

September 8, 2015

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

RE: CMS-1631-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule (Vol. 80, No. 135), July 15, 2015.

Dear Mr. Slavitt:

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) 2016.

Our detailed comments (attached) also address CMS's proposals related to the Electronic Health Record Incentive Program; the Medicare Shared Savings Program (MSSP) and the request for information on the future Merit-based Incentive Payment System. However, several areas of comment deserve particular emphasis:

- The AHA is pleased that CMS proposes to pay for advanced care payment services, which are critical for encouraging Medicare providers and beneficiaries to discuss and make known a beneficiary's treatment preferences.
- The AHA supports CMS's proposal to add two new codes to its list of approved Medicare telehealth services and encourages the agency to consider adding other services in future rulemaking.
- The AHA supports CMS's creation of new exceptions to the Stark prohibition on physician self-referral. We urge the agency to create an exception that would protect hospitals and physicians who enter into financial arrangements necessary to building clinically and financially integrated models of care.



In addition, while the AHA shares CMS's goal of promoting physician quality improvement, we strongly urge the agency to adopt the following changes to its physician quality measurement proposals:

- The AHA applauds CMS's proposal to exempt participants in certain Centers for Medicare and Medicaid Innovation (CMMI) from the CY 2017 and CY 2018 value-based payment modifier (VM). However, we strongly urge CMS to also exempt MSSP participants from the VM to avoid potentially inappropriate comparisons of performance, strengthen the incentive for physicians to participate in innovative care delivery models and minimize the risk of sending "mixed signals" to physicians about their quality performance.
- The AHA supports CMS's proposal to limit the mandatory reporting of the Physician Quality Reporting System Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey to groups using the Group Practice Reporting Option web interface for CY 2018. However, we urge CMS not to expand mandatory CAHPS reporting to groups smaller than 100 eligible professionals until it allows the use of more modern and economical methods to collect survey data, and shortens the excessively long CAHPS survey instrument. We also urge CMS to ensure that CAHPS survey data from smaller practices are reliable and accurate before tying payment to or publicly reporting those data.

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

Sincerely,

/s/

Tom Nickels
Executive Vice President

**American Hospital Association (AHA)
Detailed Comments on the Physician Fee Schedule (PFS)
Proposed Rule for Calendar Year (CY) 2016**

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American Hospital Association Detailed Comments

ADVANCED CARE PLANNING SERVICES

The AHA applauds CMS's proposal to pay explicitly for advanced care planning (ACP) services provided to Medicare beneficiaries. In the CY 2015 PFS final rule, CMS created two new Current Procedural Terminology (CPT) codes (99497 and 99498) that describe ACP services, which include the explanation and discussion of advance directives to a Medicare beneficiary by a physician or other qualified health professional. However, CMS assigned the codes an inactive status, which means they are not payable under Medicare. CMS now proposes to activate and pay for the two ACP codes, and states that they should be reported when the “described service is reasonable and necessary for the diagnosis or treatment of illness or injury.”

ACP services are critical for beneficiaries with progressive or terminal illnesses, and have been shown to have a significant, positive impact on patient quality of care. These services allow providers and their patients to discuss and make known the patients' treatment preferences. Though some ACP services have been conducted under evaluation and management (E/M) codes, those codes are not appropriate for the potentially lengthy encounters that may be needed for patients with complex needs, involving extensive discussions with patients and their family members regarding short-term and long-term treatment options. As the patients' conditions progress or as treatments fail, there may be additional discussions regarding other options, such as hospice and palliative care. **We urge CMS to finalize its proposal to pay for ACP services, which is a good step to help ensure that Medicare beneficiaries will be able to develop advanced care plans in conjunction with their medical care providers.**

MEDICARE TELEHEALTH SERVICES

The AHA supports the agency's proposal to add new CPT codes to its list of approved Medicare telehealth services. Specifically, CMS proposes to add “prolonged service in the inpatient or observation setting” (99356 and 99357) and “end-stage renal disease-related services for home dialysis” (90963, 90964, 90965 and 90966). Covering these telehealth services will expand access to care for Medicare beneficiaries, particularly in rural areas.

Hospitals are embracing the use of telehealth technologies because they offer benefits, such as virtual consultations with distant specialists, the ability to perform high-tech monitoring without requiring patients to leave their homes, and less expensive and more convenient care options for patients. However, significant barriers to the expansion of telehealth exist, limiting its use and potential. Coverage and payment for telehealth services remains a major obstacle for providers seeking to improve patient care. Medicare, in particular, lags far behind other payers due to its restrictive statutes and regulations. We acknowledge that many of the limitations on the expansion of Medicare coverage for telehealth are statutory. **However, CMS should use its own**

authority to identify services that could be effectively and efficiently furnished using telehealth and add those to the list of approved Medicare telehealth services.

CMS approves new telehealth services on a case-by-case basis, with the result that Medicare pays for only a small percentage of services when they are delivered via telehealth. This process should be simplified, such as by a presumption that Medicare-covered services also are covered when delivered via telehealth, unless CMS determines on a case-by-case basis that such coverage is inappropriate.

The AHA will continue to urge Congress to remove the statutory barriers to increased Medicare coverage of telehealth services, including the geographic and practice setting limitations on where Medicare beneficiaries may receive telehealth services and the limitations on the types of technology that providers may use to deliver services via telehealth.

