American Hospital Association™
Advancing Health in America

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September 7, 2018

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

RE: CMS-1693-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; and Medicaid Promoting Interoperability Program

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, 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) 2019.

The AHA appreciates the steps CMS is taking to give providers more time to focus on their patients by streamlining elements of the Quality Payment Program and reducing burden for clinicians. However, we are very concerned about CMS's proposal to collapse the payment rates for evaluation & management (E/M) visit codes, which would disproportionately impact hospital-based physicians who see the sickest patients and could reduce patient access to care.

Specifically, our key recommendations follow:

PAYMENT FOR EVALUATION & MANAGEMENT VISIT CODES:

- Do not finalize at this time the proposal to collapse the payment rates for level 2 through 5 E/M visits.
- Decouple proposals to reduce documentation burden associated with E/M visits from the proposed payment collapse and broaden the approaches to reducing

documentation burden to have a meaningful impact on providers' availability to see patients.

PAYMENT RATES UNDER THE PFS FOR NONEXCEPTED ITEMS AND SERVICES FURNISHED BY NONEXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS OF A HOSPITAL:

- Improve the accuracy of the methodology for calculating the PFS relativity adjuster for nonexcepted services in certain off-campus provider-based departments (PBDs) by explicitly accounting for differences in packaging between the outpatient prospective payment system (OPPS) and the PFS and ensure that both indirect and direct practice expense are taken into account.
- Set the PFS relativity adjuster at 65 percent of the OPPS amount.
- Provide additional methodological detail and explanation in the final rule as well as in future PFS rulemaking regarding how CMS arrived at its proposed PFS relativity adjuster of 40 percent.
- More closely coordinate the release of the OPPS and PFS proposed rules in future rulemaking cycles in order to ensure that stakeholders can use the full 60-day comment period.
- Continue to allow hospitals to bill for items and services furnished in nonexcepted PBDs using the institutional bill (UB04/837I).

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES:

- Do not finalize the proposal to require furnishing facilities to report appropriate use criteria (AUC) consultation information on their claims.
- Adopt the proposal to allow AUC consultations to be performed by "auxiliary personnel incident to the ordering physician or non-physician practitioner's professional service," but specify that any auxiliary personnel in the office and under the supervision of the ordering professional can perform the required clinical decision support mechanism consultation, as long as the AUC feedback is provided to the ordering professional and the ordering professional has an opportunity to revise the order if necessary.
- Develop a process through which ordering professionals can file for a blanket hardship exception to AUC requirements that covers the period of time during which the hardship occurs.

WHOLESALE ACQUISITION COST-BASED PAYMENT:

- Do not reduce payment for new Part B drugs and biologicals to 103 percent of wholesale acquisition cost without average sales price data.

CLINICAL LABORATORY FEE SCHEDULE:

- Do not finalize the proposal to remove Medicare Advantage payments from the "majority of Medicare revenues" threshold calculation.
- Do not adopt the alternative approaches using bill type 14X or the Clinical Laboratory Improvement Amendments certificate to define applicable laboratories.

PROPOSED CHANGES TO THE QUALITY PAYMENT PROGRAM:

- Adopt the proposal to allow more clinicians to take advantage of the Merit-based Incentive Payment System's (MIPS) facility-based measurement option.
- Delay until at least the CY 2022 payment year the proposal to increase the MIPS cost category weight to 15 percent, and to add eight new measures to the category.

PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY IN MIPS:

- Finalize the proposed 90-day reporting period in 2019 and removal of requirements that hold eligible clinicians responsible for the actions of others.
- Finalize a scoring approach that permits eligible clinicians to get credit for building performance in some areas while earning additional points in areas of strong performance.
- Permit eligible clinicians to offer access to at least one application, rather than any application, configured to meet the technical specifications of the application program interface in the eligible clinician's electronic health record.

EXPANSION OF ACCESS TO VIRTUAL CARE AND TELEHEALTH:

- Finalize the proposals to recognize and pay separately communication technology-based services, including virtual check-ins and remote evaluation of pre-recorded patient information.
- Educate patients regarding their cost-sharing obligations when using communication technology-based services.

We appreciate your consideration of these issues. Our detailed comments are attached. Please contact me if you have questions or feel free to have a member of your team contact Shira Hollander, senior associate director of policy, at shollander@aha.org, regarding the payment provisions, or Akin Demehin, director of policy, at ademehin@aha.org, pertaining to the quality provisions.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy

Enclosure

American Hospital Association (AHA)
Detailed Comments on the Physician Fee Schedule (PFS) Proposed Rule for Calendar Year (CY) 2019

PROPOSED CHANGES TO EVALUATION & MANAGEMENT (E/M) DOCUMENTATION AND PAYMENT

To code and bill E/M visits in office or other outpatient settings, providers select one of five levels of E/M visit codes, based upon the history of the patient's present illness, a physical examination and the provider's medical decision-making (MDM). Almost every specialty furnishes E/M visits, but they represent a greater share of total allowed services for providers who do not routinely furnish procedural interventions or diagnostic tests.

Current PFS payment rates for E/M visit codes increase with the level of visit billed in accordance with the increased resources necessary to care for more complex patients. CMS believes this structure no longer accurately reflects the services and resource costs associated with furnishing E/M visits and that its complexity contributes to the burden of documenting these visits. Thus, CMS proposes to pay blended rates for levels 2 through 5 E/M visits, with one rate for established patients and another for new patients. CMS also proposes several adjustments to the resource costs associated with different types of E/M visits and the creation of new HCPCS G-code add-ons to mitigate potential payment instability that could result from the proposed blended payment rates.

As a corollary to the proposed payment collapse, and to help offset any payment decreases, CMS proposes to require providers meet only those documentation requirements currently associated with a level 2 E/M visit (subject to certain exceptions). CMS also proposes several other changes to alleviate requirements that currently result in repetitive documentation, including eliminating extra documentation requirements for home visits; requiring documentation of the patient's history to focus only on the interval since the previous visit; and eliminating the requirement that providers re-enter information into patients' medical record that has already been documented by ancillary staff or the patients themselves.

The AHA welcomes CMS's efforts to free providers from requirements to produce repetitive documentation. However, we have serious concerns about CMS's proposals to collapse the payment rates for levels 2 through 5 E/M visits and to require only the documentation necessary for a level 2 visit. The agency has provided very little policy justification for, or analysis of, its proposals. As such, we urge CMS to not finalize these proposals at this time as they could have negative effects on patient care as well as unintended consequences. In short:

- **CMS provided no transparency as to the modeling for its proposal to collapse E/M payment rates, and it underestimated the true impact on payments to providers.**
- **The proposal results in a significant disconnect between the resource use and intensity of physician services and their compensation, which could in turn threaten access to care for vulnerable populations.**
- **Neither CMS's proposed add-on codes, nor its proposal to allow providers to default to level 2 E/M visit documentation requirements, would offset the proposed payment decrease.**

In addition, the proposed implementation date of Jan. 1, 2019 presents far too short a time frame for any provider to understand and implement this new policy. It could cause massive disruption to large and small practices, depending on their mix of specialties and volume of Medicare patients.

Lack of Transparency and Underestimation of Impact on Payments to Providers. **We are concerned that CMS did not provide sufficient information for the field to be able to fully model and analyze the impact of this E/M policy.** Specifically, in Tables 21 and 22 in the rule, the agency provides impact analyses for its proposed payment collapse of levels 2 through 5 of the E/M visit codes. Yet, the agency did not release any information about the modeling inputs it used to calculate these impacts. As such, these tables represent high-level summaries that, without more transparency, cannot be replicated, making it impossible to verify or fully understand at a detailed level the estimated impact of CMS's proposals. **We urge CMS to release the data on which it based its calculations to populate Tables 21 and 22 in the rule.**

We also are very concerned that CMS's impact analyses vastly underestimate the impact of this proposal on providers. Table 22 in the rule indicates that the maximum negative impact by specialty would be a cut of 4 percent. However, these figures are based on an analysis of changes in *allowable charges*, which is not an appropriate metric. The American Medical Association analyzed changes in actual *payment rates* – a much more appropriate metric – and found that many physician specialties would see payment cuts in excess of 10 percent. Some physicians that care for particularly sick patients, such as hematologists, medical and radiation oncologists, interventional cardiologists, and critical care physicians (known as "intensivists"), actually could see cuts of 12 to 16 percent in their Medicare payment rates. See Appendix A for the full impact of this proposal on Medicare payment rates.

Further exacerbating this underestimation is the fact that many specialists who would experience payment cuts due to the collapsed E/M payment rates could also see significant cuts to their payment for other, non-E/M services. The spillover effect of CMS's proposal contributes to the dramatic reduction in the Indirect Practice Cost Index (IPCI) values for many specialists (e.g., medical oncology, hematology/oncology, and vascular surgery), significantly decreasing their practice expense relative value units

(RVUs) and payments for non-E/M codes in which they are the predominant specialty. For example, certain drug administration codes (e.g., CPT 96409) would experience a 10 percent or more decrease in their practice expense RVUs even though the direct practice costs changed very little, and there were no changes to clinical labor input or physician work. **While CMS briefly mentions this issue, we do not believe the agency clearly understood or communicated the magnitude of this unintended consequence. Moreover, CMS did not provide sufficient data for stakeholders to understand this issue.** For example, the regulatory impact table lacks any indication of the changes to practice expense RVUs that would result from changes to the IPCI values due to the proposal to collapse E/M payment rates. **This lack of transparency could result in shocking payment cuts that disproportionately affect certain specialties. Modifying the RVUs upon which all physicians' payment for all services paid under the physician fee schedule are based is an inequitable and inappropriate way to achieve budget neutrality for CMS's E/M proposal.**

Proposal Results in Disconnect between Resources Use and Intensity of Services and Compensation, Which Could Threaten Patient Access to Care. As discussed above, the E/M proposal could result in significant payment cuts to many specialty providers, and essentially erases the connection between physicians' services and the compensation for those services. Specifically, as a result of the proposal, E/M codes would incorporate a huge range of patient severity into a single E/M payment rate. They would combine multiple unrelated services that reflect intrinsically different magnitudes of resource utilization. Removing providers' ability to code for different levels of resource use and intensity of services disconnects providers' compensation from the necessary knowledge they need to care for complex patients, the time they spend explaining care to patients and organizing patients' health care needs, and the risk they assume for caring for such complex patients.

Furthermore, the AHA is extremely concerned about the negative consequences for patient care that could result from CMS's payment proposal. By reducing payments for many providers, the proposal to collapse the payment rates for E/M visits devalues providers' time, increasing the already heavy pressure they face to maximize the number of patients they see each day. Providers also may have to reduce the time they spend with patients if the additional time needed to fully treat more complex patients no longer earns payment commensurate with that time. This could incentivize providers to instead see patients multiple times for the same issues or divert them to higher cost settings such as emergency departments (EDs), increasing care fragmentation and undermining the transition to value-based care. Providing care in this disjointed manner, in which providers can address only one or a few issues at a time, could be harmful to patients' care, as providers may lose sight of important relationships between patients' many symptoms that could have led to more prompt diagnosis and treatment. And, counter to CMS's motivation for the changes to E/M visit coding, this pressure to churn patients could increase administrative burden and exacerbate physician burnout.

In the practices that would be unable to absorb payment cuts of the magnitude anticipated, providers could elect to stop seeing Medicare beneficiaries, cutting off access to care for vulnerable patients. These payment cuts also could potentially force entire practice groups to enter into large groups or institutional settings. Medical students also could decline to choose specialties that would experience the greatest payment cuts under this proposal, exacerbating current workforce deficiencies and creating additional and longstanding issues of patient access.

Neither CMS's Proposed Add-on Codes, Nor its Proposal to Allow Providers to Default to Level 2 E/M Visit Documentation Requirements, Would Offset the Proposed Payment Decrease.

Add-on Codes for E/M Visits. CMS attempts to address potential financial disadvantages under its proposal by also proposing HCPCS G-code add-ons for primary care E/M visit complexity, E/M visit complexity for non-procedural specialties, and prolonged E/M visit services; however, these policies would not actually achieve the agency's stated goals of burden reduction and payment equity. Specifically, CMS explains that the G-codes are intended to more accurately account for the type and intensity of certain E/M visits for which the proposed single payment rate would not adequately reflect costs. In other words, it seems that this proposal aims to achieve a result similar to the existing E/M coding structure – a higher payment for providers who provide more resource-intense or time-consuming care or who care for more complex patients. **Thus, these codes actually reintroduce complexity and redundancy into a system CMS is attempting to simplify and streamline.**

In addition, the valuations and definitions of the proposed add-on codes are inequitable and unreasonable. For example, it is unclear how CMS is defining "visit complexity" and how it arrived at the proposed primary care add on payment of approximately $5 and the specialty payment of about $14. It is also unclear why the work of primary care providers, who are often asked to assess a broad array of patients' conditions and treatments and their interactions, is valued so much less than the work of specialists. The proposed "prolonged services" code is similarly out of touch with providers' realities. Specifically, it would only be billable if a visit extends 30 minutes beyond the usual service time. Overburdened providers can hardly extend every visit for an additional 30 minutes. Also, by integrating the work of other team members into care delivery, providers can efficiently manage some complex patients, but the delivery of care to these patients still requires additional resources commensurate with the complexity of the patient's condition. Under this proposal, Medicare would no longer pay for the use of those resources. Thus, providers would not recoup the payment they would lose under the proposed collapse of E/M payment rates by billing the prolonged services code with every visit as CMS intends.

For these reasons, the proposed G-code add-on codes are not an effective mechanism to offset the payment reduction CMS is proposing. And, by proposing to pay for the add-on codes with savings from the multiple procedure payment reduction, CMS, in effect, would take payment from one provider to give it to another. We do not believe this is an appropriate way to compensate providers for the care they provide.

Default to Level 2 E/M Visit Documentation Requirements. **While we appreciate CMS's efforts to ease the documentation burden facing providers, this proposal would not have a meaningful impact on providers' availability to spend time with patients, and therefore would not offset CMS's proposed payment decrease as intended.** CMS Administrator Seema Verma said in a letter to physicians shortly after the rule was proposed that "any small negative payment adjustments [that could result from the rule] would be outweighed by the significant reduction in documentation burden." But for many physicians, while a "reduction in documentation burden" might save them an hour or two of the *after-hours* charting work they do, it would have little to no impact on the *working hours* they spend on patient care, for which they would be paid less under CMS's proposals. Thus, less time spent documenting would not increase the time providers have to see patients during the day.

