several potential information-gathering methods would best allow the agency to analyze the frequency, type and payment of services furnished in off-campus provider-based hospital departments. The agency is considering:

- Creating a HCPCS modifier that would be reported with every code for services furnished in an off-campus provider-based department of a hospital via the Medicare physician and hospital outpatient claim forms;
- Asking hospitals to break out the costs and charges for their provider-based departments as outpatient service cost centers on the Medicare hospital cost report; and
- Creating a new place of service code for off-campus departments of a provider.

We agree with CMS that “hospitals...have overall higher resource requirements than physician offices because hospitals are required to meet the conditions of participation, to maintain standby capacity for emergency situations, and to be available to address a wide variety of complex medical needs in a community.” And, it is reasonable for CMS to seek ways to evaluate the trend of hospital acquisition of physician practices. While we understand CMS’s interest in learning more about this rapidly changing environment, **the AHA is concerned that the potential information-collection approaches would create additional administrative burden for hospitals and physicians and would interfere in the ability to bill consistently across payers. However, if CMS is intent on moving forward to collect such information, the least burdensome approach would be to create a new HCPCS modifier to be reported with services that are furnished in off-campus provider-based departments of the hospital. To ensure that the information collected is meaningful and comparable across payment systems, the AHA further recommends that CMS utilize the same approach in the PFS and the outpatient PPS.**

That said, the AHA urges CMS to refrain from using the information it would collect as a means to justify implementing “site-neutral” payment reductions, such as the policies that MedPAC and Congress have been pursuing in the context of federal budget cuts. Instead, CMS should recognize that this trend may reflect efforts by hospitals and health systems to provide and improve more integrated and coordinated care delivery which focuses on appropriate utilization, efficiency and outstanding measureable outcomes.

MEDICARE TELEHEALTH SERVICES

Under current law, Medicare beneficiaries are eligible for telehealth services only when those services are provided from an originating site located outside of a Metropolitan Statistical Area (MSA) or in a rural Health Professional Shortage Area (HPSA). Earlier this year, the Office of Management and Budget updated the MSAs based on the 2010 census data. As a result, the designation of nearly 100 counties changed from rural to urban. Therefore, Medicare beneficiaries who receive care in these newly urban counties are no longer eligible for telehealth services. **The**

AHA appreciates CMS's proposal to modify the geographic criteria for originating site eligibility to define rural HPSAs as those HPSAs located in rural census tracts, as determined by the Office of Rural Health Policy (ORHP). This modification will expand access to health care services for Medicare beneficiaries by allowing some rural areas within MSAs to be eligible for Medicare telehealth services.

We are concerned, however, that CMS's proposed definition of a rural HPSA for this purpose is not the definition of a rural HPSA used for rural health clinic qualification (essentially, a federally designated shortage area or a non-urbanized area, as defined by the U.S. Census Bureau). As a result, there may be existing rural health clinics that would be unable to provide telehealth services to Medicare beneficiaries. **The AHA urges CMS to modify its proposal to avoid this discrepancy and further expand its geographic criteria for originating site eligibility to include both non-urbanized areas, as defined by the U.S. Census Bureau, and those rural HPSAs located in rural census tracts, as determined by ORHP.**

CMS also proposes to add transitional care management services (CPT codes 99495 and 99496) to its list of approved Medicare telehealth services. **The AHA supports this proposal.**

Finally, the AHA appreciates and supports the agency's efforts to avoid sudden disruptions to beneficiaries' access to telehealth services by proposing to establish geographic eligibility for originating sites on an annual basis.

REQUIREMENTS FOR BILLING "INCIDENT TO" SERVICES

CMS proposes to require, as a condition of payment, that an individual who provides services and supplies "incident to" a physician's professional services must meet any applicable state requirements, including licensure, and that services and supplies must be provided in accordance with state law. The agency states that it is proposing this regulation to advance the health and safety of Medicare beneficiaries who receive services and supplies incident to a physician's services.

It is reasonable for CMS to expect that individuals who provide services and supplies incident to a physician's services do so in compliance with state law. However, the AHA is concerned with the broad nature of CMS's proposed regulatory text, which states that "[s]ervices and supplies must be furnished in accordance with applicable State law" and that individuals who provide "incident to" services must meet "any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished." Such a broad requirement would allow CMS to deny Medicare payment for technical violations of state laws that are not targeted at patient health or safety, even when care was appropriately delivered and the quality of care was not affected.