Additionally, we are pleased that CMS proposes to add certified registered nurse anesthetists (CRNAs) as practitioners who may provide telehealth services. CRNAs were originally omitted because CMS did not believe they would furnish any of the approved telehealth services, but now notes that they are licensed to provide certain services on the telehealth list, including E/M services. This proposal will allow hospitals additional flexibility to staff their telehealth programs.

PAYMENT FOR PRIMARY CARE AND CARE MANAGEMENT SERVICES

CMS requests comment on how best to pay separately for certain care management services performed by physicians and other professionals. Specifically, the agency is interested in how it might pay for:

- “Cognitive work,” such as planning and thinking critically about the individual chronic care needs of particular Medicare beneficiaries, performed by physicians who provide broad-based, ongoing treatment to manage the conditions of Medicare beneficiaries;
- Interprofessional consultations between primary care physicians and specialists as they collaborate on care for beneficiaries with multiple chronic conditions; and
- Services provided through a collaborative care model in which primary care providers and care managers work with a psychiatric consultant, such as a psychiatrist, to care for beneficiaries with common behavioral health conditions.

The AHA is pleased that CMS is exploring how to compensate physicians and other professional for the work they perform managing care for Medicare beneficiaries with chronic conditions and which falls outside the current transitional care management and chronic care management codes. **We also applaud the agency’s interest in developing separate payment for collaborative care, particularly with respect to beneficiaries with common behavioral conditions.** The delivery of behavioral health services is usually separate from and uncoordinated with the broader health care delivery system. This fragmentation compromises quality of care and clinical outcomes for individuals with both behavioral and physical health

conditions. Research shows that integration of behavioral health services and general medical care, such as through collaborative models, can reduce costs and improve outcomes for these patients. As CMS explores the development of a separate payment for collaborative care, we urge the agency to consider and evaluate such a payment's potential to help address the mental health professional shortage. We look forward to more information on these initiatives as they continue to develop.

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

The Protecting Access to Medicare Act of 2014 (PAMA) requires CMS to establish a program that promotes appropriate-use criteria (AUC) for advanced diagnostic imaging. Beginning Jan. 1, 2017, payment will be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted with a qualified clinical decision support (CDS) mechanism as to whether the ordered service adheres to the applicable AUC. This policy would apply only in certain settings – a physician's office, hospital outpatient department (including an emergency department), an ambulatory surgery center, and any other provider-led outpatient setting as determined by CMS.

In this year's rulemaking, CMS proposes to begin implementing the AUC program. The PAMA states that applicable AUC include criteria "developed or endorsed by national professional medical specialty societies or other provider-led entities." CMS proposes to define "provider-led entity" to include "an organization that is comprised of providers and is actively engaged in the practice and delivery of healthcare (for example, hospitals and health systems)." **The AHA supports CMS's proposal to include hospitals and health systems among the entities that may develop and endorse AUC.**

CMS also states that it plans to propose in future PFS rules details on additional aspects of the AUC program, including the statutory requirement for ordering professionals to consult with a CDS mechanism when ordering applicable advanced diagnostic imaging services and the resulting denial of payment to the furnishing professional if such a consultation is not made. We applaud CMS for recognizing the complexity of the AUC program and for taking a step-wise approach to implementation. However, we are concerned that CMS's timeline means that much of the real detail of this program will not be in place until the CY 2017 final PFS rule, expected around Nov. 1, 2016. This will leave providers with very little time to implement and operationalize the policy by Jan. 1, 2017. **We urge CMS to delay full implementation of this policy, including the associated payment reduction, until at least 12 months from the date that approved CDS mechanisms are announced.** In addition, we ask that CMS consider the following issues as it further develops this policy:

- **While we understand that this policy is required by law, we have significant concerns regarding the impact of this policy on hospitals. Hospital knowledge of and control over whether the ordering professional consulted a CDS mechanism as required is extremely limited, yet they will bear the reduced payment as a result of**

any failure to comply by the ordering professional. As CMS develops its proposals, we urge that the agency to consider this limitation and implement the requirement in a way that minimizes the burden for hospitals. The agency should continue to obtain stakeholder input so that as it designs this process, it can carefully consider workflow and other considerations, such as interoperability of the CDS with EMRs and across health care settings.

- **Due to the complexities of implementation and the cost-benefit derived from implementing a CDS, we urge CMS to focus initially on a limited number of imaging services, such as those that are high volume or exhibit the most variation in use, rather than applying the new policy to all advanced imaging services.** This approach would enable testing of the overall approach and allow time for practitioners and providers familiarize themselves with the new system. CMS could sync this approach with the priority clinical areas that CMS will define for outlier practitioners.
- **CMS should consider exempting services provided in an emergency department from the CDS requirement.** The statute exempts services provided under the Emergency Medical Treatment & Labor Act (EMTALA). Further, the requirement does not apply to services provided under Medicare Part A. However, it is not always possible to determine when a patient presents to the emergency department and requires imaging services whether that patient will be admitted to the hospital (and thus, services will be payable under Part A), or whether the patient will remain outpatient (with services payable under Part B). It will be important to design this policy in a way that does not lead to circumstances where medical care is inadvertently delayed because a provider in the emergency department must stop and determine whether CDS be applied.