In addition, because providers would still need to document detailed information about resources use and intensity of services to meet other Medicare requirements, the requirements of other payers, and various legal requirements, this proposal is not likely to reduce the documentation burden that providers face. In fact, providers' success in Medicare Advantage arrangements and alternative payment models is heavily influenced by their risk adjustment score in those arrangements, which is largely dependent on their documentation of patients' conditions. As another example, for integrated delivery systems in which one part of the system's payment is based on case mix index, providers must continue to capture the full range of patients' diagnoses to accurately represent the resources used, even if they no longer had to do so explicitly for billing under the PFS. Providers are therefore unlikely to relax their documentation practices across their patient populations, as doing so would hamper their ability to succeed in value-based care, among other payment arrangements the agency wishes to promote.

Moreover, good documentation is valuable for all patients and necessary from a purely clinical perspective. Providers who see more complex patients spend significant time and energy documenting their encounter with patients, synthesizing patient history, examination findings and data, and explaining the thought process that led them to certain diagnosis and management decisions, to save time for other physicians who share in the care of a patient and their own future visits with the patient. Such full and detailed documentation enables clinicians to understand and treat the whole person, which is essential for chronic care management and multidisciplinary care of a patient. This is especially important for aging patients who often present with

comorbidities. Detailed documentation allows providers to make connections between the numerous health issues these patients face and avoid asking them to repeatedly reiterate information.

The AHA Welcomes CMS's Efforts to Free Providers from Requirements to Produce Repetitive Documentation. The AHA recognizes and appreciates CMS's efforts to address long-standing issues with, and the time consuming nature of, documenting and coding office and other outpatient visits. **We welcome and support the documentation changes CMS proposes that, unlike the above proposal to maintain only the current level 2 E/M documentation requirements, would make it easier for providers to focus their documentation on the issues that are most pertinent to patient care and locate relevant information in their or other providers' notes in patients' medical records. These changes include**:

- Eliminating the requirement to document the justification for providing a home visit instead of an office visit;
- Requiring providers to document only what has changed since an established patient's last visit or pertinent items that have not changed, rather than re-documenting a defined list of required elements; and
- No longer requiring providers to re-document information regarding patients' chief complaint and history if that information was already entered into the patients' medical record by ancillary staff or the beneficiary.

In addition, to have an even more meaningful and lasting impact, we encourage CMS to engage in a broader effort to understand and implement proposals that would reduce providers' documentation burden in a meaningful way, such that providers have more time to spend with patients. Specifically, the AHA recommends that CMS consider additional changes to provider documentation requirements, such as reworking documentation guidelines to reward physicians for value-based care decisions, including contemplating conservative or less expensive treatment options, rather than for prescribing medications and deciding to perform surgery.

PAYMENT RATES UNDER THE PFS FOR NONEXCEPTED ITEMS AND SERVICES FURNISHED BY NONEXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS (PBD) OF A HOSPITAL

Section 603 of the Bipartisan Budget Act of 2015 requires that, with the exception of dedicated ED services, services furnished in off-campus PBDs that began billing under the outpatient prospective payment system (OPPS) on or after Nov. 2, 2015 are no longer to be paid under the OPPS, but rather under another applicable Part B payment system. For CY 2017, CMS finalized the PFS as the applicable Part B payment system and set payment for most nonexcepted services at 50 percent of the OPPS rate (i.e., a 50 percent PFS relativity adjuster). For CY 2018, CMS further reduced the site-neutral payment rate to 40 percent of the OPPS rate.

For CY 2019, CMS proposes to make no changes to the site-neutral payment rate under the PFS. Specifically, CMS proposes to allow nonexcepted off-campus PBDs to continue to bill for nonexcepted services on the institutional claim using a "PN" modifier and would maintain payment for nonexcepted services at 40 percent of the OPPS amount. The agency also proposes to maintain the same policies as 2018 related to supervision, beneficiary cost sharing, geographic payment adjustments, and partial hospitalization services.

CY 2019 PFS Relativity Adjuster. **While we agree with CMS's proposal to retain the fundamental methodology it used in CYs 2017 and 2018 for determining the PFS relativity adjuster, the AHA is disappointed that the agency did not propose to improve the accuracy of its methodology, as we have urged previously in our comment letter on the CY 2018 proposed rule. Specifically, CMS should explicitly account for differences in packaging across the OPPS and the PFS and ensure that both indirect and direct practice expense are accounted for in nonexcepted PBDs.**

That is, while CMS's analysis compared the OPPS rate to a rate that CMS determined physicians would have been paid for their practice expense under the PFS, the agency did not explicitly account for the fact that the OPPS incorporates far more packaging into its payments for services than the PFS. Therefore, to make its analysis truly equivalent and accurate, we continue to recommend that CMS remove from its analysis packaged costs that are incorporated in the OPPS rates, but not in the PFS practice expense rates. Furthermore, the AHA also recommends that, when making the comparison between payment for a service at the OPPS versus the PFS rate, CMS always use the full PFS payment for practice expenses in a nonfacility setting because a hospital continues to incur indirect costs, as well as direct costs, when a service is provided in the nonexcepted off-campus PBD. Without these changes, we believe that the proposed 40 percent relativity adjuster significantly underestimates the appropriate level of payment for nonexcepted services.

In the AHA's CY 2017 interim final rule comments and CY 2018 proposed rule comments, we discussed our replication of CMS's methodology for the PFS relativity adjuster, including making improvements as discussed above to account for differences in packaged costs and incorporating total practice expense. As a result, the AHA recommended a 64 percent relativity adjuster for 2017 and a 65 percent relativity adjuster for 2018. Unfortunately, due to the lack of transparency and the uncertainty regarding CMS's methodology for CY 2019 (as discussed below), we have been unable to replicate the agency's proposed relativity adjuster. We also were unable to estimate an updated CY 2019 relativity adjuster that incorporated differences in packaging and the including the total practice expense. **However, we remain confident that 65 percent of the OPPS amount, as we recommended for CY 2018, is a more reasonable relativity adjuster.**

Difficulties in Replicating CMS's Analysis. The CY 2019 PFS proposed rule is the first time that "PN" modifier claims data are available, allowing for some analysis of services furnished in nonexcepted off-campus PBDs**. However, the CY 2019 proposed rule differs from past years in that CMS does not provide the same detailed information that allowed the AHA and other interested stakeholders to replicate the agency's calculation of the PFS relativity adjuster.** For example, CMS failed to include:

- Its traditional table listing the codes it used for the analysis, the number of claims lines used for weighting, and the PFS methodology (using either the full non-facility amount, the technical component or difference between the PFS non-facility and facility amounts) used to determine PFS rate as a proportion of the OPPS payment;
- The outcome of its analysis and an explanation as to why it was using a rounded figure rather than the precise percentage obtained from its analysis;
- Its rationale for using all codes from 2017 with the "PN" modifier rather than 22 highest volume codes plus the E/M hospital outpatient clinic visit/physician office visit codes as it has used in previous years.
- Its rationale and methodology for imputing PFS values for contractor-priced codes and codes that are statutorily excluded from the PFS; and
- Whether it changed the utilization basis it used to determine the weights for services in the comparison. The proposed rule indicates that CMS weighted by "HCPCS claims" as opposed to "total claims lines" that CMS identified as the weight in previous years.

For this year's final rule and for future rulemaking, we request that CMS again provide the same information it provided in past years for analysis of the PFS relativity adjuster, as well as information regarding the above deficiencies. As a component of this we recommend that CMS make available on its website, along with other final rule information, an electronic version of the table it has included in past years containing the updated data used in its analysis. Such a practice will make CMS's policies more transparent and allow AHA and other public commenters to replicate CMS's analysis, thus allowing us to fully comment on the proposal.

In summary, the major areas of uncertainty arising from the CY 2019 proposed rule's discussion of CMS's methodology, which we recommend CMS explain in the final rule, include:

- What are "HCPCS claims"?
- What was the level of observation (claims lines, claims, units, other) used for calculation of values?
- What accounting, if any, was made for payment policies, such as multiple procedure reductions?
- Which codes were imputed?

- What were the PFS values for imputed codes?
- What were the PFS values other all other codes?
- Were all codes included, or were some excluded, such as vaccines?
- What year's payment rates were used?
- Given that this is a site-neutral policy affecting PN modifiers, were other codes that are newly proposed to be subject to site-neutral policies included, such as the hospital outpatient clinic visit E/M code with the PO modifier, as proposed in the CY 19 OPPS proposed rule?
- How were values computed when there was no OPPS rate?
- How were values computed when there was no PFS rate?
- Were there any other adjustments/overrides on values?

Furthermore, we urge the agency to ensure that in future rulemaking the PFS and OPPS proposed rules are coordinated so that they are released within a short time period of one another. The two-week gap between the release of the PFS and the OPPS proposed rules for CY 2019 means that the AHA and other interested stakeholders had an inadequate opportunity to comment on the proposed rule's site-neutral payment policy that was included in the PFS rule. That is, stakeholders effectively lost two weeks of the comment period because the OPPS data is necessary in order to run a replication of the site-neutral policy proposed in the PFS rule.

Continued Use of the Institutional Bill. **The AHA continues to strongly support CMS's decision to allow hospitals to bill for items and services furnished in nonexcepted PBDs using the institutional bill (UB04/837I). As it has noted, there also would be a significant advantage of continuing to use this payment approach for future years.** Continued use of the institutional bill will allow for these PBDs to properly use cost reporting procedures and to accurately reconcile the cost report to hospital ledgers for all services and departments and to correctly allow revenue for nonexcepted PBDs to flow through the Provider Statistical and Reimbursement (PS&R) report. Thus, hospitals will be able to continue to track their costs and charges for cost-reporting purposes and for certain important programs.

APPROPRIATE USE CRITERIA (AUC) FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

The Protecting Access to Medicare Act (PAMA) of 2014 required CMS to establish a program to promote the use of AUC for advanced diagnostic imaging that integrates AUC into the clinical workflow. The statute requires that, beginning Jan. 1, 2017, payment may 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 mechanism (CDSM) as to whether the ordered service adheres to applicable AUC. This policy applies only when applicable imaging services are provided in specific settings – a physician's office, hospital outpatient department (including an ED), an ambulatory surgical center, and

any other provider-led outpatient setting as determined by CMS. In this rule, CMS proposes to add independent diagnosing testing facilities to the list of applicable settings to which AUC consultation and reporting requirements apply.

CMS took initial steps to implement the AUC program in the CY 2016 PFS rule by defining AUC and specifying the process for developing them. In the CY 2017 PFS rule, CMS finalized a definition of and requirements for CDSMs. The agency released the first qualified CDSMs on July 13, 2017, coinciding with the release of the CY 2018 PFS proposed rule. In the CY 2018 final rule, CMS adopted a voluntary period from July 2018 to December 2019 for early adopters of AUC to report limited consultation information on Medicare claims forms. CMS also finalized a delayed start date of Jan. 1, 2020 for AUC consultation and reporting requirements, but determined that 2020 will be an "educational and operations testing year," during which CMS will pay claims regardless of whether they contain information on the required AUC consultation.

Reporting AUC Consultation Information. Section 1834(q)(4)(B) of the Social Security Act requires that payment for an applicable imaging service furnished in an applicable setting and paid for under an applicable payment system may only be made if the claim for the service includes certain information about the AUC consultation. In the CY 2018 PFS final rule, CMS specified that this requirement applied only to "furnishing professionals." However, CMS now proposes to revise its regulations to clarify that AUC consultation information must be reported on *all* claims – from both furnishing professionals *and* facilities – paid under applicable payment systems. **The AHA opposes this proposal because it does not appropriately target the AUC program to the ordering professionals to whom it is designed to apply.**

In direct contradiction to this Administration's goal of reducing regulatory burden, this proposal actually increases the regulatory burden for furnishing facilities, when it is the outlier ordering professionals that are the source of the problem. The AUC requirements introduce new data-reporting variables to the flow of information needed for hospital billing. CMS's proposal would require hospitals to capture this information and enter it into their billing systems. This would be an extremely difficult task given that there are a variety of pathways through which hospitals receive data-reporting information. Capturing this information for reporting under the AUC requirements would involve major system changes at a variety of operational areas, afflicting hospitals and health systems with steep costs of compliance with a program that governs ordering professionals who practice outside of their control. This work only would add to the burden of institutional providers who are already required to demonstrate the medical necessity of the services they provide.

Hospitals and health systems also would incur costs to develop a more formal method across hospital and physician sites for exchanging AUC information, if developing such a method would even be possible. Due to the wide range of physicians' levels of system capability, hospitals and health systems would likely be left to manually input AUC

information. And, even if hospitals and health systems devise a system by which to capture AUC information, they have no way to report it. The electronic claim standard for the institutional provider (837i) does not capture or have a placeholder for reporting the ordering physician's national provider identifier (NPI). Even if the 837i is modified, hospitals and health systems would still need to make sweeping and costly system changes to interface with a modified 837i.

These costly regulatory routines that CMS's proposal introduces inappropriately penalize hospitals and health systems, putting their payment at risk if AUC information does not appear on orders they receive from individual physicians. The AUC program was intended to evaluate physicians who order advanced diagnostic imaging services, not hospitals and health systems. By shifting the burden of compliance to furnishing providers, this proposal could force hospitals and health systems to take dollars away from patient care, driving up patient costs. This is especially true given that while CMS utilized 2014 data to analyze the impact of the AUC program, today many fewer institutional claims receive separate reimbursement for advanced diagnostic imaging services. As Medicare moves away from fee-for-service payment and hospitals and health systems increasingly enter payment arrangements with other payers and other Medicare programs, requiring facilities to report AUC information imposes additional costs that could otherwise be directed toward patient care services.

CMS's proposal also threatens patient care and access in other ways. If payment to the furnishing facility is tied to the reporting of the ordering professional's AUC consultation, furnishing professionals and facilities do not have recourse if an order lacks CDSM information. They would be forced to choose between not providing the service, thus inconveniencing the patient, and assuming that AUC was not consulted and report as such. This demonstrates the inappropriateness of forcing furnishing facilities to bear risk for the actions – or lack thereof – of ordering professionals.

The proposal also does not address the 5 percent of outlier ordering professionals whom the AUC program was intended to target, as it bears no connection to the physicians actually required to consult CDSMs. Congress intended the AUC program to serve as a way to educate physicians on the criteria they should follow for ordering advanced imaging. Yet this proposal does nothing to improve education nor dissuade bad actors from easily bypassing what the AUC rules intend. Ordering professionals could still simply select the code that indicates they consulted with the CDSM and automatically assign the coding for an advanced imaging order without altering their behavior or providing real proof of adherence to AUC requirements.