In addition, the proposed language goes farther than the existing regulations that CMS cites as examples for comparison in the rule (such as § 410.20(b), regarding physicians, and § 410.75(b), regarding nurse practitioners). Those regulations require that the relevant provider act within the

scope of practice as determined by state law – that is, the regulations focus on whether the state allows the provider to deliver the services in question. This is a more limited requirement than CMS’s proposal that those providing “incident to” services do so “in accordance with applicable State law” and must meet “any applicable requirement.” **We ask that CMS limit its proposal to declare that those providing services and supplies “incident to” a physician’s services must be licensed, trained or otherwise authorized to deliver those services under state law.**

Specifically, we urge CMS to amend proposed § 410.26(a)(1) to read: “(1)Auxiliary personnel means any individual who is acting under the supervision of a physician . . . and meets any applicable licensure, certification, or training requirements to provide the services imposed by the State in which the services are being furnished.” This would satisfy the Office of Inspector General’s concern, cited by CMS in the proposed rule, that only “non-physicians who have the necessary training, certification, and/or licensure, pursuant to State laws, State regulations, and Medicare regulations” provide “incident to” services and supplies, and would be consistent with existing regulations that require practitioners to be licensed or otherwise qualified in compliance with state law. Further, we ask that CMS eliminate proposed § 410.26(b)(7), which is overly broad and which seems redundant when read in conjunction with § 410.26(a)(1).

COMPLEX CHRONIC CARE MANAGEMENT

The AHA applauds CMS for acknowledging the critical importance of managing care for Medicare beneficiaries with complex chronic conditions and improving the quality of care for these beneficiaries while potentially reducing costs. Specifically, CMS proposes to create two new G-codes to explicitly pay physicians and qualified non-physician practitioners (NPPs) for chronic care management services. Providers who deliver at least 60 minutes of complex chronic care management services to a patient over a 90-day period could bill one code for the initial 90 days of services and a second code for a 90-day period of subsequent services. The AHA supports the creation of these codes as they would help improve care coordination and potentially decrease unnecessary emergency room visits and hospital readmissions.

CMS’s proposal, however, would impose a number of requirements on providers who seek to bill for complex chronic care management services, including a detailed informed consent procedure and notification to the beneficiary prior to billing. **In addition to the specific concerns about the proposed requirements and standards that we note below, the AHA urges CMS to consider generally whether implementation of additional requirements and standards would prove prohibitively burdensome to providers when considering whether to provide these services.**

Proposed Beneficiary Education Requirement. Providers would be required to educate beneficiaries on their coinsurance liability for these services. However, this will be difficult given that the proposed complex chronic care management codes would not include a face-to-face visit. Rather, the physician or NPP would bill and be paid for these services separately from a medical visit without seeing the patient. In addition, we are concerned that this would lead to increased bad debt for the physician. **The AHA urges CMS to work with Congress to waive beneficiary cost-sharing responsibilities for complex chronic care management services**, similar to how the *Patient Protection and Affordable Care Act* (ACA) waived beneficiary cost-sharing for certain

approved preventive services. If the law is not changed, then CMS must provide beneficiaries with significant education about this provision. For example, CMS should provide physicians with patient materials that explain the new codes and a beneficiary's 20 percent coinsurance responsibility.

Proposed Standards. CMS seeks comment on potential standards for providers of complex chronic care management services, including use of electronic health records (EHRs) that meet the most recent Department of Health and Human Services (HHS) standard for meaningful use. **The AHA discourages the agency from including meaningful use as a standard for complex chronic care management providers.** Currently, meaningful use is measured on an annual basis, and physicians can miss the requirements by a small amount and not meet meaningful use. This would then preclude them from receiving reimbursement for providing complex chronic care management services. Linking these services to meaningful use also could unnecessarily deny Medicare beneficiaries the benefit of care management. **The AHA believes that it is premature to link these services to meaningful use, and that its use as a standard should be delayed until the meaningful use policy has been stabilized and more physicians have achieved meaningful use.** CMS has reported that as of June 2013, only 44 percent of eligible professionals (EPs) have attested that they have attained meaningful use.

If CMS moves forward with meaningful use as a standard for providers of complex chronic care management services, we ask that the agency clarify how a provider new to Medicare or new to a practice would be treated. We are concerned that these providers would have to delay providing care management for a full year until they have met meaningful use, denying their patients the benefit of those services. Further, we request that CMS clarify how it would treat a provider who has previously met meaningful use, but then fails to do so in a subsequent year. Would the provider be required to pay back complex chronic care management payments? Would the provider have to stop providing these services to Medicare beneficiaries in the future?

In addition, the AHA urges CMS to allow providers to bill for subsequent services whenever they are delivered. Under CMS's proposal, providers may bill for subsequent services only when the medical needs of the patient require substantial revision of the care plan, which the agency states would typically occur when the patient's clinical condition changes significantly. However, it is clear in the rule that CMS considers complex chronic care management services to be ongoing services that would include 24-hours-a-day, seven-days-a-week access to the provider; management of care transitions; coordination with home and community-based clinical service providers; and enhanced opportunities for communication via telephone and other non-face-to-face methods. It is clear that providers of these services would be expected to make themselves available whenever the beneficiary needs them, and those circumstances may not be limited to a change in the patient's condition. Providers should therefore be allowed to bill for subsequent services whenever they have provided services beyond the threshold of 60 minutes in a 90-day period.