CHANGES TO PAYMENT FOR COMPUTED TOMOGRAPHY

CMS proposes to implement a provision of the PAMA which requires a payment reduction for computed tomography (CT) services that are furnished using equipment that fails to meet each of the attributes of National Electrical Manufacturers Association Standard XR-29-2013. CMS proposes to establish a new modifier for claims that describes CT services furnished using noncompliant equipment which would result in the applicable payment reduction (5 percent in 2016 and 15 percent in 2017 and subsequent years).

While the AHA understands that this proposal is required by law, we are concerned about the timing and burden associated with this requirement. We, therefore, request that CMS delay the use of the modifier and the related payment reductions by at least a year.

Hospitals and physicians will have had less than two years since PAMA was enacted to purchase and put into place compliant CT equipment. While the AHA does not have data indicating the proportion of CT services currently furnished on noncompliant equipment, we know that many hospitals plan to upgrade their equipment, but doing so is costly. One health system estimates that purchasing and putting into use compliant equipment would cost between \$200,000 and \$500,000 per unit. Making large capital expenditures within a hospital or health system can take

more than two years, particularly when other priorities to improve patient care also involve large capital expenditures.

“INCIDENT TO BILLING”

CMS defines “incident to” services as “services or supplies that are an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.” Currently, a physician may bill for incident to services without providing direct supervision of those services, as long as another physician is in the office to supervise. However, CMS proposes to require that the physician billing for incident to services must be the same physician who directly supervises the staff who provide those services.

The AHA urges CMS not to finalize this proposal, which would be administratively and financially burdensome for physicians and hospitals and could result in reduced access to care for Medicare beneficiaries. It would be difficult for physicians who provide services in multiple offices to arrange to be in-office to directly supervise all incident to services for their patients. This could lead to a restriction on when Medicare beneficiaries could receive care – for example, they may have access to fewer appointment dates or times in order to align with when the original physician is in the office, or they may need to travel to less convenient offices in order to receive a convenient appointment time. Further, it would be challenging for physician practices to track when those non-physician practitioners who may bill Medicare directly would bill for incident to services or directly under their own provider numbers, since that determination could be based solely on whether the ordering physician was in the office the day services were provided.

PHYSICIAN QUALITY REPORTING SYSTEM

The Physician Quality Reporting System (PQRS) requires individual eligible professions (EPs) and group practices to report quality data successfully to avoid payment penalties of 2.0 percentage points in CYs 2016 through 2018. 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 Taxpayer Identification Number (TIN). As required by the Medicare Access and CHIP Reauthorization Act (MACRA), CY 2018 is the final year for both the PQRS and the value-based payment modifier (VM) pay-for-performance program. Both programs will be supplanted by a new Merit-based Incentive Payment System (MIPS) beginning with CY 2019 payments. We first comment on CMS’s proposals for the PQRS Group Practice Reporting Option (GPRO), and address CMS’s request for preliminary input on the design of the MIPS later in this letter.

Mandatory Patient Experience Survey Reporting. The AHA supports CMS’s proposal to limit the mandatory reporting of the PQRS Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey to groups using the GPRO web interface for CY 2018. However,

we urge CMS not to expand mandatory CAHPS reporting to groups smaller than 100 EPs until it allows the use of more modern and economical methods to collect survey data, and shortens the excessively long CAHPS survey instrument. We also urge CMS to ensure that CAHPS survey data from smaller practices are reliable and accurate before publicly reporting or tying payment to those data.

CMS's current policy requires CAHPS reporting for groups of 100 or more EPs, regardless of the GPRO reporting option used (i.e., web interface, qualified registry, electronic health record (EHR)). The affected groups must pay CMS-certified survey vendors to collect and report the data. CMS now proposes to require groups of 25 or more EPs to report the CAHPS survey, but to limit this requirement to groups that report measures using the GPRO web interface.

CMS suggests this approach is appropriate because some of the group practices using the other GPRO mechanisms tend to be specialists that may not provide care that is relevant to the questions in the CAHPS survey. The AHA agrees with this assessment because the questions in the CAHPS survey focus on care that is usually delivered by office-based specialties, such as primary care physicians. It is difficult to evaluate specialists like pathologists or radiologists on the CAHPS questions related to interactions with office staff. Similarly, most of the measures in the GPRO web interface are oriented towards primary care and prevention. For these reasons, limiting a requirement to report the CAHPS survey to groups using the web interface is a reasonable approach.

However, given the significant cost of CAHPS reporting, we seriously question the ability and readiness of practices smaller than 100 EPs to mandatorily report CAHPS data. As we stated in our Aug. 27, 2014 [comment letter](#), implementing a CAHPS reporting approach may cost each group practice as much as \$517,000 per year. Practices must incur this significant cost because the once-yearly CAHPS data collection required by CMS is insufficient to inform their patient experience improvement efforts. Our larger member hospitals report that they must pay vendors for routine data collection throughout the year to have enough information to prioritize and monitor the effectiveness of improvement efforts. While larger group practices may be better positioned to absorb the costs of mandated CAHPS reporting, smaller practices may find the costs too great to bear.

The AHA also is troubled by the lack of information in the proposed rule about the reliability and validity of CAHPS data collected from smaller practices. Smaller group practices may find it challenging to have a sample size and response rate sufficient to report reliable measure results publicly, or to tie the measure to payment through the VM. We urge the agency to conduct an analysis of the reliability and validity of the CAHPS measures when applied to group practices of 25 to 99 EPs. If CMS conducted such an analysis, we urge the agency to make the results publicly available so that stakeholders can evaluate its findings.