For these reasons, the AHA recommends that furnishing facilities (hospitals and health systems) be exempt from reporting AUC requirements. We also recommend that CMS consider alternative methods of implementing this proposal that do not require

reporting by furnishing professionals or facilities, For example, CMS could modify the Merit-based Incentive Payment System (MIPS) quality score for ordering professionals to include a requirement that they demonstrate their use of CDSM tools, incentivizing providers to invest in CDSM tools. This would achieve the desired outcome of the AUC legislation: greater utilization of CDSM tools that improves quality of care. CMS also could consider requiring a yearly attestation by ordering professionals that they consult CDSMs. At a minimum, we urge the agency to include clear instructions in the final rule and in the Medicare Manuals that it is the responsibility of ordering professionals to include the necessary information on their orders. **We further urge CMS to delay the Jan. 1, 2020 AUC implementation date to allow time for the agency to determine and implement a methodology to identify outlier ordering professionals.**

Consultations by Ordering Professionals. In an effort to reduce the burden of the AUC program, CMS proposes to allow AUC consultations to be performed by "auxiliary personnel incident to the ordering physician or non-physician practitioner's professional service." **The AHA appreciates this effort by CMS to introduce flexibility into the AUC program. To further clarify the proposal, the AHA requests that CMS specify that any auxiliary personnel in the office and under the supervision of the ordering professional can perform the required CDSM consultation, as long as the AUC feedback is provided to the ordering professional and the ordering professional has an opportunity to revise the order if necessary.**

Significant Hardship Exceptions to Consulting and Reporting Requirements. In the rule, CMS proposes to implement criteria specific to the AUC program for ordering professionals to qualify for a significant hardship exception from the AUC requirements. CMS expects the situations causing hardship to be extreme and uncontrollable events "that have a significant negative impact on healthcare operations, area infrastructure or communication systems." CMS proposes to require ordering professionals to self-attest if they are experiencing a significant hardship at the time of placing an order for advanced diagnostic imaging and to support such an attestation with documentation of the hardship. Ordering professionals would then communicate the attestation and supporting documentation, along with AUC consultation information, to the furnishing professional. Furnishing professionals and facilities would be required to append a modifier to their claims to indicate the ordering professional self-attested to experiencing a significant hardship and communicated this information to the furnishing professional along with the order. Claims that include the significant hardship exception modifier would not be required to include AUC consultation information.

CMS indicated in the rule that this proposal is designed to minimize the burden involved in seeking significant hardship exceptions, but requiring ordering professionals to self-attest to experiencing a hardship on an order-by-order basis would do just the opposite. **To that end, we recommend that CMS create a process through which ordering professionals can file for a blanket hardship exception that covers the period of time during which the hardship occurs.** If CMS expects hardships to arise out of

events “that have a significant negative impact” on operations and/or infrastructure, every order during such an event would likely qualify for a hardship exception. To truly reduce burden, we urge CMS to develop a mechanism by which ordering professionals’ self-attestation of experiencing a hardship can cover all of the orders for advanced diagnostic imaging during the length of the hardship. This change also would protect payment to furnishing professionals and facilities, whose payment could be at risk due to a technicality.

PART B DRUGS: APPLICATION OF AN ADD-ON PERCENTAGE FOR CERTAIN WHOLESALE ACQUISITION COST (WAC)-BASED PAYMENTS

Currently, Medicare reimburses new Part B drugs for which average sales price (ASP) price data is unavailable during the first quarter of sales at the rate of 106 percent of WAC. The WAC is the manufacturer’s list price and does not incorporate prompt-pay or other discounts. CMS proposes to reduce payment for certain new Part B drugs and biologicals from the rate of 106 percent of WAC to 103 percent of WAC. Specifically, the proposed reduction would apply to drugs and biologicals where ASP price data is unavailable during the first quarter of sales and in circumstances when Medicare Administrative Contractors (MAC) determine pricing for new drugs that do not appear on the ASP pricing files. CMS states that this proposal is consistent with a recommendation included in the fiscal year 2019 President’s Budget Proposal and the Medicare Payment Advisory Commission’s (MedPAC) June 2017 Report to Congress.

The AHA opposes this approach because it would unfairly shift the burden for the high list prices imposed by drug manufacturers onto hospitals and physicians. Further, with the Medicare 2 percent sequestration still in effect, payment for drugs and biologicals would effectively be reduced by far more than proposed by CMS. We are concerned that such a significant reduction in payment could negatively impact the ability of some providers to afford these new WAC-priced drugs. It also would not account for the growing pharmacy overhead costs, including drug handling and storage costs, that the WAC add-on percentage was intended to cover.

Finally, we note that MedPAC proposed this WAC policy as part of a larger package of Part B drug recommendations, including a recommendation for improving ASP data reporting. Currently only drug manufacturers with Medicaid rebate agreements are required to report their ASP data and some manufacturers required to report ASP data fail to do so in a timely manner. The Commission’s June 2017 report proposed a policy to require all Part B drug manufacturers to report ASP data and give the Secretary the authority to apply penalties to manufacturers who do not report required data. **The AHA supports efforts to improve ASP data reporting by manufacturers and encourages CMS to pursue this approach in order to ensure that timely and accurate ASP data is available for rate setting.**

CLINICAL LABORATORY FEE SCHEDULE (CLFS)

Background. Starting in CY 2018, CMS sets the CLFS payment rates based on the weighted median of private payer rates collected and reported by "applicable laboratories". Currently an applicable laboratory is a laboratory that bill Medicare under its own NPI and receives more than 50 percent of its Medicare revenues during the six-month data collection period from PFS and CLFS services. This is referred to as the "majority of Medicare revenues" threshold. Clinical laboratories receiving less than $12,500 in Medicare revenues for CLFS services during the six-month data collection period are exempted from the requirement to report private payer rates. This is referred to as the "low expenditure" threshold.

CMS reports that stakeholders have expressed concerns that 2018 CLFS payments rates are based on private payer data reported by a relatively small number of laboratories. In particular, laboratory stakeholders are concerned that the data used to set the new CLFS rates included too few hospital-based outreach laboratories[1], physician office laboratories and small independent laboratories. In response, CMS requests feedback on several approaches that may result in more data being used on which to base future CLFS payment rates.

Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory. CMS proposes to change the definition of applicable laboratory to remove Medicare Advantage payments from the denominator of the majority of Medicare revenues threshold in order to increase the number and type of laboratories that would qualify as an applicable laboratory. In the proposed rule's regulatory impact analysis, CMS estimates that this would yield an increase of 43 percent in the number of laboratories meeting the majority of Medicare revenues threshold (an additional 835 laboratories) and an increase of 5 percent in the number of data points reported.

The AHA opposes CMS's proposal to remove Medicare Advantage payments from the "majority of Medicare revenues" threshold. The increased data reporting burden that would be imposed on hospital laboratories newly meeting the "applicable laboratory" definition would not be justified by what CMS itself expects to be a minimal impact on the CLFS rates. **Further, increasing the number of laboratories qualifying for applicable laboratory status and imposing additional data reporting burden with no perceptible impact expected in the CLFS rates is in direct conflict with the Administration's goal of reducing regulatory burden.** CMS's own impact analysis discussion supports our position. It states: "there is no reason to believe that increasing the level of participation would result in a measurable cost difference under the CLFS. Given that the largest laboratories with the highest test

[1] CMS describes hospital outreach laboratories as "laboratories that furnish laboratory tests for patients who are not admitted hospital inpatients or registered outpatients of the hospital and who are enrolled in Medicare separately from the hospital of which they are a part as independent laboratories that do not serve hospital patients."

volumes, by definition, dominate the weighted median of private payer rates, and the largest laboratories reported data for the determination of CY 2018 CLFS rates and are expected to report again, we do not expect the additional reported data resulting from our proposed change to the majority of Medicare revenues threshold to have a predictable, direct impact on CLFS rates."

Solicitation of Public Comment on Other Approaches to Defining Applicable Laboratory. In other efforts to include more private payer data for the next data reporting period, CMS is seeking public comment on two alternative approaches suggested by stakeholders for defining an applicable laboratory. CMS previously considered and rejected both of these alternatives in prior rulemaking.

CMS seeks comments on:

- Using Form CMS-1450 bill type 14X to determine majority of Medicare revenues and low expenditure thresholds.
- Using the Clinical Laboratory Improvement Amendments (CLIA) Certificate to Define Applicable Laboratories

The AHA opposes these refinements to CMS's methodology for all the reasons the agency itself lists in the proposed rule (as described below). We also are concerned that the systems changes that hospital laboratories newly defined as applicable laboratories would have to make in time for the Jan. 1, 2019 start of the next "data collection period" would pose nearly unsurmountable operational challenges.

Using Bill Type 14X. CMS notes that some laboratory stakeholders have advocated for increasing the number of hospital outreach laboratories required to report private payer data by using only the revenues from services reported on the CMS-1450 14X bill type (a bill type only used by hospital outreach laboratories) to calculate the "majority of Medicare revenues" threshold and the "low-volume" threshold. Such revenues would be based only on bills used for hospital laboratory services provided to non-patients. Although CMS is requesting comments, the agency expresses operational feasibility and statutory authority concerns about this approach**. The AHA agrees with and shares CMS's concerns, including:**

- The 14X bill type does not identify an entity the way an NPI does. Whereas an NPI is associated with a provider or supplier to determine specific Medicare revenues, the 14X bill type is merely a billing mechanism that is currently used only for a limited set of services. Also, some private payers may not require a laboratory to use a 14X bill type, so hospitals would need to develop their own mechanisms for identifying and reporting only applicable information associated with their outreach business. **We agree that the additional work-arounds necessary to report private payer data for hospital outreach laboratories**

under this approach would pose a significant operational burden on hospitals.

- CMS questions whether hospitals would have sufficient time after publication of a new final rule that included using the Form CMS-1450 14X bill type, and any related subregulatory guidance, to develop and implement the information systems necessary to collect private payer rate data before the start of the next data collection period, that is, Jan. 1, 2019. As noted previously, **the AHA does not believe that finalizing this change would allow hospital outreach labs sufficient time to make the necessary systems changes prior to the start of the next data collection period.**

- The agency believes that defining applicable laboratory at the NPI level, as it currently does, provides "flexibility for hospital outreach laboratories to not obtain a unique billing NPI, which may be significant particularly where a hospital outreach laboratory performs relatively few outreach services under Medicare Part B." By contrast, the 14X bill type approach would require a hospital outreach laboratory to report applicable information any time it exceeded a low revenue threshold. **The AHA agrees that the flexibility inherent in the current policy would be lost under the alternative 14X bill type approach.**

- CMS's most significant concern is that by using the 14X bill type all hospital outreach laboratories would meet the majority of Medicare revenues threshold, which the agency states would be inconsistent with the statute which defined an applicable laboratory in a way that not all laboratories qualify. **The AHA agrees that Congress did not intend all hospital outreach laboratories to qualify as applicable laboratories.**

Using the CLIA Certificate to Define Applicable Laboratories. Some stakeholders requested that CMS use the CLIA certificate, rather than the NPI, to identify a laboratory that would be considered an applicable laboratory. Under this approach, the "majority of Medicare revenues" and the "low expenditures" thresholds would be determined at the CLIA certificate level, and the definition of "applicable laboratory" would be modified to include the CLIA.

Once again, the AHA agrees with and supports the concerns that CMS expresses about this approach, including:

- Information regarding the CLIA certificate is not required on the 14X bill type, so it is not clear how a hospital would identify and distinguish revenues generated by its separate CLIA-certified laboratories for their outreach services. **Any work-around to resolve this problem would be extremely burdensome for hospitals to develop and implement.**

- One CLIA certificate could be assigned to a hospital's entire laboratory business, which would include laboratory tests performed for hospital patients as well as non-patients. As a result, a hospital outreach laboratory that otherwise could meet the definition of applicable laboratory, as currently defined at the NPI level, would not be an applicable laboratory under this approach because its laboratory revenues under the inpatient prospective payment system (IPPS) and the OPPS alone would likely far exceed the revenues it receives under the CLFS and PFS.

In addition to CMS's concerns about these two alternative approaches, the AHA believes that even if every hospital outreach laboratory were to be required to report their private payer data, it is highly unlikely that this would result in a significant change in the weighted median rates calculated by CMS due to the massive amount of private payer data that would be reported by the large independent laboratories. This is because hospital outpatient claims reported using 14X bill type make up a small percentage of total hospital claims. In a recent analysis of the number and percentage of hospital outpatient claims billed, we found that the 14X bill type represents only 12.20 percent of all hospital outpatient claims. The distribution by bill type is provided in the table below.

Bill Type Distribution Limited to Short-term PPS Providers

Bill Type	Frequency	Percent
12X	482,242	0.43
13X	98,751,362	87.37
14X	13,794,074	12.20

Source: 2017 OPPS data used in CY 2019 OPPS rule

Furthermore, the range of tests typically ordered on non-patient specimens is not representative of the laboratory's full testing menu but represents only a limited portion of testing available. The majority of the outreach laboratory testing would include cultures, urine testing, biopsies and pap smears. We believe that this limited breadth of testing would not provide the full range of market based data that the agency and laboratory stakeholders expect.

In addition, even if more hospital outreach laboratories are defined as applicable laboratories using the 14X bill type, many would not be able to report the private payer data at the CPT/HCPCS code level, as CMS requires. That is, often hospital systems do not post or have data at a CPT/HCPCS code level required to report the payments by test. This would again represent a reporting burden without significantly impacting the weighted median-based CLFS rates.

QUALITY PAYMENT PROGRAM – MERIT-BASED INCENTIVE PAYMENT SYSTEM

Mandated by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Quality Payment Program (QPP) began on Jan. 1, 2017, and includes two tracks—the default MIPS, and a track for clinicians with a sufficient level of participation in certain advanced alternative payment models (APMs). The rule proposes quality measurement changes for the CY 2019 performance period, which would affect payment in CY 2021

The AHA has urged that the MIPS be implemented in a way that measures providers accurately and fairly; minimizes unnecessary data collection and reporting burden; focuses on high-priority quality issues; and fosters collaboration across the silos of the health care delivery system. To achieve this desired state, we have recommended that CMS prioritize the following policy approaches:

- Adopt gradual, flexible changes in MIPS reporting requirements in the initial years of the program to allow the field sufficient time to plan and adapt;

- Streamline and focus the MIPS quality and cost measures to reflect the measures that matter the most to improving outcomes;

- Allow facility-based clinicians the option to use their facility's CMS quality reporting and pay-for-performance results in the MIPS;

- Employ risk adjustment rigorously – including sociodemographic adjustment, where appropriate – to ensure providers do not perform poorly in the MIPS simply because of differences in clinical severity and communities served; and

- Align the requirements for eligible clinicians in the Promoting Interoperability (formerly known as Advancing Care Information) performance category with the requirements for eligible hospitals and CAHs.

