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June 25, 2018

The Honorable Seema Verma
Administrator
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims (CMS-1694-P; 83 Fed. Reg. 20164, May 7, 2018)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Fiscal Year (FY) 2019 Proposed Rule for the Hospital Inpatient Prospective Payment System for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System. Our detailed comments are below.

In summary:

- The AMA is encouraged by CMS' efforts in this proposed rule to reduce physicians' administrative burden. While we believe some proposals need to be refined, we strongly support the new direction of the Promoting Interoperability (PI) program (previously the Meaningful Use (MU) program). We agree with CMS' goal to focus the program on interoperability and improved patient access to health information as opposed to burdensome, prescriptive data capture and measurement policies.
- The AMA supports CMS' efforts to reduce physicians' and hospitals' reporting burden by removing and de-duplicating many quality measures within the hospital quality reporting programs, and we include comments on how these proposals could be further improved.
- The AMA supports CMS' efforts throughout this rule to attempt to determine whether the costs and burdens of reporting programs outweigh the benefits. We will work closely with CMS to provide further information on the reporting costs and burdens of these programs going forward.

We believe the proposed changes to the PI and quality reporting programs are a good first step in reducing physicians' regulatory burden, and will allow physicians to spend more time focusing on patient

care while also providing needed data to CMS. We look forward to working with CMS to refine the proposals contained in this proposed rule and align them with physician PI and quality reporting programs in the future.

AMA DETAILED COMMENTS:

I. The PI Program;
II. Hospital Quality Reporting Programs;
III. Hospital Requirements to Publicly List Standard Charges;
IV. Burden Reduction for Hospitals;
V. Graduate Medical Education Issues; and
VI. The Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers.

I. Promoting Interoperability Program

The AMA applauds CMS' overhaul of the MU program and supports many of the proposals within the PI program. We agree with CMS' goals to focus the program on interoperability and improved patient access to health information as opposed to burdensome, prescriptive data capture and measurement policies. **We urge CMS to continue to limit regulatory requirements in the PI program as long as physicians can share data among themselves and with their patients.** However, CMS' continued proposed policy of an "all-or-nothing" scoring structure continues the artificial construct that all measures work for all physicians.

We further note the importance of regulatory alignment across agencies with respect to data access and caution CMS against requiring physicians to transition too quickly to new measures in both 2019 and 2020 for reasons explained below. Finally, to minimize burden on hospitals, physicians, and Electronic Health Record (EHR) developers, CMS should ensure that the PI measures outlined in the proposal align with the PI measures within the newly-renamed PI component of the Merit-Based Incentive Payment System (MIPS) (formerly Advancing Care Information (ACI)). Physicians should not have to manage requirements of two different programs across practice settings, and vendors should not be forced to design technology for compliance with two different regulatory programs.

<u>Proposals the AMA Supports</u>

- **Measure reduction:** The AMA strongly supports CMS' proposal to eliminate a number of measures from the current EHR Incentive Program that are not meaningful, are administratively burdensome, and ultimately detract from patient care. The reduction of the number of measures on which a hospital must report enhances a physician's ability to focus his or her time on providing patient care, as opposed to meeting and reporting on arbitrary requirements.
- **2019 Certified Electronic Health Record Technology (CEHRT) requirements:** The AMA supports the use of 2015 Edition CEHRT in 2019. We recognize the additional functionalities included in the new edition and agree that they will support improved patient access and interoperability. CMS should, however, closely monitor the availability of 2015 Edition CEHRT throughout 2018 to ensure hospitals have sufficient choice of products.

- **90-day reporting period in both 2019 and 2020:** The AMA has previously noted that practices, especially small practices with limited resources, often require a significant amount of time to upgrade their EHR technology, conduct tests and training, and change workflows after the EHR has passed certification. We value CMS' recognition that a 90-day reporting period will provide flexibility in reporting PI measures and help practices successfully navigate their transition to 2015 Edition CEHRT.
- **Use of health information technology (IT) beyond CEHRT:** The AMA commends CMS' recognition, through the proposed Query of Prescription Drug Monitoring Program (PDMP) measure, that the use of health IT outside of CEHRT can be useful for physicians, improve patient outcomes, and enhance patient safety. Because increased interoperability and patient access will require new combinations of technologies and services, we continue to urge the U.S. Department of Health and Human Services (HHS) to reevaluate regulations that prioritize the use of CEHRT over other non-certified digital health tools. Patients, physicians, and other care team members should be empowered to make decisions based on what works best for their needs, and not what regulatory boxes must be checked. Any new PI measures should utilize not only CEHRT but also health IT that "builds on" CEHRT—a concept taken directly from CMS' priorities in its call for new PI/ACI measures.
- **Medicaid PI program:** We support CMS' proposal to extend the Medicare PI program performance-based scoring methodology to not only Medicare-only eligible hospitals and critical access hospitals (CAHs), but also dual-eligible hospitals. We further support CMS' proposal to give states the option to adopt the performance-based scoring methodology, along with the corresponding measure proposals, for their Medicaid PI programs through their state Medicaid health IT plans. Physicians should not have to keep track of which measures they must report if they practice across care settings and payers.
- **Exclusion for the *Receive and Incorporate Health Information* Measure:** CMS should prioritize physicians sending health information over the incorporation of data received by other providers into the EHR. Just as CMS notes in the proposed rule that it is beyond a hospital's control to require patients to access their information in a particular manner, CMS should recognize that hospitals cannot require other hospitals or clinicians to send information to them. In fact, the EHR of a "sender" may not be able to communicate with a hospital's EHR if the two parties have different edition EHRs, each of which utilizes different common clinical data architectures. Consequently, a hospital will be reliant on another party to score well in the "Receive and Incorporate Health Information" measure. Furthermore, as CMS notes in the proposed rule, the Receive and Incorporate Health Information measure is new. This measure has not been tested in clinical practice and there is a lack of experience of how it will unfold in a real-world setting. For these reasons, we strongly support CMS' proposed exclusion for this measure.
- **Discontinuation of scoring *Security Risk Analysis* measure:** The AMA agrees with CMS that it is not necessary to score this measure as it is already required under the Health Information Portability and Accountability Act (HIPAA). Yet, the proposal still requires a hospital to complete or review a security risk analysis to receive any score in the PI program. A hospital's success in the PI program should not hinge on its security risk analysis; rather, the hospital should be held accountable for the privacy and security of its protected health information under HIPAA, which is regulated and enforced by the HHS Office of Civil Rights (OCR). If CMS plans to condition a hospital's success in the PI program on whether it conducts or reviews a security risk analysis in accordance with HIPAA, the hospital should receive a score that contributes to its overall PI score (e.g., 5 points for a "yes" attestation). To be clear, the AMA is not saying that a security risk analysis is unimportant. However, failure to conduct or review such an analysis is a

matter for OCR, not CMS, and such failure should not preempt a hospital's PI score. Alternatively, CMS should exclude the security risk analysis from any PI audits.