UPDATING CLINICAL LABORATORY FEE SCHEDULE PAYMENTS

In the proposed rule, CMS outlines a process to reconsider payment amounts for laboratory tests that takes into account increased efficiency and other changes driven by technological advances. The agency intends to review all 1,250 existing codes on the clinical laboratory fee schedule (CLFS) to determine whether payment adjustments are warranted as a result of technological changes. CMS expects that most payment adjustments would decrease fee schedule amounts but upward adjustments also might be proposed.

Over a five-year period using the annual PFS rulemaking process, CMS would issue a proposed rule discussing the technological changes for the specific tests for which the agency is proposing a payment adjustment and soliciting public feedback within 60 days. The first round of this review would be finalized in the CY 2015 PFS final rule. Once CMS has completed this five-year review of current CLFS codes, the agency proposes to review codes added to the CLFS after 2015 that have been on the fee schedule for at least five years. Additionally, after the initial review of current CLFS codes is completed, CMS would allow the public to nominate additional codes for review.

The AHA agrees that it is appropriate to develop a process to review and adjust the payments for laboratory services to reflect technological changes in testing. However, CMS's goal to review the entire set of CLFS laboratory tests within a five-year period may be overly ambitious, especially if the agency truly intends the process to "best allow for the greatest amount of transparency in review and the most structured and consistent opportunity for the public to provide input." The agency's proposed review process is an enormous undertaking and its complexity should not be underestimated. According to the proposed approach, CMS would review about 250 tests a year for "technological changes." The agency's recent laboratory-developed tests (LDT) gap-filling exercise, which involved far fewer tests, revealed how difficult it is for CMS and its Medicare administrative contractors (MACs) to arrive at accurate, fair prices that are based on solid and reliable data.

We encourage CMS to implement the review over a longer time period to allow for an adequate opportunity for stakeholder input about the review process prior to the start of the annual rulemaking and to allow for a smaller set of codes to undergo review during the annual rulemaking cycle.

In addition, the AHA recommends that CMS consider the following points as it develops and implements its review process:

- CMS should recognize and account for the differences between large and small laboratories. Technology changes are not monolithically applied within the laboratory industry. Larger laboratories may have the capital to make technology investments that smaller laboratories, such as hospital laboratories, do not.
- This should not be a unidirectional exercise, whereby prices on the CLFS only go down. CMS should be open to the notion that technological changes have added costs to many

tests and should be willing to pay for the increased costs that also have been realized since the CLFS was first established.

- The review process CMS finalizes must be fully transparent. The agency must be clear about what it is doing, on what basis, and how. Based on the laboratory community's recent experience with gap-filling and the difficulties it encountered in obtaining transparent information about the analyses, we do not think CMS should use its MACs for this exercise. However, if the agency uses MACs for any part of this process, the instructions they receive should be clear, consistent and available to all stakeholders.

The AHA recommends CMS develop a plan for engaging key stakeholders in the laboratory community, including hospitals, prior to the start of the CY 2015 PFS proposed rule in order to assist CMS in selecting the codes for review and assessing changes in technology and their associated costs. Stakeholder engagement would help establish a transparent and structured process for public input. In addition, early stakeholder buy-in would lend greater legitimacy and credibility to the revised laboratory test values.

PHYSICIAN VALUE-BASED PAYMENT MODIFIER (VBM)

The ACA requires CMS to implement a VBM that would apply to Medicare fee-for-service payments for certain physicians on Jan. 1, 2015, and to all physicians and physician groups by Jan. 1, 2017. The modifier would result in differential physician payments based on the quality of care provided and the cost of that care. The law did not specify the amount of the VBM, only that the VBM program must be budget neutral.

VBM for Hospital-based Physicians. The AHA continues to urge CMS to develop a VBM modifier program tailored to hospital-based physicians. We were pleased that the agency solicited comments on how to develop a VBM for hospital-based physicians in last year's proposed rule, and we remain keenly interested in working with CMS to develop such a program. Moreover, given the significant expansion of the number of physicians and groups eligible for the VBM proposed in this year's rule, we believe the window to develop a hospital-based physician VBM program is rapidly closing.

For hospitals, greater physician integration represents the potential to better align goals and processes across the care continuum. Today, hospitals employ more than 225,000 physicians, representing about 30 percent of those practicing – a 44 percent increase over the past decade. In addition to direct employment, hospitals often contract with physicians on a group or individual basis, such as emergency physicians or hospitalists. Aligning the physician VBM program with the hospital value-based purchasing (VBP) program would be desirable and would accelerate performance improvement by jointly focusing provider efforts.

Payment Adjustment. CMS proposes to increase the maximum downward payment adjustment under the VBM program from 1 percent in CY 2015 to 2 percent in CY 2016. This maximum penalty would apply to groups that have not successfully participated in the Physician Quality

Reporting System (PQRS), as well as to groups that score as poor performers using CMS's VBM scoring methodology, the Quality Tiering Model (QTM).