Notwithstanding our concerns with CMS's proposal, the AHA agrees with the value of patient experience surveys, and believes the agency could take steps to make mandatory CAHPS reporting for smaller practices more feasible and appropriate in the future. First and foremost, we urge CMS to allow the use of lower-cost survey administration

approaches – such as emailed or web-based surveys. Electronic survey distribution modes make survey data collection and aggregation less expensive, and may allow practices to increase sample size without greatly increasing costs. We strongly encourage CMS to work with the CAHPS surveys steward – the Agency for Healthcare Research and Quality (AHRQ) – to develop guidelines for emailed and web-based surveys. We believe such guidelines would benefit all providers that use other surveys from the CAHPS family, including hospitals and home health agencies.

Second, the AHA also continues to object to the excessive length of the PQRS CAHPS survey instrument, and urges CMS to consider ways of shortening it. A survey of 80 questions is burdensome for patients and may yield low response rates. Low response rates from such a long survey necessitate sampling a higher number of patients, which increase survey administration costs. The version of CAHPS that CMS is using is *almost 2.5 times longer* than the National Quality Forum (NQF)-endorsed Clinician and Group (CG) CAHPS, which includes a total of 31 items. We appreciate that many of the additional questions are drawn from other surveys in the CAHPS family, such as the CAHPS Patient-Centered Medical Home Survey and the Core CAHPS Health Plan Survey. However, it remains unclear if CMS has tested whether using this combination of survey questions in the PQRS CAHPS provides meaningful data to providers.

GRPO Qualified Clinical Data Registry (QCDR) Reporting Option. The AHA supports CMS’s proposed addition of a QCDR reporting option for group practices. As required by the MACRA, CMS proposes to allow group practices to use the QCDR reporting option that is available to individual EPs. This proposal would apply to data reported for CY 2016, which affects CY 2018 payment. In general, QCDRs differ from “qualified registries” in that CMS requires QCDRs to meet more challenging requirements. For example, QCDRs must have mechanisms for the transparency of data elements, measure specifications, risk models and benchmarking methods.

PHYSICIAN VALUE-BASED PAYMENT MODIFIER

The Affordable Care Act (ACA) requires CMS to implement a VM that applies to Medicare PFS payments starting with certain physicians on Jan. 1, 2015, and affecting all physicians and physician groups by Jan. 1, 2017. The modifier results in differential physician payments based on the quality and cost of care. In addition, after Jan. 1, 2017, the Secretary has the discretion to apply the VM to payments for other EPs, such as physician assistants (PAs) and nurse practitioners (NPs). The law does not specify the payment adjustment amount of the VM, only that the VM program must be budget neutral. That is, all funds withheld from physicians as penalties must be paid back to physicians through incentive payments.

Application of VM to Medicare Shared Savings Program (MSSP) and Center for Medicare & Medicaid Innovation (CMMI) Initiative Participants. The AHA applauds and supports CMS’s proposal to waive participation in the CYs 2017 and 2018 VM for participants in several

CMMI initiatives. However, we are very disappointed that the agency would continue to apply the VM to participants in the MSSP. We, once again, urge CMS to exempt MSSP participants from the VM to avoid potentially inappropriate comparisons of performance, strengthen the incentive for physicians to participate in innovative care delivery models and minimize the risk of sending “mixed signals” to physicians about their quality performance. At a time when CMS has set ambitious goals for encouraging participation in innovative care delivery and payment models, we remain concerned that applying the VM to MSSP weakens the incentive for physicians to participate in MSSP.

CMS proposes to invoke its authority under section 1115A(d)(1) of the Social Security Act (as amended by the ACA) to waive the application of the VM for group practices and individual EPs participating in five specific CMMI models – the Pioneer Accountable Care Organization (ACO) initiative, the Comprehensive Primary Care (CPC) initiative, the Next Generation ACO model, Oncology Care Model, and Comprehensive End-Stage Renal Disease Care Initiative. CMS will consider waiving the VM for participants in other CMMI models on a case-by-case basis using several criteria to determine whether the model uses pay-for-performance and whether the scoring methodology may conflict with the VM. However, CMS suggests it does not have sufficient statutory authority to waive participation in MSSP because the ACA requires the VM to apply to all physicians by CY 2017.

The AHA continues to believe the statute provides more than sufficient flexibility for CMS to waive the VM for MSSP participants. Specifically, section 1848(p)(5) of the ACA states that “the Secretary [of Health and Human Services] shall, as appropriate, apply the payment modifier... in a manner that promotes *systems-based care*.”¹ ACOs in the MSSP program encourage exactly the type of systems-based care contemplated in the statute, and we believe that CMS would be permitted to modify the application of the VM to participants in those programs. In ACO models, a variety of entities – physicians, hospitals, post-acute care providers – comes together to integrate and coordinate the care of patients across the care continuum to improve quality and efficiency.

Furthermore, waiving participation in the VM for MSSP participants would minimize the risk of creating inappropriate comparisons of measure performance between ACOs and other VM participants. In an attempt to reduce the likelihood of inappropriate comparisons, CMS calculates ACO VM quality performance using, in part, measures from the PQRS GPRO web interface. The GPRO web interface measures also are used in the MSSP program. However, CMS does not calculate all of the claims-based quality composite measures that apply to other VM participants. Instead, it calculates only the hospital readmissions measure. Moreover, while it is true that MSSP uses the GPRO web interface measures, there are important measurement differences between the programs. For instance, MSSP ACOs are accountable for performance on claims-based measures – such as AHRQ’s Prevention Quality Indicators (PQIs) – that are not used in the VM. Moreover, ACOs have been benchmarked against other ACOs to date, and not against all other participants in the VM. The introduction of ACOs into the broader VM program could introduce potential bias – favorable or unfavorable to ACOs – into the broader program.