CMS has made important progress in addressing the above priorities. In the first two MIPS performance years (CYs 2017 and 2018), CMS adopted gradual increases to the length of reporting periods, data standards, and the performance threshold for receiving positive or negative payment adjustments. The CY 2019 proposed rule continues this approach. **In addition, we applaud CMS for proposing a modest expansion of the facility-based measurement option the agency adopted in the CY 2018 QPP final rule. We also are greatly encouraged that CMS is using its "Meaningful Measures" framework to propose the removal of more than 30 measures from the MIPS program.**

However, we believe CMS's proposals to increase the weight of the MIPS cost category to 15 percent, and to add eight new measures to the cost category, are premature. We urge the agency to delay the implementation of this policy by at least one year. Furthermore, opportunities remain to ensure that clinicians are able to effectively transition to the 2015 edition of certified electronic health record (EHR) technology, and to improve risk adjustment.

MIPS Eligibility and Exclusions.
Expansion of Eligible Clinician Types. **The AHA supports CMS's proposal to expand the definition of "MIPS-eligible clinician" to include physical therapists, occupational therapists, clinical social workers and clinical psychologists.** The MACRA provides CMS with the discretion to expand the MIPS to include such clinicians. These clinicians are integral members of the care team, and many of them can bill under the Medicare PFS. Furthermore, these clinician types participated in the legacy Physician Quality Reporting System (PQRS). Given that the MIPS is now in its third year, we believe it is appropriate to again include these types of clinicians.

At the same time, we urge CMS to clarify some aspects of its proposals. Specifically, the agency proposes not to score these new clinician types on the MIPS Promoting Interoperability category for at least the CY 2019 reporting period. However, CMS does not state whether this policy applies only to individual clinicians and groups comprised solely of the newly added clinician types. We assume that group practices that include a combination of current MIPS clinician types and the newly proposed clinician types would still be expected to report in the promoting interoperability category. But it is not clear whether the new clinician types would be removed from the denominator of promoting interoperability measures. We ask the agency to clarify its approach policy in the final rule.

Furthermore, we ask CMS to consider how the proposed expansion applies to these new clinician types who may be billing under a hospital's tax identification number (TIN). Hospitals that employ these clinicians are paid under the PFS, but the TIN used is the hospital as the employer. However, the proposed rule does not indicate whether hospitals should report the NPI of these clinicians on the UB-04 claims used by hospitals. We ask CMS to clarify whether it intends to exclude these hospital-employed clinicians from the MIPS, or whether it would update billing instructions so that hospitals must report the NPIs of these clinicians on UB-04 claims. This step likely would be necessary since CMS relies on TIN/NPI combinations to identify MIPS-eligible clinicians. We also caution that adding these clinician types to UB-04 claims would entail significant administrative burden to hospitals.

Low-volume Threshold. **The AHA supports CMS's proposal to retain CY 2019 MIPS low-volume thresholds that are largely the same as those used for the CY 2018 performance period.** Specifically, CMS proposes to exclude from the MIPS clinicians that have $90,000 or less of allowed charges for covered professional services, provide

care to 200 or fewer Medicare beneficiaries, or provide 200 or fewer covered professional services under the PFS. Rural hospitals have continued to express concerns about their readiness to assist physicians and other clinicians in participating in the MIPS. Retaining similar thresholds as the CY 2018 performance period would provide at least one more year of time to prepare for data reporting in the MIPS.

At the same time, the AHA urges CMS to continue working with the field to evaluate the low-volume thresholds to determine when it should lower the thresholds. During this time of transition, the higher thresholds CMS has proposed provide time to prepare for the transition to value-based payment under the MIPS. At the same time, the higher thresholds make the pool of participating clinicians much smaller than it would be otherwise. In the context of a budget-neutral program, this means the potential upside of the MIPS will be quite limited until more clinicians are included.

As CMS considers including more clinicians in the MIPS, we encourage the agency to propose and adopt a "roadmap" approach in which it proposes and adopts lower thresholds for several performance years at a time. For example, in next year's proposed rule, CMS could propose the low-volume thresholds for CY 2022, CY 2023 and CY 2024. This approach would provide those clinicians excluded from the MIPS greater certainty about when they would be expected to participate.

MIPS Opt-in. **The AHA supports CMS's proposal to allow eligible clinicians to "opt-in" to the MIPS if they surpass one or two, but not all, of the MIPS low-volume threshold criteria.** These clinicians could choose "full participation" in the MIPS in which they can experience positive or negative payment adjustments, or "voluntary reporting" in which they just submit quality data. We believe this approach offers flexibility to those clinicians below the low-volume thresholds who may feel they are ready to participate fully in the MIPS. It also may encourage those clinicians who are not ready to have their payment affected by MIPS performance to test their ability to gather and submit performance data.

However, the AHA asks CMS to clarify the deadline for opting into the MIPS for a given performance year. The proposed rule notes that clinicians wishing to use one of the MIPS opt-in options must elect it through CMS's QPP web portal. However, it is not clear whether clinicians can choose to wait until the data submission deadline for a performance year, or whether they must elect it sooner than that.

Group Practice Definition. CMS proposes to continue allowing eligible clinicians to participate as individual clinicians or as part of group practices, a policy the AHA has long supported. **However, we are encouraged that, as we have previously urged, CMS is exploring the ability for group practices to better define their own groups.** For the purposes of the MIPS, a "group practice" is two or more clinicians that bill under the same TIN. Many health systems include large, multi-specialty practices that for a

variety of reasons have chosen to bill under a single TIN. However, CMS's definition of group practice means that the groups must select measures that may not be relevant to all of the clinicians in their group. The option of submitting a group roster would allow multispecialty groups to split into clinically relevant reporting groups. The use of group rosters also could allow the possibility of multiple TINs within a delivery system to report under a common group.

We recognize that CMS would need to balance the benefit of this approach with the administrative burden required to implement it. At the same time, the option could help align MIPS reporting to more accurately reflect the ways in which health care systems are organizing themselves.

MIPS Facility-based Measurement. As long urged by the AHA, CMS adopted in last year's QPP final rule a facility-based measurement option starting with the CY 2019 performance period. Under this approach, clinicians who provide 75 percent or more of their services in certain hospital and ED settings can use their hospital's CMS hospital value-based purchasing (VBP) program performance in the MIPS without having to report separate quality or cost data. In short, it means those clinicians and hospitals can focus their efforts on the same set of priorities, and see their performance rewarded in a consistent fashion.

The AHA applauds CMS for responding to our long-standing request to develop a facility-based measurement option for the MIPS, and we support all of the proposed policy updates. At the same time, we continue to urge CMS to better equip hospitals to work with the clinicians that choose to use this option, and consider future expansion of the option to a broader array of facility types, such as post-acute care providers.

Eligibility. **The AHA applauds CMS for heeding our recommendation to expand its definition of "facility-based" services.** Specifically, CMS proposes to add on-campus hospital outpatient settings (as identified by place of service (POS) code 22), as long as the clinician also bills at least one service using POS code 21 (inpatient hospital) or 23 (ED). As a result, facility-based measurement would be available to individual clinicians (of any specialty) that have at least 75 percent of their covered professional services provided in the inpatient hospital, on-campus outpatient hospital, or ED settings. The AHA agrees that this approach will help capture those clinicians who are primarily inpatient, but spend small but significant time providing care in settings, such as observation units or same-day surgical units based in hospitals.

For group practices, CMS would continue to require that at least 75 percent of clinicians in the group (as defined by TIN) meet the "facility-based" threshold for individual clinicians. **The AHA continues to urge CMS to increase the flexibility in meeting the facility-based threshold for group practices. That is, group practices should be eligible for the reporting option if 75 percent of its clinicians meet the**

individual clinician definition of facility-based, OR 75 percent of a group's total billing for covered professional services are provided in facility settings. CMS has employed a similar "either/or" approach in applying MIPS low-volume threshold and advanced APM eligibility, in which clinicians and groups qualify for exemption and inclusion respectively based on patient counts or total billing. Furthermore, the structures of group practices vary, and while some may have the vast majority of their activity performed in the inpatient and/or ED setting, not all of their clinicians may be as focused on those settings. We believe examining both individual clinicians and total group practice billing would capture additional practices that do spend most of their efforts on providing inpatient and ED care.

Automatic Application of Facility-based Measurement. **The AHA supports CMS's proposal to automatically apply facility-based scoring to those clinicians and groups that meet the definition of facility-based unless their performance is better under MIPS data they choose to submit.** We agree that this approach should result in the least administrative burden.

Data for Hospitals. **The AHA continues to urge CMS to provide a report to each hospital identifying the clinicians CMS would link to its facility under the facility-based measurement option.** We applaud CMS for sharing information with clinicians about whether they qualify for the facility-based reporting option. However, we also believe hospitals would benefit greatly from knowing which clinicians working with them may qualify for the option. While hospitals could estimate which of its employed clinicians might qualify for the option, it would be more challenging to know which contracted clinicians might qualify. The most significant benefit to a facility-based measurement option is the opportunity for hospitals and clinicians to collaborate on improving performance. A list of clinicians would facilitate this collaboration.

Future Expansion to Other Facility Types. **The AHA is greatly encouraged by CMS's interest in expanding facility-based measurement to a broader array of facility types.** The current facility-based measurement option ties to the hospital VBP program, as well as hospital inpatient and ED sites of service. This means that clinicians practicing in other facility types – such as inpatient rehabilitation facilities, skilled nursing facilities, long-term acute care hospitals and inpatient psychiatric facilities – would be unlikely to qualify for the reporting option. Each of these facility types has a Medicare quality reporting or pay-for-performance program from which to draw measures, making it feasible to implement facility-based reporting for them as well. Furthermore, our members from these facilities have noted the significant gaps in available MIPS quality and cost measures that meaningfully reflect practice in those facilities.

We urge CMS to explore methodologies for translating the performance in the CMS quality reporting programs for those facilities into MIPS scores. For example, CMS could use an approach similar to its proposal in which clinicians are scored on a composite of the measure scores from the facility-level program. For post-acute care

settings, CMS may consider calculating separate quality and cost composite scores since the reporting programs do not have a methodology similar to the hospital VBP's total points score that combines cost and quality into a single score. Alternatively, the agency could identify specific measures from the programs, and allow clinicians to have their MIPS performance tied to them.

MIPS Quality Category.

Removal of Quality Measures. **The AHA applauds CMS for beginning to use its "Meaningful Measures" framework to streamline the measures used in the MIPS. We support CMS's proposed removal of 34 MIPS measures.** The AHA has long urged the agency to reduce and prioritize the measures used in its quality programs so that they focus on the issues that matter the most to improving care and outcomes. CMS's Meaningful Measures framework identifies six overarching quality priorities and 19 specific measurement areas aligned with those priorities. The priorities CMS identified are intended to cut across the full continuum of its quality measurement programs – hospitals, physicians, post-acute care and health plans. The AHA is pleased that most of the "meaningful measure" priority areas are ones that the AHA has consistently recommended to the agency.

Measures Impacted by Clinical Guideline Changes. **The AHA urges CMS to modify its proposed policy for scoring quality measures affected by clinical guideline changes.** CMS proposes that MIPS quality measures affected by changes to clinical guidelines during a performance year would be scored as zero points, and removed from the quality category's denominator. This policy would apply regardless of whether the guideline change was one that affects patient safety, or whether it is simply not the most current.

We believe CMS's proposed policy is appropriate for measures where the guideline change affects patient safety significantly. Indeed, it would be inappropriate for providers to have their performance tied to a measure that could result in patient harm. Removing the measure from the quality category's numerator and denominator is, therefore, appropriate.

However, we do not believe the proposed policy is appropriate for measures whose guideline changes simply reflect updated clinical knowledge. Clinicians invest significant time and resources to assess and improve their performance on a measure over the course of a performance period. Removing a measure part of the way through a performance period does not appropriately recognize these efforts. Therefore, we urge CMS to retain existing quality category scoring policies for these measures, while ensuring that the updated version of the measures is incorporated into the next available performance period.

MIPS Cost Category. Using its statutory discretion under the Bipartisan Budget Act of 2018, CMS proposes to gradually increase the weight of the MIPS cost category

(currently 10 percent) by five percentage points each year through CY 2024 payments. As a result, for CY 2021, the weight of the cost category would be 15 percent. Furthermore, CMS proposes to add eight episode-based cost measures to the cost category. Clinicians would be scored on these measures in addition to the two overall cost measures already used in the category – Medicare spending per beneficiary (MSPB), and total cost per capita. Clinicians and groups would be scored on the measures for which they have a sufficient number of attributed cases.

Hospitals and clinicians alike are focused on improving the value of care, and need well-designed measures of cost and resource use to help inform their efforts. However, we urge CMS to delay its proposal to increase the weight of the cost category, and to adopt the eight episode-based cost measures, until at least CY 2022.

Serious questions remain about the accuracy and reliability of all of the measures in the cost category, making it problematic to increase the weight beyond its current amount. CMS's recent changes to the MSPB measure underscore this point. In the CY 2017 QPP final rule, CMS chose to remove specialty adjustment from the MSPB measure, and lower the MSPB minimum volume threshold from 125 cases to just 20 cases. Yet neither of these changes had strong data to support them. Specialty adjustment in MSPB is intended to account for differences in specialty mix that can affect the costs of care. CMS simply suggested it was "unclear" whether the adjustment helps to account for cost differences by specialty without a complete analysis to demonstrate this finding. We remain concerned that without specialty adjustment, certain clinicians will appear to have inferior performance on the measure because they provide needed care that is inherently more expensive.

Moreover, the MSPB measure once had a minimum case threshold of 125 cases because CMS's analyses suggested that many cases were necessary to get a statistically reliable result. We do not believe the measure materially changed in such a way that it achieves reliable results without the higher case threshold, and worry that the lowered threshold will be rewarded or penalized based on random variation, not real performance differences.