In this rule, CMS proposes that all groups must be scored using the QTM, whereas QTM scoring was previously optional. To determine a group practice's VBM score, the QTM calculates two composite scores – one based on the quality measures reported by the group, and another based on cost measures calculated by CMS. The QTM compares the quality of care composite score with the cost composite score, and classifies both scores into high, average and low performance categories.

Given that CY 2016 is the first year that all physician groups will be scored on the QTM, the AHA urges CMS to delay increasing the maximum penalty under the program until at least CY 2017. CY 2015 is the first year in which the QTM will be used to adjust physician payments based on quality, and participation is optional. CMS will not have full data to calculate the CY 2015 VBM until after the close of CY 2013. Therefore, CMS will have had only one year of experience with implementing a highly complex model before it needs to calculate the VBM for all physicians in CY 2016. Moreover, given that participation in the QTM for CY 2015 is not required, physician groups will have little time to fully understand their baseline performance under the model. By delaying the increase of the maximum penalty, CMS will gain experience with applying the VBM to a broader variety of groups, and physician groups will increase their understanding of their performance on the model.

CMS proposes that the VBM would apply to physician groups of 10 or more physicians beginning in CY 2016. The agency further proposes that groups between 10 and 99 eligible professionals (EPs) that successfully meet PQRS reporting requirements in CY 2014 would not be subject to a negative payment adjustment. Such groups would receive either a positive or 0 percent payment adjustment. **The AHA supports this proposal.**

Medicare Spending per Beneficiary (MSPB). The AHA does not support the addition of the MSPB measure to the VBM's cost composite. The MSPB measure is not intended to assess physician group performance, and the proposed attribution methodology is untested and inappropriate for the VBM. The MSPB measure includes all Medicare Part A and Part B payments during a care episode, and is currently used in the hospital inpatient quality reporting (IQR) and VBP programs. CMS defines a care "episode" as three days prior to an index admission to a subsection (d) hospital through 30 days post discharge. An "index admission" is the first patient admission to a hospital within the episode timeframe. Any subsequent hospital admissions that occur during the episode timeframe are considered "rehospitalizations," and the payments for those rehospitalizations are included in the episode. However, all payments within the episode timeframe – including those for rehospitalizations – are attributed to the hospital of the index admission. The payments for each episode are risk-adjusted to account for age and severity of illness. The payment amounts captured in the measure are "standardized," in that the effects of geographic payment adjustments and other payment factors are removed.

The MSPB measure is currently being reviewed for National Quality Forum (NQF) endorsement by the Cost and Resource Use Steering Committee. The measure testing data presented to the

steering committee appears to assess whether the measure reliably reports hospital-level, not physician group-level, performance. **At a minimum, we believe the measure would need to be re-specified and re-tested at the physician group-level before it is considered for the VBM.**

It also does not appear that CMS has asked the NQF Cost and Resource Use Committee to review the proposed MSPB measure attribution methodology for the VBM. The manner in which measure results are attributed is directly related to accountability for performance and the measure's overall accuracy. The attribution of MSPB episodes to physician groups also is complex because physicians within a group may be involved with a patient's inpatient care, post-discharge care, or both during a given episode. **If CMS wishes to include the MSPB measure in the VBM, it is imperative that the agency fully test and seek NQF endorsement of the attribution model.**

Lastly, we are concerned that the MSPB attribution model in the VBM may not encourage alignment and coordination of efforts between hospitals and physicians. The attribution models used in the hospital programs and the VBM are quite different. In the hospital IQR and VBP programs, an MSPB episode is assigned to the hospital with the index admission. For the VBM, by contrast, CMS proposes to attribute an MSPB episode to a physician group when any EP in the group submits a Medicare Part B claim under the group's Tax Identification Number (TIN) for services provided during the episode's index hospitalization. The services would need to be provided during the VBM performance period. Because of this attribution methodology, it is possible for the same index admission and corresponding MSPB episode to be attributed to more than one physician group. CMS believes that this attribution model will encourage greater coordination of care between physicians and hospitals and enable more than 11,000 physician groups to be scored on the measure.

We agree that the management of episode costs is a shared responsibility of all of the providers involved in a patient's care – hospitals, physicians and post-acute providers. However, physicians and physician groups are involved in inpatient care to a varying degree, with some being highly involved, and others not. Thus, we do not believe it is appropriate that episodes – and accordingly, all the costs included in those episodes – are attributed to *any* physician group. Suppose, for example, a patient requires a consult from a gastroenterologist during his or her index hospitalization, but does not require any follow up gastroenterology care post discharge. The group to which that gastroenterologist belongs would have that patient's MSPB episode costs attributed to it, even though that group had very little role to play in the patient's overall care episode.