Additional Recommendations from the AMA

- **Patient Access and Data Availability:** The AMA has long noted that physicians are unfairly penalized by CMS scoring physicians on measures that rely on the actions of others. We appreciate CMS' acknowledgment that, while clinicians can encourage their patients to access information in a particular way (e.g., through a patient portal), the patient's ultimate actions are beyond a physician's control. As such, **we strongly support CMS' shift to scoring physicians on providing patients with access to their protected health information in a number of ways rather than scoring physicians on how patients access their information**.

However, the AMA also urges consistency across HHS as the agency sets policy to promote information sharing and prevent information blocking. For example, there is a discrepancy between the electronic patient information that is made available via the EHR (the common clinical data set, or CCDS) versus the information contained in a patient's designated record set as required by HIPAA. Particularly in light of MyHealthEData, an initiative that the AMA supports, many patients will likely believe that application programming interfaces (APIs) will provide a "spigot" of data, enabling a free flow of all their information. This is not the case. In order to receive his/her entire medical record in an electronic format, a patient will likely still be given a CD or USB because APIs may not provide access to all of the information contained in an entire medical record. Furthermore, not all EHRs will be able to support any given app. If a patient has an app he would like to use, the physician's EHR may not support it, and the physician will have very little leverage against the vendor.

Because of the limitations of the API functionality, agencies across HHS must manage expectations about what information a patient can actually access through an app. While the AMA will continue to work with the Office of the National Coordinator for Health Information Technology (ONC) and urge vendors towards developing an API that enables patients to pull more than just CCDS data, OCR should specifically acknowledge this issue and address it through guidance or an FAQ. This guidance should clarify that physicians are not information blocking in the event that patients cannot access their entire medical record through a mobile app and cannot receive their entire medical record in a format of their choosing (e.g., an app). In sum**, federal regulation and policy must balance patient data access with the limitations placed on physicians and patients by the design and development of health IT.**

- **PI Simplification and Burden Reduction Through Attestation:** CMS seeks comment on how the PI program should evolve in future years. Rather than waiting until the future**, the AMA urges CMS to only require hospitals to attest to meeting the program's measures—i.e., hospitals should only be required to report "yes" or "no" on whether they had at least one patient in the numerator of each measure.** Each "yes" would be worth a certain amount of points. In addition to relieving reporting burden on hospitals, an attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report, and could help prioritize both existing and future gaps in health IT functionality. Because EHRs capture what functionalities are used to perform tasks, EHR vendors can easily provide such information to CMS and ONC. This data capture mechanism also provides an audit trail for CMS to ensure that hospitals actually did have

at least one patient in the numerator of each "yes" attestation. Hospitals should focus on meeting the PI program's objectives rather than worry about measurement and documentation.

2015 Edition EHRs are expected to improve interoperability and patient access—improvements that the AMA agrees are important. Through the adoption and implementation of 2015 EHRs, it is expected that physicians and patients will have new opportunities to engage with medical records and heath data in a way that makes sense for the physician's practice and their patients' needs. **The approach of combining 2015 Edition EHR adoption along with shifting PI measure reporting to attestation will promote interoperability and reduce physician burden.** Additionally, given that technology continues to evolve, current PI measures are likely to become quickly outdated or will fail to include more innovative uses of the EHR. Creating broad categories of PI measures, coupled with an attestation approach, would provide flexibility to allow patients and physicians to efficiently test new uses of technology to see what does and does not work, while encouraging further innovation. For example, CMS could create an objective called "Chronic disease management enabled by digital medicine." Measures could be developed that support physicians using not only emerging CEHRT functionalities, like APIs and patient-generated health data, but also could also promote the use of digital health tools, such as remote patient monitoring services. **We stress, however, that absent an attestation approach, any new objectives and associated measures should be optional to provide additional opportunities for hospitals and physicians to be successful in the PI program.**

If CMS must use a performance-based scoring structure, it should limit such scoring to the Provide Patient Access and Sending Health Information measures. These are areas that CMS prioritizes (patient access and interoperability). As noted in our comments above supporting the measure exclusion, the Receive and Incorporate measure is new and hospitals should not be held accountable for performance scores that depend on actions of another party.

- **Objective-level Scoring**

The AMA supports CMS' proposal to move from thresholds-based measurement to performance-based scoring. However, **we strongly oppose the proposal to require reporting on all measures to be deemed a meaningful user**. Not all of the measures work for all practices, as demonstrated by the continued number of necessary exclusions. We support CMS' alternative approach, under which hospitals would be scored at the objective level—that is, scored based on reporting one measure from each objective and receiving bonus points for any additional reported measures. Participants should be able to select among the measures within an objective on which they wish to report. While we have heard concerns that allowing physicians flexibility to select the measures they report under each objective could lead to cherry picking, we believe that instead, this flexibility would allow physicians to choose measures that are most relevant to their patient population.

Accordingly**, we support CMS' alternative proposal that CMS score measures at the objective level,** which conforms with HITECH's requirement that meaningful users e-prescribe, exchange health information electronically, and report quality measures, and permits physicians to report on a subset of optional measures.

Of note, there is precedent for not requiring meaningful users to report on quality; the base score of the PI/ACI component of MIPS does not require physicians to report to a clinical data registry. As such, **we urge CMS to ensure that hospitals are incentivized to conduct syndromic surveillance reporting or**

report to a clinical data registry, rather than required to do so. At the very least, a hospital should only be required to report to one registry.