¹ Emphasis added.

The AHA also believes exempting MSSP participants from the VM reduces the risk of physicians receiving mixed signals on their quality performance. While we appreciate that CMS has attempted to align VM and ACO measures, its proposal could still lead to ACOs scoring well in one program while performing poorly on the other. This is because the VM and ACO programs use different performance benchmarks and different approaches for determining good versus bad performance. For example, MSSP ACO quality performance is based on deciles of performance, and ACOs must surpass the 30th percentile of performance on measures to share in any savings. By contrast, the VM's quality tiering model (QTM) categorizes physicians as having low, average or high cost and quality. While providers are committed to improving quality, resources for quality measurement and improvement are finite. Receiving mixed signals on quality performance makes it considerably more challenging to prioritize resources and execute improvements.

Moreover, the ability of physicians in ACOs to focus on a single pay-for-performance program is vitally important since physicians must make considerable investments to participate in ACO programs. When the MSSP was implemented, CMS estimated it would cost approximately \$1.8 million to form an ACO and operate in the first year. However, the AHA's analysis, performed by McManis Consulting, estimated that these costs are much higher – \$11.6 million for a small ACO and \$26.1 million for a medium ACO.

Application of VM to Nonphysician Practitioners. **The AHA supports CMS's proposal to limit the application of the CY 2018 VM to physicians, PAs, NPs, clinical nurse specialists (CNS) and CRNAs.** In the CY 2015 PFS final rule CMS expanded the application of the VM to all nonphysician individual EPs and groups of EPs billing under the PFS beginning in CY 2018. However, as required by the MACRA, the VM will sunset after CY 2018. Furthermore, the MACRA requires that the CYs 2019 and 2020 MIPS apply only to physicians, PAs, NPs, CNSs and CRNAs. The Secretary may not expand the MIPS to other non-physician EPs until 2021 at the earliest. Thus, we believe CMS's proposed policy change appropriately brings the application of pay-for-performance to non-physician practitioners into alignment with the new MIPS.

MEDICARE SHARED SAVINGS PROGRAM

Measure Addition. **The AHA does not support CMS's proposal to add one quality measure, Statin Therapy for the Prevention and Treatment of Cardiovascular Disease, to the Preventive Health domain starting in 2016.** This measure is not NQF-endorsed and was not recommended for inclusion in the MSSP by the Measure Applications Partnership (MAP). Rather, the MAP recommended that the measure undergo further development.

As a result of the MAP recommendation that the measure be further developed, CMS asks for comment on how it should be incorporated into the MSSP, such as whether it should be a single measure with weighted denominators or three separate measures. We point out that when the MAP suggests that a measure should undergo continued development, such a suggestion has

never meant further development by specifically proposing it through the rulemaking process. Measures should be fully developed *before* they are presented to the public for comment about inclusion in federal quality reporting programs. While helpful information can be gathered through the rulemaking process, CMS could have sought comments about the measure without specifically proposing it. Because quality measures can influence behavior, it is important that they be fully developed and analyzed before they are put into widespread use.

Further, the purpose of the MAP, in part, is to flag measures that are not ready for implementation. It is unclear why CMS is ignoring the guidance of experts from whom it sought recommendations. **CMS should continue to work with relevant experts in cardiovascular health to adjust this measure, and then consider resubmitting it to both NQF for endorsement and the MAP for recommendation for inclusion in federal quality reporting programs. Only then should CMS propose its inclusion in the MSSP.**

Policy Change. We ask CMS to amend its proposed policy change related to measures that become problematic after incorporation into federal quality reporting programs. Specifically, CMS recognizes that quality measures can become misaligned as clinical guidelines change. Further, evidence may emerge that the application of a quality measure is harmful to patients. Therefore, CMS proposes to adopt a policy that would allow a measure to continue as pay-for-performance, or be converted back to pay-for-reporting, if a measure owner finds that the measure no longer represents best clinical practice or if evidence indicates the measure could be harmful to patients. CMS would subsequently make any necessary changes regarding the measure's status in the next PFS rulemaking process, such as retiring the measure or maintaining it as pay-for-reporting. However, it is unclear why a measure that is harmful to patients would be collected at all. **The AHA strongly urges that CMS immediately suspend measures that are harmful or no longer consistent with the best available science on care, as the agency has done in the past.** Further, such measures should not be publicly reported or used in pay-for-reporting programs.

Health Information Technology (IT) Request for Comment. CMS asks for comment on how the current measure, Percent of Primary Care Physicians who Successfully Meet Meaningful Use Requirements (ACO-11) might evolve in the future to incentivize and reward providers for pursuing more advanced IT functionality (and ultimately, interoperability). **The AHA strongly urges CMS to direct its efforts toward supporting provider success with the existing EHR Incentive Program requirements before considering potential revisions to ACO-11. Specifically, the AHA recommends that once 75 percent of hospitals and EPs have met Stage 2 meaningful use, and a robust and efficient health information exchange is available, then CMS should move forward to consider provider requirements linked to advanced health IT functionality.**

The current meaningful use requirements presume a level of program participation and EHR technology maturity that is not yet present. More than 60 percent of hospitals and about 90 percent of physicians have yet to attest to Stage 2. The requirements for meaningful use Stage 2 are, in some cases, too proscriptive and hold providers accountable for events outside their control. We commend CMS for proposing an EHR Incentive Program modification rule for 2015

that could, if finalized, offer program flexibility in meeting challenging objectives, such as the summary of care.