If CMS wishes to use the MSPB measure in the VBM, the agency should develop and test an attribution methodology more closely aligned with the measure used for hospitals. For example, given that hospitals are attributed an MSPB episode if they provide care during the index hospitalization, we believe it may be more appropriate to attribute an MSPB episode to a physician group if it provides the plurality of Part B services during an index hospitalization. This approach may allow hospitals and physician groups that work together most frequently to work collaboratively on cost reduction efforts. Regardless of the attribution method chosen, it must be fully tested and endorsed by the NQF.

PHYSICIAN QUALITY REPORTING SYSTEM

PQRS is a pay-for-reporting program that ties the successful reporting of quality measures to payment incentives through CY 2014 and payment penalties beginning in CY 2015. To earn an incentive or avoid a penalty, individual EPs and group practices are required to report data on quality measures for covered services provided to Medicare Part B recipients during an applicable data reporting period. As finalized in the CY 2013 PFS rule, a “group practice” is defined as having two or more EPs, as identified by their National Provider Numbers (NPIs), who have reassigned their Medicare billing rights to a single TIN.

Group Practice Reporting Option (GPRO) Patient Experience Survey Reporting. Beginning with CY 2014 reporting, CMS proposes to allow group practices of 25 or more EPs to count the reporting of the Clinician Group Consumer Assessment of Healthcare Providers and Systems (CG CAHPS) towards PQRS requirements. To support this new option, the agency proposes to require the eligible group practices to collect and report CG CAHPS survey data using certified survey vendors. To obtain CMS certification, CG CAHPS survey administration vendors would be required to undergo training, comply with CMS’s survey administration processes and standards, and submit a quality assurance plan. Group practices that wish to report CG CAHPS survey data would be required to elect this option on the GPRO registration website.

In general, the AHA supports allowing physician groups to count the reporting of CG CAHPS survey data towards PQRS reporting requirements. Indeed, several of our member hospitals with employed or affiliated physicians are already using the CG CAHPS survey to obtain data that supports their efforts to improve the patient experience in their physician practices. **However, the AHA is concerned that the survey administration timeframe and attribution approach limits the kinds of group practices that can use the voluntary CG CAHPS reporting option, and restricts how group practices collect CG CAHPS data. We recommend several changes that would enable more physicians to use the CG CAHPS reporting option, and provide greater flexibility in how the survey is implemented. We also urge the agency to recognize the significant costs of collecting patient survey data by considering the use of less expensive survey collection modes, such as e-mail and web-based surveys.**

Survey Attribution Approach. CMS proposes that the CG CAHPS survey would be administered by survey vendors to participating physician groups. However, it does not appear that group practices can work directly with the survey vendors to create the list of patients that would be sampled to collect survey data. Instead, beneficiaries would be assigned to a physician group based on whether the group provides the plurality of primary care services to the patient. Because of this attribution methodology, the agency notes that the survey is “not an appropriate option for groups of physicians...that do not provide primary care services,” such as surgeons. The proposed attribution methodology also is used for physician groups participating in the GPRO web interface reporting option, and for Accountable Care Organizations (ACOs) using that same interface for the Medicare Shared Saving Program (MSSP).

We believe the proposed attribution methodology unnecessarily limits the type of group practices that can use the CG CAHPS reporting option. The large, and often multi-specialty group practices that tend to use the GPRO web reporting interface are likely to have primary care physicians. However, other kinds of group practices may benefit from using the CG CAHPS survey to measure and improve the patient experience. Indeed, the CG CAHPS survey is designed for use in a variety of physician practices, not just primary care practices or large multi-specialty practices. We believe that the CG CAHPS reporting option should be an option that benefits *all* kinds of group practices in the years to come.

We also are concerned that the proposed attribution approach, when coupled with the survey administration timeframe, would limit the usefulness of CG CAHPS data for benchmarking and improvement purposes. CMS proposes to administer the survey only after groups have self-nominated in September, with data collection taking place later the same calendar year or early in the subsequent calendar year. This would provide a limited window of CG CAHPS data. Moreover, because patients would be attributed to practices late in the year, group practices would have limited ability to track the experience of their patient populations over time.

Instead of the proposed attribution approach, CMS should work with the Agency for Healthcare Research and Quality (AHRQ) to update AHRQ's existing survey sampling and administration guidelines, thereby allowing group practices to identify their own lists of patients attributable to them for the survey. With updated survey guidelines, the agency could commence CG CAHPS data collection during the last quarter of CY 2014, but allow practices to collect data throughout a given calendar year, starting in CY 2015. AHRQ has been the measure steward for the CG CAHPS survey for many years, and has already developed guidelines for identifying the patient population relevant to a group practice. It also has developed guidance for how to administer the survey.¹ Some of our members have used these guidelines to help craft their CG CAHPS survey administration approach.