Additionally, we strongly recommend that CMS reconsider its requirement that clinical registry reporting be conditional based on "end-to-end" electronic reporting. Physician-led clinical data registries continue to highlight that some data may not be captured or reported easily from an EHR. It is an incorrect assumption that chart-abstracted or hand-keyed data has any less value than end-to-end electronically captured and reported data. Many registries still rely on both automated and manual data entry. Most EHRs cannot support all the necessary data elements needed for advanced quality measures or analytics, and therefore registries still support a hybrid approach to data collection.

While end-to-end electronic reporting is a goal for many registries, it is critical that CMS not place too much value on purely end-to-end reporting. Rather, CMS should reward physicians for utilizing registries, leveraging electronic capture, reporting where it makes sense, and using alternative methods when they are more efficient. We caution CMS from incentivizing end-to-end reporting simply because it bypasses a sometimes necessary manual data entry step. **The AMA recommends that CMS expand their Public Health and Clinical Data Exchange objective requirement to include a mixture of methods for data capture or reporting.**

- **The Query of Prescription Drug Monitoring Program Measure**

The AMA is committed to addressing the country's opioid epidemic. **We support CMS' proposal to provide a bonus PI score in 2019 to hospitals who choose to utilize a PDMP when clinically appropriate and in accordance with state law. However, CMS should continue rewarding the activity with bonus points in 2020.** The measure is new to clinicians and hospitals and there are a variety of unknowns in how the measure will be operationalized in facilities. Further, there are a wide variety of PDMP technologies that operate differently across facilities that interface with a multitude of EHRs. There are also questions of how to best document the information gleaned from a PDMP into the EHR, in a secure manner, while ensuring that the information is associated with the correct patient. Further, by continuing to score this measure as a bonus for an additional year, CMS can keep the Provide Patients Electronic Access measure's value at 40 points in 2020, which will underscore the agency's commitment to patient access while incentivizing clinicians and the organizations in which they practice to become familiar with the PDMP measure and its integration into their workflow for another year.

CMS acknowledges and seeks input on barriers to the implementation of electronic prescribing for controlled substances (EPCS). As the AMA described in a March 2018 letter to the Drug Enforcement Administration (DEA), the current EPCS regulations, which have been unchanged since 2010, prevent user-friendly devices that are widely available in medical practices from being deployed to meet the multifactor authentication standards in the DEA rules. The AMA letter outlined specific changes that are needed in the regulations for biometric devices in order to make it simpler and less expensive for physicians to adopt EPCS and have it integrated into their practice workflows. These requests are consistent with a recommendation from the President's Commission on Combating Drug Addiction and the Opioid Crisis that the DEA should increase EPCS to prevent diversion and forgery and revise the EPCS regulations. Although the numbers of physicians checking PDMPs has accelerated rapidly in recent years, the current low rate of adoption of EPCS means that tying a measure of PDMP utilization to use of EPCS is premature.

CMS is also seeking comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP. Physicians need access to interoperable and usable health IT that is well-integrated into their workflows. Ultimately, all PDMPs and EHRs should standardize around a common approach for data exchange. Not only will this reduce the variations in PDMP usability, but it will also reduce costs, improve real-time data access, and better integrate PDMP data into health IT functions like clinical decision support and quality measurement. However, the AMA cautions CMS and ONC from going down the path of regulating technology. **We believe the best approach is for CMS to continue promoting the use of PDPMs with positive incentives and for ONC to focus its efforts on ensuring health IT vendors develop and implement API interfaces in a standardized and consistent fashion. This concept is explored further in our interoperability RFI comments below.**

- **Participation in the Trusted Exchange Framework and Common Agreement (TEFCA)**

The AMA is interested in the idea of considering participation in the TEFCA a health IT activity that could count for credit within the Health Information Exchange objective in lieu of reporting on measures for this objective. We cannot comment fully, however, until the final TEFCA is released by ONC outlining what is required for participation. There are too many unknowns to make an informed decision at this time. For instance, the AMA seeks more clarity around the definition of "participation" and exactly how it would be measured. Would participation require both the hospital and its health IT vendor to jointly sign the Common Agreement? Regardless, if participation in the TEFCA is finalized as a measure under the Health Information Exchange objective, it should be in addition to, not instead of, the other measures required under the objective. Furthermore, we recommend that CMS also consider similar trust agreements and not limit potential Health Information Exchange objective options to just the TEFCA.

- **Maintaining an Open API**

As stated throughout our comments, the AMA supports patient access and believes that an open API is an efficient and relatively non-burdensome manner of providing such access. We foresee APIs enhancing access to data in the EHR while concurrently expanding the opportunities for physicians and patients to use medical information in new and exciting ways. For this to occur, we believe a number of considerations must also be addressed, which are discussed in the interoperability RFI section of our comments. Nevertheless, once an EHR-enabled API is turned on and shown to provide improved access to data, hospitals and physicians will want to maintain access—regardless of CMS-mandated reporting periods.

While APIs have a lot of potential, enabling a new interface that provides access to sensitive or protected health information also increases the potential for unauthorized access to that information. Many physicians and hospitals are still working through the complications and security requirements to limit the exposure surfaces on their EHRs. APIs will add to this by creating another threat vector for hacking or other cybersecurity attacks. The API is also a new EHR function which has largely gone untested in real-world use. As EHR vendors continue to update, patch, or make changes to the EHR, there will be instances where APIs will need to be brought offline for maintenance. Additionally, as with any complex technology, APIs may be interdependent with other health IT products. If those products fail, access to the API may also be compromised.

The AMA stresses that it is neither appropriate nor necessary to impose further requirements on hospitals or physicians—beyond the proposed PI objective requirements—to maintain APIs once they are enabled.

As described above, there are legitimate reasons why, for a short period of time, hospitals, physicians, or EHR vendors may need to disable APIs—resulting in temporarily limited data access—defend, protect, or improve the security of patient data or the functionality of the EHR as a whole. We strongly urge CMS to take this into consideration and to limit any additional API requirements that would result in unintended consequences.