Additionally, the absence of a robust and efficient health information exchange infrastructure presents new challenges to the use of advanced health IT functionality. The health IT tools currently available do not generally support the new requirements for health information sharing and analysis, necessitating undue expense by providers to build work-arounds. Efficient and effective sharing of health information will require greater use of and adherence to data and other technical standards; transparency on how health IT vendors support interoperability through conformance to standards and implementation guides; and an improved federal EHR certification program that includes robust testing of EHRs that reflects real-world conditions.

Health IT adoption and use are key underpinnings of new models of care. Increasing the level of provider participation in the EHR Incentive Program and measureable provider progress in meeting the information exchange requirements in the program should inform future comments about provider use of advanced health IT functionality.

PHYSICIAN COMPARE

For CY 2016, CMS proposes to continue expanding the data available on *Physician Compare* by publicly reporting all measures collected through all three of the PQRS GPRO reporting options – qualified registry, EHRs and web interface. Physician groups of all sizes participating in the GPRO web interface, as well as ACOs participating in the MSSP, would be included in the reporting. Physicians would have a 30-day period to preview their measure performance before data are posted to *Physician Compare*.

In general, the AHA supports transparency efforts, but urges CMS to assess carefully whether all of the measure data reported on *Physician Compare* are sufficiently reliable and valid for public reporting before posting them. Transparency efforts are valuable to providers and patients only if the information provides an accurate picture of performance. If any of the measures is deemed unreliable or inaccurate, we urge CMS to remove it from *Physician Compare* and either improve the measure to an appropriate level of reliability or replace the measure with one that is more important and more reliable so that greater transparency is achieved within a shorter time.

The AHA also urges CMS not to adopt its proposal to report a five-star rating for individual measures reported on *Physician Compare* in CY 2016 using the Achievable Benchmark of Care (ABC) methodology. We acknowledge the intent of CMS's proposal is to provide quality information in an easy-to-understand format. Given that "star ratings" are used in a variety of other industries, we also understand the conceptual appeal of star ratings. Nevertheless, physician quality measurement efforts will be altered significantly by the implementation of the MIPS starting in CY 2019. We believe the agency should ensure any public reporting approach is aligned with the goals for this new program.

Furthermore, we believe CMS has not vetted the ABC methodology sufficiently, and several pieces of information needed to assess the methodology are missing from the proposed rule. In contrast to its efforts to implement star rating systems for other providers, CMS did not convene a technical expert panel (TEP) to advise it on star ratings for *Physician Compare*. The use of a TEP would equip the agency with expert insight on the validity and reliability of its methodology. We also do not understand how CMS will translate the ABC score into a specific star rating because the agency does not describe those details in the rule. At a minimum, the agency should make detailed methodology document available for public comment.

Lastly, before implementing any star rating approach, we strongly encourage the agency to conduct a “dry run” so that physicians can understand how they score before results are publicly reported. The agency recently concluded a dry run for its proposed methodology for hospital star ratings, and many of our members expressed their appreciation for an opportunity to better understand their performance under this new methodology and data display.

ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM

Revised definition of certified EHRs. The AHA opposes the proposed change to the definition of certified EHR for CY 2016 because it is inconsistent with the current definition of certified EHR established by the Office of the National Coordinator for Health Information Technology (ONC). We urge CMS to wait for a final determination on the proposed redefinition of certified EHR for CY 2018 and the designation of the agency that will define certified EHR in CY 2016 and thereafter.

CMS proposes to revise the definition of certified EHR technology for 2015 through 2017 to state that providers must have certified EHRs that support the “form and manner” of quality measure submission accepted by CMS if the provider submits electronically. Specifically, the proposed rule would require providers to have EHRs that are certified to support the Quality Reporting Document Architecture Category I (individual patient-level) and Category III (aggregate patient-level) data standards and the CMS “form and manner” requirement. The proposed revisions would apply for EPs, eligible hospitals, and critical access hospitals. However, in the fiscal year 2016 inpatient prospective payment system (PPS) final rule, CMS states the intention to not finalize proposed certification criteria supporting electronic clinical quality measure (eCQM) reporting, adding that it expects to finalize rules later in 2015 on certification criterion and the versions of the standards that should be adopted for the criterion. We agree with the approach taken in the FY 2016 inpatient PPS final rule. Finalizing an amended certified EHR definition in the PFS rule in advance of final statements by CMS and ONC on proposals more generally to redefine certified EHR and potentially change the agency responsible for the definition will create significant uncertainty for providers concerning the expected functionality of the health IT tools that providers must use.