The AHA also remains concerned that the basic performance attribution approach for the MSPB and cost per capita measures in the MIPS lacks a "line of sight" from clinician actions to measure performance. The measures do not reflect the performance of just the clinician or group practice. Rather, the measures attribute *all* of the Medicare Parts A and B costs for a beneficiary during a defined episode (three days prior to 30 days after an inpatient admission for MSPB, and a full year for total cost per capita). Yet these costs reflect the actions of a multitude of health care entities – hospitals, physicians, post-acute providers, etc. The ability for any clinician or group to influence overall measure performance will vary significantly depending on local market factors, including the prevalence of clinically integrated networks.

Furthermore, while we appreciate the concept behind the episode-based measures, we are concerned that clinicians have had limited time to understand their baseline performance and implement changes to improve performance. In contrast to the two total cost measures, the episode-based measures include only the items and services related to the episode of care for a particular treatment or condition. This measurement approach can result in a more clinically coherent set of information about cost. However, this approach also necessitates the use of algorithms for identifying costs relevant to an episode, and a multi-step approach for attributing measure performance. This methodology adds necessary rigor, but also complexity. Yet, clinicians only have information from a "dry run" of the episode measures that CMS conducted using data from 2016. Clinicians do not yet have data on their 2017 performance, let alone their 2018 performance.

In addition, we are concerned that the measures have not yet been endorsed by the National Quality Forum (NQF). The AHA believes that all measures used in public reporting and pay-for-performance programs should be NQF-endorsed because the process gives important insights into the reliability, validity, and usability of measures.

Lastly, before increasing the weight of the cost category further, we urge CMS to assess the extent to which sociodemographic factors impact cost measure performance. Sociodemographic adjustment should be incorporated as needed. The evidence showing the link between sociodemographic factors and patient outcomes continues to grow. Most recently, this connection is clearly evident in a report to Congress from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and in the National Academy of Medicine's (NAM) series of reports on accounting for social risk factors in Medicare programs. Both reports provide evidence-based confirmation of what hospitals and other providers have long known – patients' sociodemographic and other social risk factors matter greatly when trying to assess the performance of health care providers.

The NAM reports show that performance on a variety of outcomes – readmissions, cost and patient experiences – is affected by social risk factors. The ASPE report demonstrates that clinicians, hospitals, and post-acute providers alike are more likely to score worse on CMS pay-for-performance programs when they care for large numbers of poor patients. As we note in the next section, CMS took an important step towards recognizing the impact of these factors by implementing a MIPS "complex patient bonus," but we believe that bonus should be viewed as an interim step while more sophisticated approaches to accounting for social risk factors are developed.

MIPS Final Score.
Small Practice Bonus. **The AHA opposes CMS's proposal to add MIPS small practice bonus points to only the MIPS quality category score. We urge CMS to retain its existing policy in which the small practice bonus is added to the total**

MIPS final score. For practices of 15 or fewer clinicians, CMS proposes to add three points to the quality category score for practices that submit at least one quality measure. This is in contrast to the existing small practice bonus approach in which eligible clinicians receive five bonus points added to their total MIPS score if they submit data on at least one MIPS performance category.

By de-valuing the small practice bonus, we are concerned that CMS's proposed approach fails to recognize the significant investment of resources required for practices to participate in the MIPS. It also creates a disincentive for smaller practices to "opt-in" to the MIPS. Given the agency's stated goals of moving the field towards value, we believe the existing policy should be retained at this time.

Complex Patient Bonus. **The AHA continues to support the use of a complex patient bonus, but urges CMS to view it as an interim step while methodologies for accounting for social and clinical risk continue to evolve.** CMS took an important step toward recognizing the impact of sociodemographic and other risk factors on outcomes by adopting a "complex patient bonus" in the MIPS in 2018. Clinicians receive up to five bonus points on their MIPS final scores based on a Medicare claims-derived proxy for patient complexity (Hierarchical Condition Categories, or HCCs), as well as the number of patients dually eligible for Medicare and Medicaid that a clinician or group treats. Dual-eligible status is a proxy for sociodemographic factors.

However, experience from the use of HCC scores in the value-based payment modifier (VM) raises significant questions about its adequacy in accounting for patient risk. CMS used HCC scores to provide modest increases to performance scores to groups treating significant numbers of high-risk patients. Unfortunately, the results of the 2016 VM program show that group practices caring for patients with more clinical risk factors were still significantly more likely to receive negative VM adjustments. Furthermore, while dual-eligibility is an established proxy for sociodemographic status, there are others – such as income and education – that may be more accurate adjusters for particular measures.

QUALITY PAYMENT PROGRAM – ADVANCED APMS

Recognizing Investment Risk. There remains strong interest from the field in participating in advanced APMs to support new models of care, and to qualify for the bonus payment and exemption from the MIPS. However, opportunities to access the advanced APM track remain significantly constrained. Indeed, data in the proposed rule suggest that as few as 15 percent of eligible clinicians likely would qualify for the advanced APM track in 2019.

CMS proposes to continue most CY 2018 policies governing the advanced APM track into CY 2019. Disappointingly, this includes criteria for downside financial risk that

exclude most of the Medicare APMs in which many hospitals, health systems and clinicians participate, including Track 1 of the Medicare Shared Savings Program (MSSP). **The AHA remains concerned that this approach fails to recognize the significant resources providers invest in the development of APMs. We continue to urge CMS to expand its definition of financial risk to include the investment risk borne by providers who participate in APMs and to develop a method to capture and quantify such risk.**

The successful implementation of an APM requires providers to acquire and deploy infrastructure and to enhance their knowledge base in areas, such as data analytics, care management, and care redesign. Further, one metric for APM success – meeting financial targets – may require providers to reduce utilization of certain high-cost services, such as ED visits and hospitalizations through earlier interventions and on-going supports to meet patient needs. However, this reduced utilization may result in lower revenues. Providers participating in APMs accept the risk that they will invest resources to build infrastructure and potentially see reduced revenues from decreased utilization, in exchange for the potential reward of providing care that better meets the needs of their patients and communities and generates shared savings. This risk is the same even in those models that do not require the provider to repay Medicare if actual spending exceeds projected spending.

Advanced APM Requirements. The MACRA requires that advanced APMs meet three general criteria:

- Require participants to use certified EHR technology;
- Condition some amount of payment for covered professional services on quality measures comparable to those in the MIPS quality performance category; and
- Require that APM entities bear risk for monetary losses of more than a nominal amount.

CMS proposes changes to each of these criteria for the CY 2019 performance period

Use of Certified EHR Technology. **The AHA urges CMS not to finalize its proposal to increase the required percentage of clinicians in an advanced APM using certified EHR technology from 50 percent to 75 percent.** We appreciate that CMS proposes to increase this threshold to align with the agency's priority of promoting the interoperability of EHRs. However, we are concerned that if finalized, this proposal would create another barrier to entry into advanced APMs. At a time when the agency is intent on promoting the move towards innovative value-based payment arrangements, this proposal could undermine this move.

Quality Measures. **The AHA supports CMS's proposal to require advanced APM models to use at least one outcome measure that is used in the MIPS**, endorsed by a consensus-based entity or is otherwise evidence based. This proposal would eliminate the exception for models where there are no available outcome measures

applicable to the model. In general, the AHA believes this proposal is reasonable given the growth in the use of outcome measures.

Generally Applicable Financial Risk Standard. **The AHA applauds CMS's proposal to continue its 8-percent revenue-based risk standard through the CY 2024 performance period.** In 2016, CMS finalized a standard that sets the total potential risk (i.e., the maximum potential payment for which an entity could be liable under the model) that most models must require to be considered an advanced APM. Specifically, under the standard finalized by CMS, the standard is met if the terms of the APM require that an APM entity potentially owes or forgoes the following amount:

- Three percent of the expected expenditures for which an APM entity is responsible under the APM, such as through a benchmark or target price (the "benchmark standard"), or
- Eight percent of the average estimated total Medicare Parts A and B revenues of participating APM entities (the "revenue-based standard").

CMS previously finalized the revenue-based standard only for the CY 2017 through CY 2020 performance periods, stating that it intended to increase the standard in subsequent years. We believe extending this standard further provides the stability and predictability that can help attract more clinicians into advanced APMs.

Multi-year Other Payer Advanced APM Determination. **The AHA supports CMS's proposal to allow other payer advanced APMs to submit multi-year arrangements that would not require them to go through the advanced APM determination process each year.** In the CY 2018 QPP final rule, CMS established a "determination process" allowing for payers such as Medicare Advantage, Medicaid, multi-payer models, and private payers – to submit their models to qualify as advanced APMs. These other models would enable clinicians to qualify for advanced APM status under the "all-payer advanced APM option," in which CMS considers participation in both Medicare advanced APMs and other payer APMs. The policy adopted last year would require other payer APMs to re-submit all information on annual basis. Under CMS's proposed policy, an advanced APM that submits a multi-year arrangement would not have to re-submit information unless the arrangement was changing substantially.

TIN-level All-payer Qualifying Participant (QP) Determination. **The AHA supports CMS's proposal to allow QP determinations to be requested at the TIN-level in addition to the APM entity and individual eligible clinician levels.** CMS previously finalized that it would determine whether QPs using the all-payer combination meet the advanced APM participation thresholds at only the individual clinician and APM entity levels. However, as the agency noted, contracting often is executed at the TIN level. Thus allowing the determinations to be done at the TIN-level should lessen administrative burden.

AHA Recommendations Supporting the Transition to the Promoting Interoperability Performance Category

Background. CMS proposes several changes to the Promoting Interoperability performance category, formerly the Advancing Care Information performance category, to focus on relieving regulatory burden and to emphasize the role of electronic exchange of health information among providers and with patients. **AHA appreciates the introduction of added flexibility in the requirements for MIPS-eligible clinicians. Specifically, AHA supports the following proposals:**

- **Removing the objective and measures that hold eligible clinicians responsible for the actions of others;**
- **Shifting to a performance-based scoring methodology that eliminates required thresholds and permits eligible clinicians to get credit for building performance in some areas while earning additional points in areas of strong performance; and**
- **Setting the reporting period to be of a minimum of any continuous 90-day period in CYs 2019.**

AHA believes that MIPS-eligible clinicians would benefit from additional time to implement and optimize the 2015 edition certified EHR technology. Experience to date indicates that the transition to a new edition of certified EHR technology is challenging due to lack of vendor readiness, the necessity to update other systems to support the new data requirements, and the time required to review and modify workflows and build performance. We are concerned that the 2019 transition would present additional challenges due to new reporting requirements and requirements to use EHR functionality that was not included in the 2015 edition certification criteria. To address these challenges and to provide additional relief to providers, the AHA offers several recommendations intended to facilitate an effective transition to the Promoting Interoperability performance category and the safe use of 2015 edition certified EHRs.

Advance the Proposed Performance-based Scoring Methodology. CMS proposes a new scoring methodology for MIPS-eligible clinicians applied to four objectives derived from objectives found in the Advancing Care Information (ACI) performance category: Electronic Prescribing, Patient Electronic Access to Health Information, Health Information Exchange and Public Health and Clinical Data Registry Reporting. The Protect Patient Health Information objective would be the fifth objective in the Promoting Interoperability Program and would continue as a required yes/no attestation. CMS proposes to eliminate the Coordination of Care through Patient Engagement objectives and associated measures included in the ACI performance category.

Objective	Measures	Maximum Points
e-Prescribing	e-Prescribing Query of Prescription Drug Monitoring Program Verify Opioid Treatment Agreement	20 points in 2019 (includes 10 bonus points for new opioid measures) 15 points in 2020
Health Information Exchange	Create and Send Summary of Care Receive Summary of Care and Conduct Clinical Information Reconciliation	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points in 2019, 35 points in 2020
Public Health and Clinical Data Exchange	Select any two for reporting: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Registry Reporting Public Health Registry Reporting Clinical Data Registry Reporting	10 points
MIPS-eligible clinicians must report on all required objectives and measures. *The Protecting Patient Health Information objective does not have a performance-based measure but MIPS-eligible clinicians are required to attest to meeting the Security Risk Analysis measure requirements.*		

CMS states each measure would be scored based on the performance for that measure, determined by the submission of a numerator and denominator, except for the measures associated with the Public Health and Clinical Data Exchange objective, which requires "yes or no" submissions. The performance rate of the individual measure would be multiplied by the maximum points available for a particular measure. **The AHA supports the proposed scoring methodology and recommends that CMS establish a minimum threshold of 50 points to meet the measure scoring requirements for the Promoting Interoperability performance category. This aligns with the scoring methodology minimum requirement for eligible hospitals and critical access hospitals in the Promoting Interoperability program as finalized in the FY 2019 IPPS rule.**

Make the New e-Prescribing Measures Available for Bonus Points beyond CY 2019. *Query of Prescription Drug Monitoring Program (PDMP)*. **The AHA strongly supports the intent to use the health information technology infrastructure to provide insight on Schedule II opioid prescribing practices.** The first measure would require the MIPS-eligible clinician to use data from certified EHRs to conduct a query of a PDMP for prescription drug history for Schedule II opioids electronically prescribed using a certified EHR and report on the percent of patients prescribed an opioid for whom this occurred.

In the preamble, CMS acknowledges that PDMP integration with certified EHRs is not widespread and states that MIPS-eligible clinicians likely would need to enter data manually into the certified EHR to document the completion of the query and conduct manual calculation of the measure. We understand that laws in several states do not permit PDMP data to be brought into and stored within a certified EHR, thereby extending the need for manual data entry and manual calculation of the measure indefinitely. The development of interfaces to connect EHRs and a gateway to the PDMP vendor solution is underway. However, our members communicate that the cost to access electronically the PDMP technology gateway is as high as $200 per prescribing clinician per year. To access this gateway, clinicians are generally required to leave their workflow and log into a separate PDMP website where they can query the PDMP and view a patient's PDMP report. In some instances, an option for a single sign-on in the EHR enables access to the PDMP gateway. Also, in some locations, a state may have its own PDMP database, supported by a health information exchange and use an open application programming interface (API) to allow vendors to connect EHRs to the PDMP without additional charge.

In order to ensure that the new opioid measure is meaningful, reduces burden, and reflects the diversity of approaches currently used to access PDMPs, the AHA has a number of recommendations.