II. Quality Reporting Programs

We appreciate CMS taking a holistic view of the various hospital quality reporting programs in an effort to ease provider reporting burden and better focus quality and patient safety efforts. Routinely, we hear from physicians who practice in a hospital setting that the redundancy and overlap of the measures in the hospital quality reporting programs are hindering patient care. The proposed changes will begin to allow physicians and hospitals to better work together, reduce administrative burden and spend more time focusing on patient care. Specifically, we support CMS' proposal to remove the Hospital Acquired Condition (HAC) measures from the Hospital Value Based Purchasing Program (VBP) because hospitals will no longer be scored in two payment programs on the same measures. However, we believe CMS could further streamline other programs, such as the Inpatient Quality Reporting (IQR) program. CMS has maintained measures that are problematic and lack appropriate risk-adjustment in the IQR program, and there are many measures which CMS removed that hospitals must still report in other programs.

There is also an urgent need to re-evaluate the Hospital Readmission Reduction program as there is emerging evidence that the program and the associated measures may be leading to negative unintended patient consequences and no longer capturing the appropriate patient population due to the structure and timeframe of the measures. We encourage CMS to work with the AMA and the provider community to further streamline the hospital quality reporting programs to reduce physician burden and better understand the impact CMS policies have on readmissions and patient outcomes.

It is also unclear which measures will now contribute to the Hospital Compare Star Ratings program since CMS does not address public reporting on Hospital Compare in the 2019 IPPS proposed rule. Historically, the star ratings measures stemmed from the IQR program. As CMS makes changes to quality programs it must consider the implications across programs, including Hospital Compare and we urge CMS to provide clarification on the Hospital Compare program through notice and comment rulemaking.

The AMA appreciates CMS' proposals to the hospital quality reporting programs that are aimed at reducing physicians' and hospitals' administrative burden. While we believe further improvements are needed, we look forward to working with CMS to ensure quality reporting requirements become less duplicative, more meaningful and less burdensome for physicians.

<u>Hospital Inpatient Quality Reporting Program</u>

We support CMS' proposal to remove 18 previously adopted measures and de-duplicate 21 measures to simplify and streamline measures across programs. Over the years in comments we have raised concerns with several of the IQR measures CMS has proposed for removal, and we appreciate CMS' responsiveness to our concerns in this proposed rule.

- **Measure Removal Factors**

As part of CMS' effort to move to a more holistic and less burdensome IQR program, CMS proposes to adopt the following new measure removal factor and to update the Hospital IQR Program's measures to reflect the additional factor: the cost associated with a measure outweighs the benefit of its continued use in the program.

While we strongly support the intent of the new factor, we seek clarification from CMS on the financial/cost threshold CMS has utilized in this proposed rule and plans to utilize when determining whether the cost outweighs the benefit in the future. It would be useful to understand what cost estimates and evidence providers must present to demonstrate that this new factor should be applied to a measure. Ideally, quality measures incorporated into CMS programs should demonstrate that by measuring a certain process or outcome, a hospital or physician can improve on performance in a meaningful way. In addition, ideally the costs associated with the data collection and reporting of the measure would be worthwhile, for example, the measure will save an estimated number of lives or prevent a minimum number of infections.

SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock serves as a good example of how this new factor could be applied. Many hospitals and physicians have noted the significant time and effort required to report this measure. In addition, the measure relies on questionable evidence and demonstrates poor data element validity. To date, the developer has not proven that the amount of effort and cost required to collect data and report on this measure is outweighed by the number of lives saved. Costs required to report the Severe Sepsis measure balanced against the lack of a clear benefit of the measure provide a good example of the elements that should be considered when reviewing measures against this new factor. We believe CMS should consider each measure currently included or proposed in the future for hospital reporting programs based on available evidence demonstrating whether the measure truly drives quality improvements and whether the costs of data collection and reporting that each hospital must undertake are worthwhile.

We also seek clarification on whether patient harm is addressed in any of the removal factors. We believe that it may fall under Factor 4, performance or improvement on a measure does not result in better patient outcomes; however, the current definition is vague. We recommend that CMS clarify whether patient harm is intended to be captured in Factor 4 and if not, address this important issue.

Currently, Factor 3 (availability of a more broadly applicable measure), Factor 4 (performance or improvement on a measure does not result in better patient outcomes), and Factor 5 (availability of a measure that is more strongly associated with desired patient outcomes for the particular topic) focus on a replacement with a "better" measure based on its association with outcomes. We also recommend that CMS propose an additional removal factor around reliability and/or validity. Specifically, when there is a new measure available that provides results which are more reliable and/or valid, its availability should be considered. As measure development and implementation becomes more sophisticated and measures are better able to precisely and accurately represent the quality of care provided to patients, this removal process should recognize and facilitate replacement with these "better" measures.

In addition, CMS proposes to further align policies adopted in the Hospital IQR Program with the Hospital VBP program and proposes that if CMS believes continued use of a measure in the Hospital VBP program poses specific patient safety concerns, CMS may promptly remove the measures from the

program without rulemaking and notify hospitals and the public through routine communication channels. We support CMS promptly addressing patient safety concerns, but we seek clarification on the level of evidence needed to rapidly remove a measure(s) from a program without rulemaking.

We also believe this standard should apply across all of the hospital programs, not just IQR or VBP. For example, the AMA has highlighted in previous comment letters our significant safety concerns with the *SEP-1 Early Management Bundle, Severe Sepsis/Septic Shock* measures in the IQR program. However, CMS has maintained the measure in the program and not proposed the measure for removal. As noted in previous comments, there is emerging evidence that this composite may improve care; however, it has the potential to misrepresent performance due to questionable reliability and validity results. Because of these limitations, we believe that the use of the measure is leading to negative unintended consequences. As noted in an article in the *American Journal of Medical Quality*, the sepsis bundle as currently specified could lead to patient harm and other unintended consequences.[1] For example, if a patient has severe systolic dysfunction (LVSD), a physician may determine that treating the patient with the amount of fluids required under this composite would be harmful to the patient, possibly causing fluid overload. More than 60 percent of patients who present with septic shock have LVSD, yet research shows that this treatment can be harmful to patients with LVSD.[2] If a physician provides the appropriate care to the patient in this circumstance (limiting the fluids), it would impact their ability to comply with the measure.