Comprehensive Primary Care (CPC) Initiative Aligned Reporting. **The AHA urges CMS to release, in the immediate future, a final rule modifying the meaningful use requirements under the Medicare and Medicaid EHR Incentive Programs for FY 2015 through 2017. Clarity from CMS on the EHR objectives and measures required in CY 2016 will help better align current and future Medicare programs that foster coordination of care, such as the CPC Initiative, with the EHR Incentive Program requirements.** In the CY 2016 PFS proposed rule, CMS proposes that EPs who are part of a CPC practice site and are in their first year of demonstrating meaningful use in CY 2016 have the option to select the CPC group reporting option to report their CQMs electronically or may report eCQMs by attestation. CMS also states that if a CPC practice site is unsuccessful in reporting the eCQMs, EPs who are part of the site would still have the opportunity to report eCQMs according to the Medicare EHR Incentive Program requirements. We recommend that CMS provide clarity on the EHR Incentive Program requirements to allow providers in the CPC practice site to make an informed decision about their reporting options for CY 2016.

We also recommend that CMS clarify the hardship exception categories available in the EHR Incentive Program given the conflicting deadlines in the proposed CPC Initiative aligned reporting option of eCQMs for EPs in their first year of meaningful use. Absent a stated hardship exception for aligned reporting for first year participants in the EHR Incentive Program, we recommend that CMS refrain from offering an aligned reporting option that subjects a provider to penalties due to misaligned program submission deadlines for eCQM reporting. Currently, EPs who are first-time meaningful users in the EHR Incentive Program must submit their data by the deadline established for CY 2016, which is Oct. 1, 2016. The EPs who choose the CPC group reporting option for eCQMs must submit data during the submission period of Jan. 1 through Feb. 28, 2017. EPs that miss the submission deadline will be subject to a Medicare payment adjustment. The EHR Incentive Program offers hardship exceptions for providers unable to attest for reasons such as infrastructure, unforeseen circumstances such as a natural disaster, lack of patient interaction, or lack of control over availability of certified EHR for more than 50 percent of patient encounters. A hardship exception does not exist for providers that submit data to meet reporting requirements of multiple programs when the programs have distinct submission deadlines. The PFS proposed rule states that these EPs will receive reduced payments under the PFS in CY 2017 for failing to demonstrate meaningful use, if they have not applied and been approved for a significant hardship exception under the EHR Incentive Program. We urge CMS to allow a new category of hardship exception will be available due to program submission deadlines for eCQM reporting that are misaligned.

REQUEST FOR INPUT ON THE MERIT-BASED INCENTIVE PAYMENT SYSTEM

The MACRA created the MIPS as new payment system for physicians and other professionals paid under the PFS beginning in CY 2019. The law sunsets three current-law reporting and pay-for-performance programs – PQRS, Medicare EHR Incentive Programs for EPs, and the VM – and consolidates the measures and processes of these programs into the MIPS. In the proposed

rule, CMS seeks comment on some aspects of the MIPS in preparation for future rulemaking. **The AHA applauds CMS for seeking early input from the field on the design of the MIPS, and encourages the agency to provide as much opportunity for stakeholder feedback on MIPS implementation as possible.** We have begun to engage our membership in discussions about the implications of the MIPS and alternative payment models (APMs), and look forward to sharing more detailed insights in the coming months. In the interim, we offer several general recommendations.

Ensure Focus and Parsimony in Measure Selection. **The AHA urges CMS to use the implementation of the MIPS to streamline and refocus physician quality measurement efforts so they are aligned with concrete national priority areas for improvement across the entire health care system.** There are more than 250 individual measures in the PQRS and VM programs that affect payment for CY 2017. We acknowledge that the volume of measures stems partially from the need to have measures relevant to the variety of specialties participating in these programs. Nevertheless, measures have proliferated without a well-articulated link to specific national priorities or goals. Regardless of the specialty, the significant improvement in outcomes and health that patients expect and deserve is best achieved when *all* parties in the health care system are working towards the achievement of the same objectives.

The AHA has repeatedly urged CMS to identify concrete, actionable national goals for quality improvement, and to use those goals to select a small number of reliable, accurate and care-setting appropriate measures to ensure each relevant part of the health care system contributes to the overall goals. For this reason, we again strongly urge CMS to consider adopting the recommendations outlined in the Institute of Medicine's (IOM) *Vital Signs* report for streamlining and focusing national quality measurement efforts. If adopted, the report's recommendations would facilitate better use of quality measures by all stakeholders to advance health care.

The *Vital Signs* report notes that progress in improving the quality of health care has been stymied by discordant, uncoordinated measurement requirements from CMS and others. Hospitals and other care providers spend significant resources interpreting measure specifications, training staff on reporting requirements and collecting data. Resources spent on these activities are not available to engage in important opportunities to improve care. To ensure that all parts of the health care system – hospitals, physicians, the federal government, private payers and others – are working in concert to address priority issues, the *Vital Signs* report recommends 15 “Core Measure” areas with 39 associated priority measures. Each stakeholder would be measured on the areas most relevant to their role in achieving common goals and objectives. These core areas could be updated over time, “retiring” areas where sufficient progress has been achieved, and replacing them with new core areas that address emerging issues.

To be clear, the IOM *Vital Signs* report is intended to provide measurement priorities for all health care stakeholders, and not just physicians. We strongly caution CMS against using the IOM list to measure providers on aspects of care that may be beyond the scope of their operations. For example, in applying measures of cost and resource, CMS must ensure it is

focused on the provider being measured, and not the entirety of the delivery system. CMS also should ensure measures are appropriately adjusted for factors beyond the control of providers that can affect performance, such as sociodemographic factors. Nevertheless, the *Vital Signs* report provides an important unifying framework that will help make all stakeholders more accountable and engaged in measurement and improvement.