First, given the significant burden that would be associated with calculating a percentage measure, **AHA recommends that the measure be reported as either Yes, the MIPS-eligible clinician has the capability for prescribers to check the PDMP, or No, they do not. We also recommend that this measure be eligible for five bonus points in both CY 2019 and CY2020.**

Second, **we recommend that CMS clarify that MIPS-eligible clinicians are permitted to continue use of the health information exchange to gain access to Schedule II opioid prescription drug history and thereby earn points for this measure.**

Third, we urge CMS to monitor the development of electronic means within the provider workflow to query, retain and use prescribing histories retained in PDMPs and the ability of a PDMP to share information with another state.

Finally, CMS states that in order to meet this measure, MIPS-eligible clinicians must use the capabilities and standards as defined for certified EHRs, specifically the certification criteria supporting e-prescribing and drug formulary query and preferred drug list. However, certification criteria specific to support PDMP query are not included in the 2015 edition EHRs, and it is unclear whether the Office of the National Coordinator for Health Information Technology (ONC) would promulgate updated certification requirements to support this functionality. **In the absence of technology and infrastructure specifically supporting a direct electronic query of a PDMP,**

retention of the prescribing history identified and use of the information for measure calculation, AHA recommends that CMS remove the requirement that MIPS-eligible clinicians use capabilities and standards of certified EHR technology for querying the PDMP.

Verify Opioid Treatment Agreement. CMS proposes that MIPS-eligible clinicians seek to identify the existence of a signed opioid treatment agreement and incorporate it into the EHR if a Schedule II opioid was electronically prescribed by the MIPS-eligible clinician using certified EHR and the total duration of the patient's Schedule II opioid prescription is at least 30 cumulative days within a six-month look-back period. AHA commends the intent to identify an opioid treatment agreement in support of care coordination and care planning by the patient and the provider. However, we are concerned that this measure lacks a standard that specifies the data to be included in the agreement. Without such standards, and accompanying certification requirements, it is unclear how a provider's certified EHR technology could support this activity. **AHA recommends that the measure remain available for bonus points until such time that standards and certification criteria are developed to identify the data necessary to support the measure intent.**

Provide Additional Flexibility to Support Health Information Exchange. CMS proposes two measures for health information exchange in support of transitions of care or referrals to another care setting. The first measure requires the creation and sending of a summary of care record using certified EHR. The second measure requires the receipt and clinical information reconciliation of the information received in the electronic summary of care record. The 2015 edition EHR certification criteria that support the creation, sending and receipt of a summary of care record is limited to the consolidated continuity of care document (C-CDA), referral summary and discharge summary document. Other document templates are available but EHRs are not required to be certified to support them. The ONC's proposal for a Trusted Exchange Framework and Common Agreement (TEFCA) may create opportunities for MIPS-eligible clinicians to utilize other formats or mechanisms to enable health information exchange. As an interim step in this journey, **AHA recommends that CMS allow the use of certified EHR technology or other options supported by health information technology (IT) to meet CY 2019 reporting requirements. Specifically, permit providers the choice to use any of the Health Level 7 formats available to meet the health information requirement to create and electronically send a summary of care in support of transitions of care.**

The AHA also recommends that CMS continue to work with federal partners to support the widespread availability of patient identifiers. Providers continue to experiencing challenges in identifying patients and matching them to their medical records. Safe and effective interoperability of health information that originates in disparate sources depends on the accurate link of a patient with the correct record. The nation lacks a single national mechanism for identifying individuals such as a unique

patient identifier. A single solution that would match individuals across IT systems would allow providers to know with confidence that a patient being treated in an ED is the same patient that a physician in another location diagnosed with an acute or chronic health condition that requires ongoing management. Patient safety concerns arise when data are incorrectly matched, such as a patient's current medication not being listed in the medical record or the wrong medications are included in the record. The 2015 edition certified EHRs are required to certify to the ability to create a transition of care/referral summary document that contains the data elements in accordance with the specified standards/constraints. The health IT is not required to demonstrate how it performs patient matching with these data. For example, the C-CDA template can accommodate more than one address but cannot distinguish between the historical and current address. Successful attainment of a level of performance in CY 2019 would be easier to achieve with advancement of a patient matching solution that is widely followed and widely available.

Increase Confidence in the Security of Provider to Patient Exchange. CMS proposes to create an objective titled Provider to Patient Exchange that is worth up to 40 points. The single measure for this objective states that MIPS-eligible clinicians would be required to provide patients (or their representatives) electronic access to their health information through two mechanisms:

(i) "The patient (or patient-authorized representative) is provided timely access to view online, download and transmit his or her health information; and"
(ii) "The MIPS-eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API [application programming interface] in the clinician's CEHRT."

Securely sharing health information is central to providing high-quality coordinated care, supporting new models of care and engaging patients in their health. New tools and technologies, including APIs and apps, would allow for more convenient and flexible access to health information and new ways for individuals to engage in their health. **However, we believe that CMS must balance the pace for moving in this positive direction with the real and developing risks that this approach raises for systems security and the confidentiality of health information.** To ensure a successful transition, stakeholders must work together to develop a secure app ecosystem and health care providers must move forward deliberately to gain experience in using these tools. The federal government also must make clear how steps to secure systems would be considered as it enforces the rules against information blocks.

Recommended Changes to the Measure. The requirement to connect "*any application*" of the patient's choice, without allowing evaluation of the app for security or testing that it functions as expected, poses particular challenges for systems security. This is particularly true given the lack of a secure app ecosystem. This requirement also assumes a level of experience with the use APIs that is not yet achieved.

To ensure a measured transition that allows the development of a secure app ecosystem and provides time for providers to develop competence in using and securing APIs, we recommend that CMS revise the second part of the measure to read:

(ii) "The MIPS-eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using **at least one** application that is configured to meet the technical specifications of the API in the clinician's CEHRT."

We also recommend that CMS provide an exclusion for this measure in FY 2019 for MIPS-eligible clinicians that cannot successfully identify an app that meets their security needs.

Systems Security. It is not an overstatement to say that the health care sector is under attack by cyber criminals and nation states looking to infiltrate systems and steal patient data. Connecting a wide-range of unfamiliar apps that are presented by patients creates a significant risk by serving as a possible point of entry for malware into systems. According to Symantec, mobile devices, which are the primary platform for apps, are now a key target for cyber attacks, with the "number of new mobile malware variants increased by 54 percent in 2017, as compared to 2016. And last year, an average of 24,000 malicious mobile applications were blocked each day."[2]

Furthermore, the apps presented by patients would be running on devices that are not controlled by hospitals and health systems. Updating operating systems is a key tool in preventing cyber attacks. However, Symantec further notes that "While threats are on the increase, the problem is exacerbated by the continued use of older operating systems. In particular, on Android™, only 20 percent of devices are running the newest major version and only 2.3 percent are on the latest minor release."

Finally, as the global WannaCry cyber attack experience showed, the impact of malware can move far beyond information systems to affect health care operations and even patient safety. The risk landscape is constantly changing, as cyber criminals identify previously unknown vulnerabilities and new forms of attack. For these reasons, the federal government has declared health care and public health to be a part of the nation's critical infrastructure that must be diligent in protecting against cyberattack.

Given the alarming trend in cyber attacks in health care, providers must be granted the right to control the technology that is connected to their systems in order to keep them secure. While we acknowledge that there are encryption and patient authentication specifications within the technical specifications of the API, connecting an app still poses risks for injection of malware into a provider's information

[2] Symantec Internet Security Report. March 2018. Available at https://www.symantec.com/content/dam/symantec/docs/reports/istr-23-executive-summary-en.pdf.

system. In addition, providers must monitor for and guard against malware that could attempt to access data for patients other than the individual that has provided authorization for access. If a malicious app were to successfully inject malware or access data for multiple patients, the provider could face catastrophic effects on its information systems and clinical operations. It also could be in violation of HIPAA and could face significant penalties for noncompliance, despite the cause of the problem stemming from a patient's app. Therefore, providers must have the ability to deploy and maintain strong security safeguards.

Patient Confidentiality. Since the passage of the Health Insurance Portability and Access Act (HIPAA) of 1996, patients have understood that their sensitive health information will be kept confidential, and providers have operated under the HIPAA privacy rules. However, commercial app companies generally are not HIPAA-covered entities. Therefore, when information flows from a provider's information system to an app, it likely will no longer be protected by HIPAA. Most individuals would not be aware of this change and may be surprised when commercial app companies share their sensitive health information obtained from a provider, such as diagnoses, medications, or test results, in ways that are not allowed by HIPAA. Furthermore, individuals may consider the provider to be responsible if their data held by the app developer is sold to a third party or used for marketing or other purposes.

ONC has released a voluntary model privacy notice for app companies. Use of this notice, however, is not required. Recent studies have shown that the majority of health apps on the market today do not have adequate privacy policies and routinely share sensitive health information with third parties. In one study of diabetes apps, almost 80 percent did not even have privacy policies, and about half of those with a privacy policy indicated that they would share data with third parties. Only a handful indicated that they would ask for permission from the individual before sharing personal health information.[3] Research also shows that individuals generally do not fully understand the privacy policies presented by commercial app companies, and from a practical point of view have no option but to agree to them if they want to use a product.[4] And, recent headlines indicate that even large technologies companies, such as Facebook, have shared people's data without their consent, while the Federal Trade Commission (FTC) is reportedly investigating the privacy practices of companies that collect and analyze genetic information from consumers.

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[3] Blenner, Sarah R., et al. Privacy Policies of Android Diabetes Apps and Sharing of Health Information, JAMA, March 8, 2016, available at http://jama.jamanetwork.com/article.aspx?articleid=2499265).

[4] See, for example, Obar, Jonathan A. and Oeldorf-Hirsch, Anne, Clickwrap Impact: Quick-Join Options and Ignoring Privacy and Terms of Service Policies of Social Networking Services (June 1, 2017). In Proceedings of the 8th International Conference on Social Media & Society (p. 50). ACM. Available at https://ssrn.com/abstract=3017277.

While we understand that patients have the right to share their data as they see fit, and may be willing to take the risk of less privacy when using commercial apps, we believe that significant consumer education efforts are needed to help individuals understand the vastly different, and less stringent, federal privacy requirements for entities not covered by HIPAA.

Therefore, to address concerns about patient privacy, we recommend that CMS work with the FTC, which provides consumer protection, and the Office for Civil Rights (OCR) to provide model language that health care providers can present to their patients that choose to access their data via an app. This language should clearly explain that data held by the commercial app likely will no longer be protected by HIPAA, but be governed by the privacy policy and terms of service of the commercial app company. The language should also make clear that the health care provider bears no responsibility for the use of patient data by the commercial app company and that any concerns about how data are used after being shared with an app should be directed to the FTC.

We also strongly recommend that CMS work with the OCR and the FTC to develop an extensive education program so that all consumers can become aware of how app companies may use their data, and the importance of reviewing the privacy practices of any app that they choose to use to access their sensitive health information.

Building Expertise. Very few providers have experience in offering API access to patient-facing apps. This functionality is part of the 2015 Edition CEHRT, which has yet to be fully implemented across the country. In addition, those seeking to gain experience report that there are very few apps available for them to test out. For example, many of the products in EHR vendor “app stores” are still in testing versions.

Once providers have the technology and apps available to them, deploying an API approach for patient-facing applications requires significant work and collaboration from EHR vendors to build connections, understand how the API works within their health information system, and ensure that these new connections do not inadvertently damage other parts of the network. IT staff must be trained, processes for monitoring the use of the API must be created, and identifying both possible malware and attempts to access more data than is authorized by the individual must be established. They also must evaluate how this new connection point affects their risk management and compliance strategies. Providers also would need to develop a communications plan for their patients and train front-line staff on how to answer patient questions. Smaller practices with fewer resources would likely need more time to develop expertise in deploying APIs, and may face significant financial and human capital constraints.

Secure App Ecosystem. To ensure a robust, secure set of tools for individuals to engage with providers via apps, stakeholders would need to work together to build an

app ecosystem that is based on a rigorous and continuous vetting process that takes into account evolving risks. This could be done in the public sector, through certification, or through a public-private partnership. There are examples of this type of approach in other sectors, such as the Payment Card Industry Data Security Standard for processing bank cards. Any entity that wants to process bank card payments must attest to following these standards.

In the health sector, Medicare has developed a vetting process for apps that connect to Medicare claims data via the Blue Button 2.0 API. CMS will not connect just any app that meets the technical specifications to its API. Rather, it has developed a process to evaluate apps before they are connected, and applies a number of security and privacy requirements. The full guidelines for Blue Button developers are available at https://bludbutton.cms.gov/developers/. However, as an overview, Medicare requires the following:

- Developers must request access to the Blue Button production API by email.
- Approval will take one to two weeks and involve a phone call and demo to the CMS Blue Button API team.
- Developers must be U.S.-based companies.
- Developers must articulate to CMS both their business model and the value the app will provide to beneficiaries.
- Developers must demonstrate to CMS how data will be protected within the app.
- Developers must agree to future audits by CMS as part of a Production API access renewal process.
- Developers must provide a url to their privacy policies and terms and conditions when registering their app with CMS.
- The agency also requires agreement to additional terms of service that include, among other things, a statement that "CMS reserves the right (though not the obligation) to: (1) refuse to provide the API to you, if it is CMS's opinion that use violates any CMS policy; or (2) terminate or deny you access to and use of all or part of the API at any time for any other reason which in its sole discretion it deems necessary to in order to prevent abuse." The full terms of service are available at: https://bluebutton.cms.gov/terms/.

Taken together, these protections established by CMS could serve as a starting point for a sector-wide approach to developing a trusted app ecosystem.

Implications for Information Blocking. Providers need clarity in understanding how steps they might need to take to secure their systems would be treated as CMS and the Office of the Inspector General (OIG) enforce the provisions against information blocking promulgated in the 21st Century Cures Act. They are concerned that denying access to a suspect commercial app would be considered information blocking and subject a provider to a payment penalty. **To ensure that reasonable actions to secure systems are not considered noncompliant, we recommend that CMS work with ONC and**

OIG to ensure that these protective measures are included in the forthcoming guidance on actions that do *not* constitute information blocking.

In addition, we note that information sharing about security risks is a best practice that is encouraged under the Cybersecurity Information Sharing Act of 2015. **To advance information sharing about risks posed by health apps, we recommend that CMS work with ONC and FTC to develop a place for providers to report suspect apps so that others can be aware and take needed steps.**

Offer Additional Scoring Opportunities. The rule also proposes to eliminate the opportunity for MIPS-eligible clinicians to earn bonus points when using a certified EHR to complete certain activities in the Improvement Activities performance category. MIPS-eligible clinicians with 2015 edition certified EHR that wish to use the technology for an activity in the Improvement Activity performance category should not be discouraged from doing so. **The AHA recommends that CMS retain the availability of bonus points** using a certified EHR for Improvement Activities in CY 2019.