Therefore, the developer and CMS have a duty to ensure that the specifications are flexible enough to allow for individual patient differences, while also enabling hospitals to demonstrate the quality of care provided. This precision should include addressing how unique patient characteristics and unplanned drug shortages can impact an individual's hospital's performance. For example, a study published in 2017 examined the impact that the norepinephrine shortage in 2011 had on inpatient mortality for patients with septic shock. Researchers found that an increase in inpatient mortality was associated with hospitals identified as having a shortage of this front-line vasopressor.[3] Therefore, based on CMS' criteria for prompt removal of a measure that raises patient safety concerns the SEP-1 Early Management Bundle should be removed from the IQR program given the existing specifications.

In addition, the identification of potential unintended consequences of a composite that calls for multiple components leads us to question whether the measure continues to be based on strong evidence. Kalil and colleagues examined more than 35 observational studies and randomized clinical trials to determine why results in more recent studies were not supportive of the original trials from 2015.[4] The review found that patient survival rates were primarily driven by prompt and appropriate antibiotic administration rather than early goal-directed therapy (EGDT). In addition, EGDT was associated with higher mortality rates in patients that had higher disease severity. A similar analysis by the PRISM investigators found no differences in outcomes for patients who received EGDT versus usual care and those same patients had

[1] Pronovost et al. (2017) *Finding Balance: Standardizing Practice in Corseting Physician Judgement.* American Journal of Medical Quality.

[2] Baciak K. (2015). Sepsis care – what's new? The CMS guidelines for severe sepsis and septic shock have arrived. Available at: http://www.emdocs.net/sepsis-care-whats-new-the-cms-guidelines-for-severe-sepsis-and-septic-shock-have-arrived/; Boyd et al. (2011) *Fluid resuscitation in septic shock: A positive fluid balance and elevated central venous pressure are associated with increased mortality.* Critical Care Medicine 39(2): 259-265; Pulido et al. (2012). Clinical spectrum, frequency, and significance of myocardial dysfunction in severe sepsis and septic shock. Mayo Clinic Proceedings 87(7): 620-628.

[3] Vail et al. (2017). *Norepinephrine Shortage and Mortality among Patients with Septic Shock*. JAMA 317 (14) 1433-1442.

[4] Kalil AC, Johnson DW, Lisco SJ, Sun J. Early goal-directed therapy for sepsis: a novel solution for discordant survival outcomes in clinical trials. Critical Care Medicine. 2017;45:607-614. DOI: 10.1097/CCM.0000000000002235.

higher costs associated with the hospitalization.[5] Therefore, we urge CMS, the measure developer, and the National Quality Forum (NQF) to reevaluate the sepsis management bundle given the evidence in recent studies of unintended consequences.

We also continue to remain concerned with the lack of adequate evaluation of this composite's reliability and validity when the measure underwent maintenance evaluation at NQF during 2017. During the NQF Infectious Disease Committee discussion, NQF staff instructed committee members to focus solely on the measure score reliability testing and not the data element validity testing provided by the developer. The rationale for this focus was due to the criteria around composite measures, but the AMA has reviewed the NQF criteria and we do not believe the guidance followed the consensus process. While the criteria emphasizes that committees must be able to evaluate how the composite with its individual components performs together, the Composite Performance Measure Guidance report also states that "the individual components may not be sufficiently reliable independently, but could contribute to the reliability of the composite performance measure." In addition, at the time the criteria in 2D asked that missing data be addressed. In the data element validity testing provided in section 2B, 40 of the data elements did not achieve agreement rates of at least 90 percent. Therefore, the degree of agreement or lack thereof is an important component to be factored into the assessment of validity and it must also be addressed when evaluating Criteria 2D as it demonstrates a critical issue with the measure—missing data.

The AMA urges CMS to work with NQF and request that the Infectious Disease Committee reevaluate their ratings on evidence and scientific acceptability. In addition, in light of the emerging evidence that calls the basis for the Sepsis bundle into question, and ongoing concerns over the reliability and validity of the measure results. Therefore, since as currently specified CMS has not demonstrated how the measure truly drives improvement and whether the cost of data collection leads to better patient outcomes, we urge CMS to remove the measure from the Hospital IQR program until these issues can be addressed.

- **Mortality Outcome Measures**

While we are supportive of CMS' proposal to remove duplicative measures from the hospital quality programs and its specific proposal to remove the condition specific mortality measures from the IQR program due to methodological flaws, CMS is not eliminating burden because the measures must still be reported in the Hospital VBP program. We also do not believe the Hospital-Wide (All-Cause) Mortality Outcome Measure in the Hospital VBP program is an appropriate substitute for the specific mortality measures. The AMA supports condition specific-mortality measures over all-cause measures because all-cause measures do not provide enough precision for providers to understand the reasons for mortality and implement changes. However, we still believe there are improvements that need to be made to the condition specific mortality measures.

Specifically, we are concerned with CMS maintaining the *Hospital 30-Day, All-Cause, Risk Standardized Mortality Rate following Acute Ischemic Stroke Hospitalization* (Stroke Mortality Measure- MORT-30-STK) in the IQR program. In the 2018 IPPS final rule, CMS finalized refinements to the MORT-30-STK measure starting with the FY 2023 payment determination (using discharges occurring between July 1,

[5] The PRISM Investigators (2017). Early, Goal-Directed Therapy for Septic Shock – A Patient-Level Meta-Analysis. Available at http://www.nejm.org/doi/full/10.1056/NEJMoa1701380#t=abstract. Accessed May 31, 2017.

2018 and June 30, 2021). However, CMS does not address the measure in the 2019 IPPS proposed rule and maintains the condition-specific stroke mortality measure in the IQR program.