We encourage CMS and AHRQ to solicit feedback from a broad variety of stakeholders to inform the design of the updated survey administration guidelines. We believe some of the guidelines – particularly the minimum sample size needed to report – should be revisited to ensure they are not unduly burdensome for groups to implement. Nevertheless, they offer a solid starting point.

Cost Burden of CG CAHPS. While the CG CAHPS survey instrument is available free of charge, groups would be required to work with survey vendors to administer the surveys. Those vendors also would likely provide hospitals with a performance report for internal use and facilitate data reporting to external agencies, such as CMS. Typically, group practices seek to obtain as much data as possible from these surveys. While these additional data add rigor to patient experience performance improvement efforts, physician groups must pay higher fees to obtain a larger sample size of responses.

Therefore, the AHA urges CMS to allow group practices to use less costly survey administration modes, such as e-mailed or web-based surveys, to mitigate the costs of

¹ See http://cahps.ahrq.gov/clinician_group/cgsurvey/fieldingcahps-cgsurveys.pdf

administering CG CAHPS. The CG CAHPS survey administration protocol from AHRQ provides guidelines for administering surveys via e-mail, and CMS should allow practices to use them. Electronic survey distribution modes make survey data collection and aggregation less expensive, and may allow hospitals to increase sample size without greatly increasing costs.

Qualified Clinical Data Registry Reporting Option for Individual EPs. As mandated by the ATRA, CMS proposes to add a new mechanism for individual EPs to satisfy PQRS program requirements – participation in a CMS-qualified clinical data registry. In the rule, the agency defines a qualified clinical data registry as a “CMS-approved entity (such as a registry, certification board, collaborative, etc.) that collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care furnished to patients.” The rule proposes several requirements that qualified clinical data registries must complete to obtain CMS certification for use in meeting PQRS program requirements. CMS distinguishes the qualified clinical data registry option from the existing “qualified registry” option by noting that clinical data registries are expected to meet more challenging requirements. For example, qualified clinical data registries must have mechanisms for the transparency of data elements, measure specifications, risk models and benchmarking methods.

In general, the AHA supports the use of qualified clinical data registries, and appreciates that the agency proposes stringent qualification criteria for the registries. The number and type of clinical data registries has greatly expanded in recent years. However, the rigor of the data collection, validation and reporting capabilities of these registries varies. The criteria CMS has proposed have the potential to promote reliable and accurate data reporting.

However, adding this new reporting mechanism introduces another layer of complexity to the PQRS program. There are now multiple reporting mechanisms for individual EPs and group practices, but it is unclear to what extent the data generated from each reporting option are comparable. Our member hospitals also have expressed concern that clinical data registry participation requires considerable resources, ranging from subscription fees to the expertise of clinical personnel to abstract and report data. **For these reasons, CMS must carefully evaluate the experience of using this reporting option in the PQRS before expanding it to other quality reporting programs, including those for hospitals.** This would allow CMS to weigh the costs of participating in such registries with the benefits to all stakeholders.

Use of Retooled Hospital Quality Measures in PQRS. In response to feedback that measures from the hospital IQR program better reflect care provided by hospital-based physicians, CMS states that it has “retooled” seven measures currently reported in the hospital IQR program for use in PQRS, and proposes to include them in CY 2014 PQRS reporting. The agency solicits comment on whether it should retool additional IQR measures for use in PQRS.

We appreciate CMS’s recognition that physician groups and hospitals have become increasingly linked, necessitating stronger alignment of measurement across its quality reporting programs. **However, we urge CMS to provide additional information about how it has “retooled” these measures.** The proposed rule does not include updated measure specifications or testing results for the seven retooled measures. This information is important because the seven IQR measures

are specified, tested, and endorsed by the NQF for use in evaluating hospital quality. PQRS, however, is a quality reporting program for physicians and physician groups. **Without updated specifications and testing data, the AHA cannot be confident that the measures would accurately reflect physician and physician-group level performance and cannot comment on whether they should be included in PQRS.**

Moreover, a piecemeal migration of measures from the IQR program to PQRS would require considerable resources, and may not foster true integration of quality reporting and payment activities between hospitals and hospital-based physicians. Each measure imported from the IQR into PQRS would need its measure specifications updated, tested and NQF-endorsed to ensure it accurately captures physician and physician-group level performance. Given that measure development resources are limited, this approach is likely to be very time consuming and expensive. Moreover, the PQRS program and hospital IQR program rely on very different mechanisms for data reporting and performance benchmarking. This makes it possible to have disparate performance in each program. We believe that hospital-based physicians are invested not just in the performance of their group, but in the performance of the hospital as a whole. Indeed, many hospital-based physicians have reassigned their benefits to hospitals and health systems through various employment models. **For that reason, true integration of quality efforts requires that hospitals and hospital-based physicians be evaluated in the same manner.**

Instead of retooling measures, CMS should allow hospital-based physicians to fulfill PQRS reporting requirements by using their hospital's IQR and outpatient quality reporting (OQR) program. This approach is less cumbersome than retooling individual IQR measures for hospital-based physician groups. Hospital-based physicians and hospitals would be able to work on common performance targets. This approach also aligns with the AHA's repeated calls for CMS to develop a VBM program for hospital-based physicians. The inpatient measures have been in place for more than a decade and are well developed. While the outpatient measures have been adopted more recently, hospitals, and thus hospital-based physicians, are currently focused on reporting these measures and improving their performance. Including the hospital-based measures would be a positive step forward in aligning the incentives between hospitals and physicians, which would lead to improved quality and efficiency for patients.