MEDICAID PROMOTING INTEROPERABILITY PROGRAM

Proposed Revisions to Stage 3 Meaningful Use Measures for Medicaid-eligible Professionals. CMS proposes reporting changes for the eligible professionals in the Medicaid Promoting Interoperability program. For the Coordination of Care through Patient Engagement objective, CMS proposes to revise the threshold for the view, download, or transmit measure from 10 percent to 5 percent for CY 2019 and subsequent years. The AHA agrees with CMS that the view, download, transmit measure requires a positive action by patients which cannot be controlled by the Medicaid-eligible professional. A threshold reduction would allow additional time for eligible professional to communicate with their patients about accessing their health information. **However, the AHA recommends the measure threshold be revised to at least one patient seen by the Medicaid-eligible professional, rather than five percent of all patients. Additionally, to ensure a measured transition that allows the development of a secure app ecosystem and provides time for providers to develop competence in using and securing APIs, we also recommend that CMS revise the second part of the measure to read:**

> (2) The Medicaid-eligible professional ensures the patient's health information is available for the patient (or patient-authorized representative) to access using **at least one application** that is configured to meet the technical specifications of the API in the clinician's CEHRT.

CMS proposes to revise Public Health and Clinical Data Registry Reporting Measure 2 (Syndromic Surveillance Reporting) to include any eligible professional defined by the state or local public health agency as a provider who can submit syndromic surveillance data. An exclusion would remain for eligible professionals not in a category of health

care providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system. **The AHA supports this flexibility that enables additional eligible professionals to report to a syndromic surveillance system**.

eCQM reporting period for eligible professionals under the Medicaid Promoting Interoperability Program. CMS also proposes a full calendar year eCQM reporting period in 2019 for eligible professionals who previously demonstrated meaningful use. For the eligible professionals demonstrating meaningful use for the first time, the proposed eCQM reporting period would remain any continuous 90-day reporting period. AHA supports proposals in the rule to reduce reporting burden and believes that includes consistency in the eCQM reporting period across programs. **AHA recommends that CMS offer eligible professionals who previously demonstrated meaningful use an eCQM reporting period of any continuous 90 days in CY 2019.** This would align the eCQM reporting period for eligible professionals attesting to the EHR Incentive Program Stage 3 and MIPS-eligible clinicians that select the eCQM reporting option in CY 2019.

MEDICARE ADVANTAGE QUALIFYING PAYMENT ARRANGEMENT INCENTIVE (MAQI) DEMONSTRATION

In conjunction with this proposed rule, CMS announced its proposal for the MAQI demonstration. The demonstration would test whether excluding MIPS-eligible clinicians who participate in certain payment arrangements with Medicare Advantage organizations (MAOs) from the MIPS reporting requirements and payment adjustment would increase or maintain participation in these payment arrangements and change the delivery of care. In the rule, CMS proposes regulations to administer the demonstration. **The AHA supports the proposed demonstration and appreciates CMS's consideration of clinicians' participation in Qualifying Payment Arrangements with MAOs that meet the criteria to be Other Payer Advanced APMs a year before the All-Payer Combination Option is available to clinicians.**

However, unlike the All-Payer Combination Option, the MAQI demonstration does not give providers access to the 5 percent bonus payment under the advanced APM track of the QPP. **Given that CMS proposes to make requirements for Qualifying Payment Arrangements under the demonstration consistent with the criteria for Other Payer Advanced APMs under the QPP, we urge it to extend the five percent bonus payment to demonstration participants in the same way participants in Other Payer Advanced APMs will be eligible for the bonus payment when the All-Payer Combination Option becomes available.** Additionally, to improve the demonstration program, CMS may wish to consider allowing clinicians to apply for participation at the group level so as to align the demonstration with both the MIPS participation options that include individual- and group-level participation and the TIN-level QP determination process for Advanced APMs proposed in this rule.

PROPOSED CHANGES TO EXPAND ACCESS TO VIRTUAL CARE AND TELEHEALTH

The AHA supports CMS's proposal to recognize and pay separately for communication technology-based services, including virtual check-ins and remote evaluation of pre-recorded patient information. Covering these services would increase efficiency for Medicare patients and expand access to care for patients in rural areas. However, patients may not think about their cost-sharing obligations when conducting internet- or telephone-based communication with their providers. **To that end, we recommend that CMS provide education to patients regarding their cost-sharing obligations when using communication technology-based services.** The AHA also supports CMS's proposal to add two new Current Procedural Terminology (CPT) codes for prolonged preventive services to its list of approved Medicare telehealth services.

Yet, we note that, overall, limited Medicare coverage and payment for telehealth services remains a major obstacle for providers seeking to improve patient care. We acknowledge that many of the limitations to expanding 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. Currently, the agency 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. However, 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.

MEDICARE SHARED SAVINGS PROGRAM

CMS recently unveiled its "Meaningful Measures" framework that seeks to streamline and prioritize the quality measures used across all CMS quality reporting and value programs so that they focus on the issues that matter the most to improving care. Consistent with this framework, CMS proposes to remove 10 measures from, while adding three measures to, the CY 2019 MSSP quality measure set. If the proposals are finalized, the MSSP would have a total of 24 measures starting in CY 2019. **The AHA supports these proposals, and appreciates that CMS is looking across all of its programs to identify ways of streamlining and focusing the measure sets.**

PHYSICIAN SELF-REFERRAL LAW

The AHA welcomes CMS's proposals to bring consistency to its regulations related to the physician self-referral law, or Stark law. Specifically, CMS proposes revisions to (1) address any actual or perceived differences between statutory language included in the Bipartisan Budget Act (BiBA) of 2018 and regulatory language; (2) codify its existing policy on satisfying the writing requirement in many Stark law exceptions; and (3) apply BiBA policies to exceptions to Stark regulations that CMS created through its authority. **However, to truly enable providers to coordinate care for patients and transition to value-based care, we urge CMS to take a more holistic approach to Stark law reform, as detailed in our response to CMS's request for information regarding the physician self-referral law.**

REQUEST FOR INFORMATION ON PRICE TRANSPARENCY

The AHA is committed to improving patients' access to information on the price of their care and, more specifically, on their out-of-pocket cost obligation. In general, advancing price transparency has been challenging for the health care system due to the inherent uncertainty in the course of disease and treatment, as well as the need to share data and information across multiple payers and providers. For more detailed input, we point CMS to our previous comments on this issue, submitted as part of our response to the 2019 IPPS proposed rule.

REQUEST FOR INFORMATION ON PROMOTING INTEROPERABILITY

In this proposed rule, CMS asks for input regarding the opportunity to further advance interoperability of health information through the creation of conditions of participation (CoPs) for hospitals and CAHs and conditions for coverage (CfCs) for other providers. CMS invites comments, noting a number of other related initiatives it has undertaken to promote broader adoption of EHR systems, and the use of these systems to facilitate communication among the providers caring for individual patients as well as between providers and patients. CMS observes that some of its previous initiatives have resulted in significant advances in the use of EHR systems while others have not yet been finalized, such as the proposed discharge rule of 2015, or have only recently been finalized by CMS and have not yet realized their full impact in terms of changing the delivery of health care. **The AHA strongly opposes creating additional CoPs/CfCs to promote interoperability of health information as described further below**.

Background. **The AHA strongly supports the creation of an efficient and effective infrastructure for health information exchange. This is central to the efforts of hospitals and health systems to provide high-quality coordinated care, support new models of care, and engage patients in their health. However, we do not believe a new mandate tied to CoPs is the right mechanism to advance health information exchange**. We are making progress on information exchange, due to the

investment and concerted efforts of hospitals and health systems. According to AHA survey data[5], 93 percent of hospitals and health systems provide patients with the ability to access their electronic health records online, up from only 27 percent in 2012. Consumers also can download their information and choose to send it to a third party. Hospitals and health systems increasingly offer other online services, such as prescription refills, appointment scheduling, and secure messaging that make care more convenient. AHA data[6] also show that hospitals and health systems have deployed systems to share health records with other providers of care to better support care coordination and transitions across care settings. Seventy-one percent of hospitals and health systems share clinical or summary of care records with ambulatory care providers outside their system, up from 37 percent in 2012.

However, the commitment of health care providers is not sufficient by itself to create interoperability. The technical and organizational infrastructure must be available and allow for efficient exchange, and all parties to the exchange must be using compatible technology in consistent ways. All of this must be achieved in a way that simultaneously allows the free flow of information to others who have a legitimate reason to have the information while protecting the information from hackers and others with nefarious intent.

We urge CMS to recognize the impediments to information sharing described below and address them directly. We do not believe that creating a CoP or CfC that would apply to only one set of actors is an appropriate strategy. Further, it is not clear that such requirements would have any greater impact on interoperability than the existing federal requirements to share information, but they could have unfortunate consequences for some hospitals and communities.

The Imposition of CoPs and CfCs has Practical Implications. CMS's CoPs/CfCs are taken seriously by health care providers because failure to comply carries a heavy penalty. Declaring a hospital to be out of compliance with the CoPs can be extremely disruptive for patients, providers, and communities, as it means that a hospital could be removed from these programs and would no longer be able to care for Medicare or Medicaid patients. The penalty of not meeting an interoperability CoP is too stringent, especially given that the journey towards interoperability is still underway. Moreover, use of the CoPs/CfCs to promote interoperability are misguided for the following reasons:

[5] Sharing Health Information for Treatment. https://www.aha.org/guidesreports/2018-03-01-sharing-health-information-treatment.

[6] Expanding Electronic Patient Engagement. https://www.aha.org/guidesreports/2018-03-01-expanding-electronic-patient-engagement.

1) CoPs/CfCs are requirements to ensure safe health care delivery, and care can be delivered safely without the interoperability of EHRs. The Social Security Act (Title 18, Section 1861) authorizes the Secretary to establish requirements that are necessary for the health and safety of those being cared for in hospitals and other organizations. Clearly, the timely exchange of information among providers caring for an individual is an important step forward in ensuring that the relevant clinical information about the patient's diagnoses and treatment plan are in the hands of those providing care. This can help prevent errors in care as well as ensure the continued provision of the right care at the right time to patients. Because patients and their designated family members are a critical part of the care team, it is important that they, too have access to the patient's information in an accurate, complete and timely manner to ensure high-quality, safe care.

We agree that interoperable EHRs should be capable of achieving information exchange. No other form of communication has the potential to enable such a complete set of information in a manner that can easily be searched by the recipient so that vital facts can quickly be identified and used. To the extent EHRs are capable of this type of information exchange, hospitals are already using them, and there already are substantial incentives in place for hospitals and some other providers through the now Promoting Interoperability Program (formerly known as Meaningful Use), as noted below. It is not clear that a CoP or CfC would increase the feasibility of information sharing by these health care organizations. Since neither the CoPs nor the CfCs apply to government agencies, patients, or others with whom hospitals and other providers would be trying to exchange information, we believe such requirements would have limited effect in promoting interoperability. **Instead, the AHA urges CMS to focus its attention on resolving problems created by the lack of a fully implemented exchange framework, adoption of common standards and incentives for EHR and other IT vendors to adhere to standards.**

2) It is premature for CMS to consider imposing COPs/CfCs until the barriers to exchange have been addressed and all of those affected by the requirements can, in fact, achieve compliance. Compliance is impossible when there is no commonly accepted operational definition of interoperability and no commonly accepted metrics for interoperability. The implementation of EHR in general acute care hospitals is widespread. Our latest survey data from 2016 show that 96 percent of hospital have a certified EHR. Similarly, many physician practices have implemented EHRs that are compliant with the requirements imposed on physician practices for achieving meaningful use. However, the uptake of EHR systems in other parts of health care is less robust because other care providers did not have the same incentives provided under the meaningful use program.

Other barriers to interoperability exist as hospitals and health systems try to electronically send, receive, or query patient health information to and from other care

settings or organizations. In responding to the AHA Survey, hospitals identified the following challenges:

- The information sent is not useful to recipients;
- The workflow required to enter and send information from their ehr is cumbersome;
- Identifying the correct patient between systems is difficult because there is no single patient identifier; and
- Exchanging information across different vendor platforms is difficult.

Almost half of respondents noted they experience greater challenges exchanging information across different vendor platforms, and more than one-third reported difficulty matching or identifying the correct patient between systems.[7] Some provider organizations, particularly those that are small or that serve a large number of patients with limited insurance coverage, simply do not have the resources to invest in expensive EHR systems. Regardless of why some providers do not have EHR systems, it is extremely difficult to achieve interoperability with those who are not using a system.

Further, although the ONC was charged with developing standards for collecting information in EHRs so that it could be readily exchanged with other providers, those standards have yet to be consistently implemented across systems in ways that make exchange efficient and effective. This is largely the reason why it is challenging to exchange information between providers on two different types of EHRs and, in some cases, between providers using EHRs manufactured by the same company, but with different versions and different installations. Considerable efforts are underway, and progress is being made. However, exchange across settings, such as between two hospitals or a hospital and a post-acute care setting or clinician office, is very challenging. And, without the exchange infrastructure discussed below, can require expensive point-to-point interfaces.

3) Modification of the CoPs/CfCs require clear and unambiguous evidence that compliance could be readily seen by a survey team charged with assessing the facility's compliance. Health care organizations want to be in compliance with the CoPs/CfCs at all times. They view this as their obligation to the patients they serve. Yet, to be in compliance, they must have a clear and unambiguous understanding of what is expected and how they are to be judged as being in compliance. Since there are no clear, common metrics of interoperability, and since the survey team only visits the facility they are assessing, what evidence would they be looking for to assess the ability of the hospital or other provider to transmit/receive patient information to/from other providers, state or federal agencies, or others with whom they are to achieve interoperable exchange of information? Further, what would surveyors rate as full compliance with the requirement? If the hospital or other provider can transmit the

[7] Sharing Health Information for Treatment. https://www.aha.org/guidesreports/2018-03-01-sharing-health-information-treatment p 3- 4.

information, but the intended recipient cannot receive it, has interoperability been achieved? If not, is it right or fair to hold the hospital or other provider accountable for the other organization's failure to be able to receive the data, especially since failure to comply with a CoP/CfC on interoperability can put a hospital or other organization in jeopardy of losing its ability to participate in Medicare and Medicaid. This seems to be too steep a penalty for not being able to communicate with another entity, especially if that failure is not within the hospital's ability to correct.