Develop a MIPS Participation Option for Hospital-based Physicians. The MACRA includes a provision allowing CMS to develop MIPS participation options for hospital-based physicians. The AHA has long supported PQRS and VM participation options for hospital-based physicians where their reporting and performance is based on measure data from the hospital quality reporting and pay-for-performance programs. **For hospitals and physicians alike, greater integration represents the potential to better align goals and processes across the care continuum.**

The AHA recommends that CMS allow physicians and groups to self-designate whether they qualify as hospital-based. 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 GPRO in PQRS. 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 potentially validate the relationship using claims data elements, such as inpatient and hospital outpatient department place of service codes.

PROPOSED PHYSICIAN SELF-REFERRAL CHANGES

The physician self-referral statute (also known as the Stark law) prohibits hospitals from submitting Medicare claims for certain designated health services (DHS) if the referring physician (or an immediate family member) has a financial relationship with the hospital, unless an exception applies. In the proposed rule, CMS states that it has identified – through provider disclosures under the self-referral disclosure protocol – areas of confusion or concern with respect to the specific requirements of certain exceptions to the statute. The agency proposes two new exceptions to the prohibition on self-referral, as well as a number of technical changes, with the stated intent of clarifying certain regulatory provisions and expanding needed access to health care services. Specifically, CMS proposes new exceptions that would:

- Permit payments from a hospital, federally qualified health center (FQHC) or rural health center (RHC) to a physician to assist the physician in employing a non-physician practitioner (NPP) in the geographic area of the hospital, FQHC or RHC.
- Permit timeshare arrangements, by which hospitals or physician practices allow physicians to license space – such as a fully furnished and operational medical office suite – on a limited or as-needed basis to provide services to patients. These licensing arrangements are an alternative to a lease agreement.

The AHA welcomes CMS use of the PFS rulemaking process to update and clarify the regulations. We urge CMS to regularly provide needed and timely improvements. Further, we support CMS's proposals to create the two new exceptions. With respect to the proposal to allow hospitals to provide financial assistance to recruit NPPs, we urge the agency to consider broadening the exception so that it would not be limited solely to arrangements to provide primary care services. While NPPs can play a critical role in improving access to primary care services, they also can contribute to addressing specialty workforce shortages, particularly in underserved and rural areas. Hospitals and physicians are in the best position to gauge their communities' particular staffing needs, and should have flexibility under this exception to recruit the NPP best suited to fulfill those needs. To fully realize CMS' stated goal of expanding access to care, the NPP exception should be available to meet other gaps in access to care.

SELF-REFERRAL BARRIERS TO DELIVERY SYSTEM REFORM

In the proposed rule CMS also solicits comment on the impact of the physician self-referral law on health care delivery and payment reform, including perceived barriers to clinical and financial integration and the "volume or value" and "other business generated" standards. We welcome CMS's acknowledgment that the underpinnings of the compensation provisions in the statute and regulations are out of step with the close working relationships and sharing of risk and reward between hospitals and physicians that are essential to achieving success under new payment models. **We believe a fundamental change in oversight is needed to facilitate those relationships.**

In and of itself, a statute designed to keep hospitals and physicians apart is not compatible with the demands for payment and system reform being driven by Congress, the Administration and private payers. In fact, the Secretary's goal is to move most traditional Medicare payments to alternative payment models or payment based on quality or value by 2018. **The Stark statute and CMS's implementing regulations are not suited to regulate the financial relationships necessary to achieve those goals.** Compensation arrangements are already subject to oversight by other laws better suited to do so, such as the Anti-kickback statute. **The optimal solution is a change in statute that removes compensation arrangements from the definition of "financial relationships" that are subject to the Stark law. In the interim, CMS should create a regulatory exception that is designed for and provides protection to hospitals and physicians that enter into financial arrangements necessary to building clinically and financially integrated models of care that reward and incentivize performance.**

Fair Market Value and Value or Volume. Paramount among the problems with the Stark law are the very standards on which CMS now seeks comment – "fair market value," and "not accounting for the value or volume of referrals or other business generated." Fair market value has become a rigid measure of hourly wage equivalents, a measure that is fundamentally incompatible with today's new payment models that reward and incentivize performance.

The "volume and value" standard may well make it practically impossible for hospitals to reasonably conclude that their financial relationships are in compliance. The "volume or value"

standard requires that physician compensation may not be determined in any manner that takes into account the value or volume of referrals. The absence of clear statutory or regulatory guidance on how courts should apply the “volume or value” standard in the evolving world of health care payment has been shown by recent developments in the courts to present unpredictable risks of catastrophically punitive fines and penalties that bear no relation to the value or volume of the harm novel relationships may cause the federal health care programs. The specter of such financial penalties, emanating from recent FCA decisions (including where the Department of Justice intervened) will no doubt chill, and could extinguish, the development of new relationships essential to the success of the new reimbursement models. See 3d Circuit decision in *United States ex rel. Kosenske v. Carlisle HMA*, referenced in the preamble. And even worse, the informal guidance approach CMS utilized in the past has now been shown to be irrelevant as a defense to hospitals who relied on it. See 4th Circuit decision in *United States ex rel. Drakeford v. Tuomey* issued in July. Current enforcement initiatives by both the attorneys representing private individuals (*qui tam* relators) and the U.S. Department of Justice are simply inconsistent with the goals of a government intent on fostering new ways to secure increased access to health care, increased accountability for providers, and reduced cost for payers.