To operationalize this approach, CMS should allow physicians and groups to self-designate whether they qualify as hospital-based. Hospitals also would be asked to confirm this relationship. CMS could allow physicians to self-designate hospital-based status through a process that is similar to how physician group practices currently self-designate for the PQRS program. If needed, the agency could set parameters that ensure a strong relationship between a physician and hospital. For example, CMS could require active membership on the medical staff or an employment contract. The agency could utilize claims data elements, such as inpatient and hospital outpatient department place of service codes, to validate the relationship.

PHYSICIAN COMPARE WEBSITE

Earlier this year, CMS initiated the collection of patient experience data through the CG CAHPS survey for two groups: 1) group practices submitting data via the GPRO web interface, and 2) ACOs participating in the MSSP. CMS administers the CG CAHPS surveys for these two groups based on a sample of their beneficiaries. CMS proposes to continue publicly reporting CG CAHPS survey data for group practices and ACOs with more than 100 EPs. **The AHA supports this proposal.**

CMS also proposes to publicly report CG CAHPS survey data for smaller group practices that voluntarily submit them to meet PQRS reporting requirements. **The AHA supports this change, but asks the agency to clarify the size of group practice for which it intends to publicly report CG CAHPS scores.** In one part of the rule, CMS states it intends to “publicly report on patient experience measures for 2014...for group practices of 25 or more professionals...” However, elsewhere in the *Physician Compare* section of the proposed rule, CMS proposes to publicly report CG CAHPS scores for “...any group practice (regardless of size) that voluntarily chooses to report CG CAHPS.” **We believe that group practices of 25 EPs or more are more likely to have statistically valid CG CAHPS data. Thus, the AHA urges CMS to report CG CAHPS scores for group practices of 25 EPs or more.**

MEDICARE SHARED SAVINGS PROGRAM

CMS proposes a methodology to increase the “spread” of performance on quality measures whose performance is tightly clustered around the same score. Specifically, CMS defines a “tightly clustered” measure as one whose performance scores across ACOs have a less than a 6-percentage point spread between the 30th and 90th percentiles. To increase the spread of scores across percentiles, CMS would use the 60th percentile as a starting point. CMS would then create “spread” by increasing or decreasing the 60th percentile score by one point for each decile between the 30th and 90th percentiles. CMS chooses these percentile thresholds because the 30th percentile is the “minimum attainment” level below which ACOs do not receive points for quality performance. Similarly, ACOs that score in the 90th percentile or above receive maximum points in the MSSP.

The AHA appreciates the intent behind this proposal; it is problematic to pay providers differently based on small differences in performance scores that are unlikely to be clinically meaningful. **However, we believe that CMS’s approach would still fail to pay ACOs based on true differences in clinical performance. Therefore, the AHA opposes this proposal.**

The purpose of pay-for-performance programs is to encourage lower performing providers to improve their performance, and to reward those providers that have demonstrated superior performance. When there is a very limited variation in performance, it is far less clear which providers have meaningfully distinguished themselves and are, therefore, deserving of higher payments. CMS’s approach would alter performance benchmarks, thereby creating a separation of performance among ACOs. **Nevertheless, a provider’s actual underlying performance**

relative to its peers would remain totally unchanged. CMS's approach would indeed create differences in payment, but those differences would be based on artificially created performance variation. In short, this approach creates spread within a performance cluster when it does not exist.

Performance benchmarks based on actual data give providers an accurate picture of the overall performance of the field, and allow them to understand their opportunities to improve performance. **Indeed, a tightly clustered performance distribution is a helpful and important signal to the field.** When providers are performing uniformly well, it indicates that measure performance may have "topped out." Measures with uniformly high performance should be retired from pay-for-performance efforts and replaced with others that have an opportunity for improvement. When performance is clustered but lower than desired, the field's improvement efforts may have plateaued and different improvement approaches may be needed. The field can then turn to providers that are "positive outliers," and learn the approaches such providers use to perform significantly better than the rest of the field. By assigning larger rewards to "positive outliers," providers have greater inducements to study and adopt the approaches of high performers. **Instead of seeking to create performance spread where it does not exist, CMS should structure its distribution of points to provide higher rewards to "positive outliers."**