While the AMA believes the refinements finalized in 2018 to the MORT-30-STK measure are improvements to the previous measure, we still have serious concerns with the measure specifications and implementation of the measure and do not support the existing MORT-30-STK measure or the refined version. First, there is still a lack of adjustment for tissue plasminogen activator/thrombectomy. In addition, while International Classification of Diseases, Tenth Revision (ICD-10) allows for more robust coding we are concerned with the reliability and accuracy of comparability across sites due to imprecise coding and an over reliance on claims data. There is an onerous amount of detail and documentation that goes into assigning a code and physicians often pick the one that requires the least amount of documentation, not the one that is the most accurate. It is also unclear whether the information can be consistently obtained across sites or from nurse to nurse, which may cause neurological changes not to be documented. More specifically, it is unclear which National Institutes of Health Stroke score and at what point in time CMS will use. The score is collected at multiple points in time and by various providers treating the patient (the attending physician, resident or nurse). Therefore**, we urge CMS to remove the measure from the program until methodological issues can be resolved.**

- **Coordination of Care Measures**

We support CMS removing the condition-specific readmission measures from the IQR program but would like to highlight that CMS' proposal is not a true burden reduction. Historically, submitting for IQR meant automatically submitting the measures for another program. In the case of the condition-specific readmission measures it means the measures must still be reported in the Hospital Readmission Reduction Program (HRRP). We do not believe that the removal of these measures from only one program reduces the burden of reporting.

We also recommend that CMS remove from the IQR program the *Hospital-wide All-Cause Readmission measure* (HWR). The HWR measure is duplicative of the condition specific measures that CMS is maintaining in the HRRP. We believe condition specific measures are more informative because they facilitate quality improvement, whereas an aggregated measure, such as HWR is less useful. There is also emerging evidence questioning the validity of the timeframe of the HWR measure—30-day post-discharge. According to a recent study in the *Annals of Internal Medicine*, the preventability of readmissions might change over the post-discharge time frame.[6] As the authors highlight, readmissions within seven days of discharge differ from those between eight and 30 days after discharge with respect to preventability. Early readmissions were more likely to be preventable and amenable to hospital-based interventions. Late readmissions were less likely to be preventable and were more amenable to ambulatory and home-based interventions. Therefore, post-seven-days hospital discharge there is potentially little influence a hospital has over a patient being readmitted to a hospital.

Furthermore, we recommend CMS remove the *Excess Days in Acute Care After Hospitalization Measures* (for acute myocardial infarction, heart failure and pneumonia) from the IQR Care Coordination domain. As currently specified, the excess days measures overlap with the readmission measures in the HRRP since readmissions are one of the excess days categories. It is unclear why CMS is maintaining

[6] Graham, Kelly. Et al (2018). Preventability of Early Versus Late Hospital Readmissions in a National Cohort of General Medicine Patients. Ann Intern Med. Doi. 10.7326/M17-1724

measures in the IQR program that would penalize hospitals twice for the same patient care. We urge CMS to eliminate this redundancy across measures. In addition, we have concerns with the lack of socioeconomic and demographic (SDS) adjustments within the measures.

For additional information on our concerns with the readmission measures, see the Hospital Readmission Reduction Program section.

- **Resource Use Payment Measures**

We support CMS' proposal to remove the following clinical-episode based payment measures from the IQR program; however, we do not fully support CMS' justification for removal—that these measures overlap with the Medicare Spending Per Beneficiary (MSPB) measure in the VBP program:

- Gastrointestinal Hemorrhage Clinical Episode-Based Payment Measure
- Kidney/Urinary Tract Infection Clinical Episode-Based Payment Measure
- Aortic Aneurysm Procedure Clinical Episode-Based Payment Measure
- Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure
- Spinal Fusion Clinical Episode-Based Payment Measure

These condition-specific payment measures have not been adequately assessed to address methodological issues, such as attribution. We believe the measures warrant removal due to the methodological concerns. We also do not support the measures due to concern over the lack of social risk factor risk-adjustments within the measures. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) found that there was an association between higher costs and a beneficiary's dual-eligible status for the MSPB measure and it is very likely that the measures examining costs for a specific condition could demonstrate similar results. We also remain concerned with CMS' use of the MSPB measure in the VBP program. For more specific details on our ongoing concerns with the MSPB measure, please see the VBP section.

Another CMS contractor (Acumen, LLC) has been engaged to develop episode cost measures for use in the Merit-based Incentive Payment System (MIPS). These measures have had very significant input from clinicians and either already include or are expected to eventually include the remaining areas addressed in the IQR. Due to the transparency and rigor of the Acumen measure development process, the AMA believes the MIPS measures will prove superior to the current IQR measures. We therefore urge that CMS restrain from extending any of the IQR measures to MIPS and that where possible, IQR measures be re-examined and harmonized with relevant MIPS episodes.

- **Potential New Measures**

Claims-Only Hospital-Wide, All-Cause, Risk Standardized Mortality and Hybrid Hospital-Wide, All-Cause, Risk-Standardized Mortality measure: The AMA questions the need for an all-cause risk-standardized mortality measure given the number of condition-specific mortality measures available and in use now in the VBP program. We also would not support the use of the measure in the Medicare and Medicaid PI Programs, as CMS proposes. We do not believe that reporting on the 30-day mortality rate for each hospital is truly reflective of the quality of care provided to their patients, particularly given the lack of adequate risk adjustment for social risk factors. Developers must continue to be responsive to emerging measure methodologies and the traditional approach of risk adjusting at the patient level may not be appropriate for measures where the measurement period includes care that is outside of the control

of the hospital. The AMA believes that there may be community-level variables that could impact the risk model of this measure that are not addressed. Measures that extend beyond the hospital stay or outside the locus of control of the measured entity should continue to have adjustment for social risk factors addressed and new variables analyzed at different levels (e.g., patient, hospital, and community). We recommend that CMS work with the developer to continue to explore new variables that directly relate to the community in which a patient resides, particularly given the report from the ASPE.

We also do not believe that the measure is useful for quality improvement or accountability given the limited variability in performance scores. The testing results released for public comment in January 2018 show that only six hospitals were identified as statistically worse than the national average and the majority of the hospitals (92.4 percent) were no different than the national average. Given the lack of variation across hospitals, we do not believe that the measure provides meaningful and actionable information for hospitals, physicians and patients.