We also are concerned about the costs of compliance. Based on our survey to understand the regulatory costs associated with health IT, on average, surveyed hospitals spend $760,000 annually meeting regulatory requirements, most of which is being used to hire and maintain additional staff. Hospitals made additional IT investments averaging $411,000 during the year for the Promoting Interoperability Program, an investment more than 2.9 times larger than that made in any other area.[8] Small provider organizations or those serving communities with few resources may simply be unable to afford the necessary investment in EHR technology, personnel and support systems to sustain this kind of interoperability.

The AHA urges CMS not to move forward with a plan to require interoperability as a CoP/CfC until such time as it is reasonably feasible to efficiently and effectively achieve such communication across the majority of providers delivering health care in a region. **Instead, CMS should coordinate with ONC on implementation of the TEFCA and other steps needed to create the infrastructure that would support interoperability.**

Other Opportunities Exist to Further Interoperability. CMS already holds hospitals accountable for supporting interoperability under the Promoting Interoperability Program. The agency requires hospitals to attest to three separate statements indicating it:

- Did not "knowingly and willfully take action to limit or restrict the compatibility or interoperability" of their certified EHR;
- Have implemented the technology to support "secure and trusted bidirectional exchange" of health information; and
- Have "responded in good faith and in a timely manner" to requests for exchange information from others.

Those failing to attest face significant financial penalties under the IPPS and CAH programs. Further, the specific requirements of the Promoting Interoperability Program promote information sharing across providers and with patients.

[8] Regulatory Overload. Assessing the Regulatory Burden on Health Systems, Hospitals and Post-Acute Providers. https://www.aha.org/system/files/2018-02/regulatory-overload-report.pdf

Greater Availability of Health Information Technology is Needed in the Post-acute Care Settings to Support Widespread Health Information Exchange. Sharing information across the continuum of care is a clear priority. Post-acute care hospitals were not included in the EHR Incentive Program yet have worked diligently to identify and deploy technology to support their care delivery and care coordination goals. However, challenges to attainment of this goal persist as post-acute providers vary in size and resources and have more limited options than acute care providers when choosing an EHR related to their size, locations and technology, and implementation costs. **The AHA recommends that CMS not implement a CoP/CfC to increase interoperability across the continuum of care because post-acute care providers were not provided the resources or incentives to adopt health IT organizations. Such a requirement would only be acceptable if all facilities were afforded the same opportunity to acquire certified EHRs that actually conformed to standards that enable the kind of interoperability CMS envisions**.

An Information Exchange Framework is Necessary to Assess Interoperability across Settings. We recognize that today's health information exchange landscape is comprised of a complex set of existing networks that include large national networks, regional, and state networks and networks maintained by individual electronic health record vendors. There are initiatives to connect across networks but the work is nascent at this time. **The AHA supports the advancement of and adherence to a framework for interoperability so that the technology and the rules governing the exchange of health information are universally and consistently implemented and the implementation can be clearly demonstrated. We strongly urge CMS and ONC to focus on creating the infrastructure for exchange and continuing to build toward consistent use of standards across vendor platforms.**

Any framework and common agreement must specify minimum standards and essential elements needed to facilitate exchange so that end-users have assurance that all health information exchange networks are following the same rules of the road to ensure that exchange is trustworthy, reliable and efficient. The framework and common agreement should address, among other things:

- The minimum standards and implementation requirements that must be met to ensure efficient exchange, including standards to secure information;
- The permitted purposes for exchange;
- A clear understanding of the means to identify and authenticate participants of an individual exchange;
- A clear understanding of how the identity of individuals will be matched and managed across networks; and
- Assurance that each network will be transparent in the terms and conditions of exchange, including any technical prerequisites and costs of participating in exchange.

On Jan. 5, 2018, ONC released the draft TEFCA, which describes a set of legal relationships, governance approaches and types of information exchange that would allow for more efficient and effective sharing of health information across the country. The draft TEFCA puts forward six principles and more than 100 minimum required terms and conditions that would apply to those entities that voluntarily choose to share information under the trusted exchange framework. It also creates a structure for trusted information exchange and sets forward six "permitted purposes" for information exchange – treatment, payment, health care operations, public health, individual access to health information, and benefits determination (specific to determining eligibility for disability benefits under the Department of Veterans Affairs and Social Security Administration). It describes three "use cases," representing the ways in which exchange may happen and include:

- A broadcast query to all participants in the exchange asking for information about a specific individual(s);
- A directed query to a specific organization(s); and
- Population level data requesting information about multiple individuals in a single query (with no upper bound provided).

At this time, we understand that work is underway to revise the draft TEFCA in response to stakeholder feedback. **The AHA recommends that CMS postpone initiatives to advance requirements for interoperability prior to the finalization of TEFCA.**

Appendix A
Estimated Impact of CY 2019 E/M Proposed Policy by Medicare Specialty*
Prepared by the American Medical Association

**Includes CPT Codes 99201-99215, GCG0X, GPC1X, GPD0X and GPD1X, but does not include GPRO1 - prolonged service. Analysis uses Estimated CY2017 Medicare Utilization and CY2019 Medicare CF for both "Current Method" and "Proposed Method"; E/M MPPR Estimate based on 2016 Medicare Carrier 5% Standard Analytic File*
Excludes specialties with less than $1 million in CY2017 allowed charges for 99201-99215 or claims with unknown specialty designation.

Medicare Designated Specialty	**Total Medicare Payment for Office Visits w/o Policy Changes (Using CY2018 Total RVUs)**	**Change in Payment Due To Proposed E/M Collapse Policy (includes G codes*)**	**Additional Change in Payment Due to E/M MPPR Policy**	**Net Change Due to E/M Collapse and E/M MPPR Policies**	**Total Medicare Payment for Office Visits Under Proposed Method (E/M Collapse and E/M MPPR) (Using Proposed CY2019 Total RVUs)**	**Percent Change in Payment for Office Visits (Both E/M Collapse and E/M MPPR Policies)**
TOTAL	$23,298,623,446					
HOSPICE AND PALLIATIVE MEDICINE	$6,491,871	($1,278,816)	($21,072)	($1,299,888)	$5,191,983	-20%
HEMATOLOGY	$35,814,877	($5,616,074)	($76,952)	($5,693,026)	$30,121,850	-16%
GYNECOLOGY/ ONCOLOGY	$28,857,336	($3,997,258)	($547,163)	($4,544,421)	$24,312,915	-16%
MEDICAL ONCOLOGY	$217,094,796	($31,098,224)	($182,736)	($31,280,960)	$185,813,836	-14%
NEUROPSYCHIATRY	$3,342,298	($410,887)	($23,423)	($434,310)	$2,907,988	-13%

NEPHROLOGY	$366,158,222	($47,203,589)	($302,888)	($47,506,478)	$318,651,744	-13%
NUCLEAR MEDICINE	$3,261,367	($405,925)	($12,208)	($418,133)	$2,843,234	-13%
CARDIAC ELECTROPHYSIOLOGY	$123,640,581	($15,324,933)	($146,856)	($15,471,789)	$108,168,792	-13%
CRITICAL CARE (INTENSIVISTS)	$35,990,339	($4,325,639)	($100,505)	($4,426,144)	$31,564,195	-12%
RADIATION ONCOLOGY	$85,243,662	($9,893,434)	($574,960)	($10,468,394)	$74,775,268	-12%
PODIATRY	$645,600,644	($10,733,858)	($65,687,368)	($76,421,226)	$569,179,418	-12%
INTERVENTIONAL CARDIOLOGY	$230,977,054	($25,262,896)	($255,653)	($25,518,549)	$205,458,505	-11%
PULMONARY DISEASE	$519,566,122	($56,585,347)	($692,200)	($57,277,547)	$462,288,575	-11%
CARDIAC SURGERY	$23,265,687	($2,414,967)	($60,075)	($2,475,041)	$20,790,646	-11%
THORACIC SURGERY	$34,448,176	($3,351,307)	($95,221)	($3,446,528)	$31,001,648	-10%
SLEEP MEDICINE	$18,791,073	($1,820,388)	($3,618)	($1,824,006)	$16,967,067	-10%
INFECTIOUS DISEASE	$87,007,974	($7,183,264)	($765,556)	($7,948,821)	$79,059,153	-9%
GERIATRIC MEDICINE	$62,649,142	($5,263,125)	($425,824)	($5,688,949)	$56,960,193	-9%
COLORECTAL SURGERY	$32,609,046	$2,177,018	($4,743,104)	($2,566,086)	$30,042,961	-8%
SURGICAL ONCOLOGY	$18,788,106	($1,078,188)	($285,170)	($1,363,357)	$17,424,749	-7%
PHYSICAL MEDICINE AND REHABILITATION	$296,738,502	($4,498,950)	($11,065,012)	($15,563,961)	$281,174,540	-5%
DERMATOLOGY	$883,036,919	$209,244,544	($251,123,409)	($41,878,865)	$841,158,054	-5%
NEUROLOGY	$670,721,588	($24,948,472)	($5,341,041)	($30,289,513)	$640,432,075	-5%
PERIPERAL VASCULAR DISEASE	$3,031,756	($80,774)	($35,394)	($116,168)	$2,915,588	-4%
OPHTHALMOLOGY	$515,715,805	$3,971,043	($23,714,332)	($19,743,289)	$495,972,516	-4%
ANESTHESIOLOGY	$169,519,002	($204,291)	($5,065,536)	($5,269,827)	$164,249,175	-3%
SPORTS MEDICINE	$42,181,673	$3,583,247	($4,861,167)	($1,277,920)	$40,903,753	-3%
GERIATRIC PSYCHIATRY	$5,170,221	($156,210)	$0	($156,210)	$5,014,011	-3%
CERTIFIED CLINICAL NURSE SPECIALIST	$29,322,926	($747,025)	($17,505)	($764,530)	$28,558,397	-3%

EMERGENCY MEDICINE	$164,829,846	($37,175)	($3,767,129)	($3,804,304)	$161,025,541	-2%
GASTROENTEROLOGY	$494,407,166	($9,707,187)	($1,359,395)	($11,066,582)	$483,340,584	-2%
PREVENTIVE MEDICINE	$6,380,418	$107,663	($244,648)	($136,985)	$6,243,434	-2%
CERTIFIED REGISTERED NURSE ANESTHETIST	$1,206,868	($17,505)	($6,755)	($24,260)	$1,182,608	-2%
ADDICTION MEDICINE	$4,621,434	($63,406)	($6,164)	($69,570)	$4,551,864	-2%
PATHOLOGY	$2,881,831	$331,366	($373,663)	($42,297)	$2,839,534	-1%
RHEUMATOLOGY	$375,417,278	$13,205,481	($17,540,236)	($4,334,755)	$371,082,523	-1%
PEDIATRIC MEDICINE	$25,857,819	$269,554	($484,578)	($215,024)	$25,642,796	-1%
ENDOCRINOLOGY	$374,423,628	($1,129,450)	($186,831)	($1,316,281)	$373,107,347	0%
INTERNAL MEDICINE	$3,871,679,750	$31,325,279	($24,729,341)	$6,595,938	$3,878,275,688	0%
INTERVENTIONAL RADIOLOGY	$9,484,370	$469,734	($413,873)	$55,861	$9,540,231	1%
NEUROSURGERY	$116,272,265	$1,791,395	($323,774)	$1,467,620	$117,739,886	1%
HEMATOLOGY/ONCOLOGY	$697,545,442	$10,699,495	($986,631)	$9,712,865	$707,258,306	1%
FAMILY MEDICINE	$3,606,747,571	$113,138,550	($56,711,076)	$56,427,473	$3,663,175,044	2%
OSTEOPATHIC MANIPULATIVE MEDICINE	$20,490,031	$761,315	($365,507)	$395,808	$20,885,840	2%
ORTHOPEDIC SURGERY	$947,571,929	$121,325,332	($94,947,028)	$26,378,304	$973,950,233	3%
CARDIOLOGY	$1,673,787,386	$50,259,515	($1,261,621)	$48,997,894	$1,722,785,281	3%
PSYCHIATRY	$428,733,813	$13,881,946	($31,113)	$13,850,833	$442,584,645	3%
GENERAL SURGERY	$331,303,718	$24,316,111	($9,332,412)	$14,983,698	$346,287,416	5%
NURSE PRACTITIONERS	$1,441,181,453	$93,149,384	($25,035,363)	$68,114,021	$1,509,295,474	5%
HAND SURGERY	$61,951,012	$10,538,938	($7,241,524)	$3,297,414	$65,248,426	5%
DIAGNOSTIC RADIOLOGY	$12,237,942	$907,940	($232,960)	$674,980	$12,912,923	6%
PHYSICIANS ASSISTANT	$880,931,609	$100,911,145	($51,442,398)	$49,468,747	$930,400,356	6%
OTOLARYNGOLOGY	$483,766,537	$120,847,876	($92,891,766)	$27,956,110	$511,722,647	6%
ORAL SURGERY	$8,519,498	$808,496	($304,336)	$504,160	$9,023,658	6%
GENERAL PRACTICE	$181,231,116	$13,894,726	($3,084,777)	$10,809,949	$192,041,065	6%

VASCULAR SURGERY	$115,959,089	$9,653,737	($1,658,179)	$7,995,558	$123,954,646	7%
PAIN MANAGEMENT	$166,806,512	$21,764,031	($6,627,973)	$15,136,058	$181,942,570	9%
OPTOMETRY	$273,100,554	$26,752,277	($1,697,949)	$25,054,327	$298,154,881	9%
INTERVENTIONAL PAIN MANAGEMENT	$168,203,323	$22,545,559	($6,788,185)	$15,757,374	$183,960,697	9%
PLASTIC AND RECONSTRUCTIVE SURGERY	$55,565,227	$10,280,479	($4,526,105)	$5,754,374	$61,319,601	10%
UROLOGY	$752,497,473	$126,343,272	($41,574,022)	$84,769,250	$837,266,723	11%
ALLERGY/IMMUNOLOGY	$95,801,235	$13,194,385	($603,585)	$12,590,800	$108,392,035	13%
CERTIFIED NURSE MIDWIFE	$2,144,561	$312,479	($20,735)	$291,744	$2,436,305	14%
OBSTETRICS/GYNECOLOGY	$225,275,520	$47,309,295	($9,018,841)	$38,290,454	$263,565,974	17%
MAXILLOFACIAL SURGERY	$4,558,435	$978,386	($146,599)	$831,787	$5,390,222	18%