For example, CMS could define "clustered performance" as it has proposed, but simply assign the same number of points to ACOs performing between the 30th and 90th percentile. In this way, providers in that range of performance would not be paid differently based on clinically insignificant differences in performance, and would be neither helped nor hurt in comparison to their peers. Moreover, the program would be more likely to achieve the goals of pay-for-performance – that is, to fairly reward those providers whose performance is clearly superior, and to better encourage the field as a whole to improve

EHR INCENTIVE PROGRAM

Claims-based Reporting Mechanism in PQRS. CMS seeks comment as to whether it should eliminate the claims-based reporting mechanism in PQRS in favor of an EHR-based reporting mechanism beginning with CY 2017, which is the reporting period for the 2019 PQRS payment adjustment. CMS notes that the claims-based reporting mechanism allows for the most errors in reporting. The AHA strongly supports the long-term goal of using EHRs to streamline and reduce the burden of quality reporting while increasing access to real-time information to improve care. **However, based on the experience of certified EHRs in support of quality reporting, it is premature to propose any specific date for the use of an EHR-based reporting mechanism in lieu of a claims-based mechanism for quality measure reporting.**

Providers have reported that electronic data capture using certified EHRs has significant problems that result in inaccurate assessments of performance. In 2011, CMS recognized this issue and provided sub-regulatory guidance stating that the EHR Incentive Program requires providers to attest only that quality measures were generated as output from the certified EHR in order to successfully demonstrate meaningful use. Therefore, providers are gaining experience in the use

of certified EHRs but have had very limited, if any, experience with generating and attesting to the accuracy of electronic quality measures in the Medicare EHR Incentive Program.

The electronic clinical quality measures (eCQMs) that must be reported by providers regardless of their year in meaningful use require a level of clinical documentation and the use of coded data fields that are far more extensive than the meaningful use Stage 1 requirements. Moreover, the certification process for EHRs specifically does not include testing the accuracy of the embedded measure calculations, nor does it examine if the needed data are, in fact, available in the EHR. It requires only that vendors, using their own data, show that their product can electronically produce numerators, denominators and exclusions in the required standardized format.

At this time, it is not yet known which quality measures EHR vendors will support. As outlined in the final rule for the standards and certification criteria of EHRs used in the EHR Incentive Program, eCQM requirements will move from attesting to obtaining the results from a certified EHR, to reporting of the actual results. However, vendors also will be permitted to select which eCQMs they will support under the “modular certification” construct in the EHR Incentive Program. They will not be required to support all eCQMs.

Therefore, the AHA recommends that CMS continue the option for the claims-based mechanism for quality measure reporting, while studying the experience of providers using EHR-based reporting to determine the appropriate timeframe for a transition from the claims-based reporting mechanism.

Reporting Electronically Specified Clinical Quality Measures. CMS proposes to require EPs participating in the Medicare EHR Incentive Program to report eCQMs in accordance with the 2013 version of the eCQM specifications or report eCQMs via attestation. As justification, the agency cites its inability to receive reports using different versions of the eCQM specifications. This statement highlights the misaligned mandates from government agencies that regulate different aspects of the EHR Incentive Program. As a result of the misalignment, CMS’s proposal would place the onus on providers to be accountable for meeting the eCQM reporting requirement, while relieving the EHR vendors of the requirement to offer products that support compliance with government mandates on their customers. Additionally, the proposal illustrates that CMS lacks an infrastructure for the receipt of multiple e-specifications. This directly conflicts with CMS’s communication that it will accept all versions of the eCQMs’ specifications for meaningful use, including those finalized in the Dec. 4, 2012 CMS-Office of the National Coordinator (ONC) interim final rule and the e-specifications released in June.

The AHA recommends that CMS address the underlying e-specification challenge rather than requiring all providers to use one set of approved e-specifications or creating an attestation option for electronic reporting of eCQMs. **Specifically, we recommend that CMS work with ONC to revise the development and implementation timeline for e-specifications for eCQMs.** A methodical process would ensure that accurate e-specifications enable a generation of eCQMs that are valid, feasible to collect and comparable to chart-abstracted measures, and would further support successful provider compliance with CMS quality reporting requirements.

Ms. Marilyn Tavenner

August 30, 2013

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In addition, **the AHA recommends that CMS improve its readiness to receive the data submitted in accordance with requirements included in the EHR Incentive Program and Medicare quality reporting programs.** CMS and ONC developed an infrastructure intended to address several aspects of the data capture and reporting challenges found in Stage 1. However, the process for reporting eCQM data to CMS remains problematic.

Once again, the AHA appreciates the opportunity to comment on the proposed rule for the PFS and offers our comments and insights to improve the operation, fairness and accuracy of the Medicare program for its beneficiaries. If you have any questions concerning our comments, please feel free to contact me or Melissa Jackson, AHA senior associate director for policy, at (202) 626-2356 or mjackson@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President