Hospital Harm – Opioid-Related Adverse Events Electronic Clinical Quality Measure (eCQM): The AMA supports the development of measures that are targeted at reducing and eliminating adverse events that lead to patient harm. While the intent of the proposed measure appears to be appropriate, no detailed specifications and only limited testing results have been released for stakeholders to review and analyze. As a result, questions including whether there is true variation in care across hospitals and whether the measure yields information and data that is useful for quality improvement are not yet answered. We are also concerned that implementation may lead to potential unintended consequences and there is a need to balance this measure with measures assessing appropriate use of naloxone and adequate pain control. Therefore, we believe it is premature for CMS to move forward with including the measure in the IQR or PI programs.

- **Accounting for Social Risk Factors in the Hospital IQR Program**

CMS should explore whether payment adjustments should be modified based on the stratified results and other approaches, as discussed in the ASPE 2017 report on social risk factors in value-based purchasing programs.[7] Stratifying quality measures by social risk-factors can allow providers to better understand patients underlying demographic and clinical factors, but stratification alone is not sufficient. Stratification only adjusts a providers' payment, but can still imply that hospitals treating patients in socio-economically disadvantaged areas provide lower quality care, when in fact their poorer outcomes may all be related to their patient mix.

Without continued exploration and incorporation of social risk-factors into risk-adjustment methodology CMS may continue to unfairly assess hospitals and physicians and disincentive care of high risk patients. In addition, CMS must consider and incorporate risk-adjustment for social-risk factors in its other quality programs, not just IQR.

[7] REPORT TO CONGRESS: SOCIAL RISK FACTORS AND PERFORMANCE UNDER MEDICARE'S VALUE-BASED PURCHASING PROGRAMS (2017). Office of the Assistant Secretary for Planning and Evaluation. https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs. Accessed: 05/31/2018

If CMS moves forward with publicly reporting stratified results of quality measures on Hospital Compare then CMS must ensure the results are reliable. Otherwise, there is significant risk that hospital performance for these at risk populations will be misrepresented.

We offer additional items for CMS to consider on accounting for social risk-factors:

- The AMA believes the most effective approach may be to incorporate social risk factors by risk-adjusting at the individual measure level. However, we also encourage CMS to study the issue at the program level. It is possible that a particular socioeconomic factor or set of factors is not significant enough to affect outcomes at the individual measure level, but is statistically significant when measures are evaluated at the program level or when certain types of measures are bundled together (such as readmission, cost, and clinical outcome measures).
- We recognize that NQF has extended its trial period on risk-adjustment and while the AMA is highly supportive of NQF's trial period, we do not believe that appropriate risk-models have been tested by developers within the trial period. For example, the traditional approach of risk-adjusting at the patient level may not be appropriate for readmission measures that include care that is outside the control of the hospital, such as a 30-day post-acute phase. Therefore, CMS must work with each measure developer to determine the most accurate way to include and account for social risk-factors within each measure.
- We also caution CMS as it explores ways to incentivize providers to care for patients with social risk factors not to rely on an approach that is financed through withholds or reductions in payments to other providers.

Hospital Value-Based Purchasing Program

We appreciate CMS taking steps to refine the VBP program by removing measures that are included in the Hospital IQR or HAC Reduction Program measure sets. However, we remain concerned with some of the measures still included in the VBP program.

- **Measure Removal Factors**

We support CMS' proposal to adopt the same measure removal factors for the VBP program that were previously finalized for the IQR program, as well as the new measure removal factor, cost, proposed for 2019. However, we do not agree with how CMS is applying its cost assumptions. We do not see how costs can be reduced for hospitals by removing a measure from one program when the measure remains in another reporting program. As mentioned earlier, measures incorporated into CMS programs should have to demonstrate that by measuring a certain process or outcome, a hospital or physician can improve performance in a meaningful way and that the costs associated with the data collection and reporting are worthwhile, for example, will save an estimated number of lives or prevent a minimum number of infections.

Currently, Factor 3 (availability of a more broadly applicable measure), Factor 4 (performance or improvement on a measure does not result in better patient outcomes), and Factor 5 (availability of a measure that is more strongly associated with desired patient outcomes for the particular topic) focus on a replacement with a "better" measure based on its association with outcomes. As also noted earlier, we further recommend that CMS propose an additional removal factor around reliability and/or validity. Specifically, when there is a new measure available that provides results which are more reliable and/or valid, its availability should be considered. As measure development and implementation becomes more

sophisticated and measures are better able to precisely and accurately represent the quality of care provided to patients, this removal process should recognize and facilitate replacement with these "better" measures.

- **Safety domain-Healthcare-Associated Infection Measures**

We support removal of the Healthcare-Associated Infection (HAC) measures from the VBP program. Removal of the HAC measures from the VBP will lead to greater alignment and consistency across programs because providers will no longer be scored in two payment programs on the same measures.

- **Person and Community Engagement domain -** Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) **Survey Measures**

The AMA continues to remain concerned with the amount of weight placed on the Person and Community Engagement domain because it is strictly based on HCAHPS survey measures. While measuring patient experience is important, it is extremely subjective and can force hospitals to overemphasize experience as opposed to making improvements to clinical care. Patient experience is also subject to gaming and can lead to unintended consequences.

The AMA and other stakeholders have repeatedly expressed our concerns that the original HCAHPS pain management questions could have the unintended consequences of promoting patient expectations of a pain-free recovery and an over reliance on opioid analgesics, potentially contributing to the growing epidemic of opioid overdose deaths. In the 2017 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems final rule with comment period, CMS finalized its plans to remove the existing pain measures beginning in 2018 and develop modified measures regarding pain management for future program years. In our comment letter on the 2017 OPPS/ASC final rule, the AMA supported the removal of the current pain management questions from the HCAHPS survey, but cautioned CMS that, while patients' pain must be acknowledged and treated, any future modified pain questions must avoid focusing on medication as the only modality for pain management and avoid creating unrealistic expectations about the complete elimination of pain.

While the AMA believes patient-satisfaction surveys have a valuable place in evaluating health care, there are significant dangers in tying them to publicly reported ratings and accountability. In the 2018 IPPS final rule, CMS finalized the replacement of the HCAHPS survey measures pain management questions with new questions that address "Communication about Pain during Hospital Stay," beginning with the FY 2020 payment determination year. The new pain questions CMS finalized are as follows:

- During this hospital stay, did you have any pain? (Yes, No)
- During this hospital stay, how often did hospital staff talk with you about how much pain you had? (Never, Sometimes, Usually, Always)
- During this hospital stay, how often did hospital staff talk to you about how to treat your pain? (Never, Sometimes, Usually, Always)

Once again, the AMA strongly urges CMS not to adopt the new Communication about Pain composite measure and is extremely disappointed that CMS has not taken the time to address the AMA's concerns. We strongly believe CMS should take additional time to study and test whether it is appropriate to incorporate pain measures into a patient experience survey that is used in a payment program with incentives, penalties, and publicly reported results. If CMS insists on moving forward with new pain management measures, it must use caution and allow adequate time to study and test how to best phrase pain questions so that they are appropriately understood by patients and provide useful data. Given the history of pain management questions and standards, and the resulting unintended consequences that

many believe have contributed to the opioid epidemic, this is an area that deserves significant time and research prior to the implementation of any new measures.

As CMS noted in the 2018 IPPS proposed rule, the Communication about Pain composite measure was reviewed by the Measures Application Partnership (MAP) in December 2016. The AMA submitted comments both to the MAP and CMS recommending they not adopt the measure, as we believe it may create similar unintended consequences to the original pain measures by creating patient expectations that hospital personnel should "always" discuss pain and its treatment with patients. This is precisely the type of approach to pain management that can encourage inappropriate prescribing and unrealistic expectations. The MAP recommended that this composite measure be refined and resubmitted prior to rulemaking. The MAP also recommended that the measure be sent to the NQF for review and endorsement. Instead of heeding the MAP's advice and delaying the implementation of these questions until further review could be conducted, CMS has continued to move ahead by finalizing the new pain measurement questions in the 2018 IPPS rule and re-finalizing the questions in the 2019 proposed rule.

The need for additional time to develop and test pain management questions was further highlighted by Dr. David Baker, Executive Vice President in the Division of Health Care Quality Evaluation at The Joint Commission.[8] He described the thin evidence upon which The Joint Commission pain assessment requirements were based, and the negative unintended consequences that have ensued from the implementation of the requirements. He noted that after evidence of negative unintended consequences emerged, The Joint Commission removed the phrase "pain as the fifth vial sign" from accreditation standards, eliminated the standard that pain be assessed in all patients, and is currently working to revise its pain standards. Furthermore, he provides a summary of lessons learned which include the need to fully consider possible unintended consequences prior to implementation of pain questions or standards, and the need to fully review literature and studies before implementing any pain management programs. This article illustrates the need for further evaluation and testing of the new pain management questions prior to implementation.

We recognize CMS states in the 2018 IPPS rule that the questions have been tested, have excellent reliability, and have internal consistency as composite, a Kronbeck offer of 0.81. While the testing may indicate that the composite meets certain technical criteria, it may be measuring the wrong data. Therefore, unless CMS can validate that these questions lead to improved outcomes, CMS should not move forward with the measures.

In addition, the wording of the new pain management questions is problematic. Under the new pain management scoring, a patient must report that the hospital staff "always" talked to them about how much pain they had and "always" talked to them about how to treat their pain in order for the hospital to receive full credit for the measure. In practice, this will encourage hospital staff to "never" stop talking about pain and overemphasize pain when it may not even be an issue for the patient. A better approach might be to ask if there was no conversation, some conversation, just the right amount of conversation, or too much conversation with patients about managing their pain. CMS should test a variety of questions and answer options to see which questions provide the most accurate data without negatively affecting patient care.

[8] Baker, David. (2017) History of The Joint Commission's Pain Standards Lessons for Today's Prescription Opioid Epidemic. Journal of the American Medical Association, 317 (11). Retrieved from: http://jamanetwork.com/journals/jama/fullarticle/2606790.

Furthermore, the concerns AMA has repeatedly expressed regarding the earlier pain management questions were not addressed in the new questions CMS has finalized. While we believe the removal of a reference to medication for pain management is an improvement, the questions should explicitly address variations in pain treatment regimens due to physician preference, patient behavior, or health care facility practices. There are also clinical challenges in populations particularly vulnerable to inadequate pain assessment or management including the elderly, pregnant women, individuals with English as a second language, and those with low socioeconomic status.

The AMA urges CMS to restart the process of developing new pain management measures with additional testing and research prior to measure development. The measure development should also be integrated into an implementation plan for the National Pain Strategy to ensure there is consensus around the desired outcomes of inpatient pain management. CMS must work with stakeholders to reach consensus on the intent of the pain measures to ensure there are no unintended consequences, that the measures are understood by patients, and that the measures lead to improved patient outcomes.

- **Cost Efficiency domain-Resource Use/Payment Measures**

We remain concerned with CMS' use of the MSPB measure in the VBP program. Given the refinements to the domain weights a hospital's VBP cost score could be based off a single flawed measure. As we highlighted in previous comments, we are concerned about the reliability and validity of the measure. We do not believe the measure meets NQF's scientific acceptability criteria. Currently, 84 percent of the spending is driven by post-discharge activities, and the extent to which hospitals can control these costs is not clear. As a result, there may be negative unintended consequences where high costs are attributed to a hospital that may be outside of its control. In addition, the testing provided by the developer in 2012 found that there was a weak association between MSPB and the readmission measures, and no new comparisons were made during the 2017 submission period. Given the general belief that cost and resource use measures should be paired with quality measures, it is unclear what value the MSPB provides since there is no demonstrated association between this measure and quality measures.

The AMA also continues to have significant concerns regarding the lack of responsiveness from the developer on the inclusion of social risk factors in the risk model for this measure. Several of the NQF committee members noted that the conceptual basis provided was inadequate; yet, this omission did not impact the evaluation of the risk adjustment subcriterion. We completed a brief literature search and identified several factors that should have been included in the conceptual basis such as living alone, unmet functional needs, lack of self-management skills, limited education, inadequate health literacy, low education levels, occupation, renting versus owning a home, and poor access to medical care. None of these factors were identified and as a result, we do not believe that the developer met the minimum expectations required in the SDS trial period. Specifically, we do not know whether data is available, or the degree to which any one of these additional factors could impact a hospital's performance. Based on the lack of responsiveness to the socioeconomic status testing requirement alone, we do not believe that the requirements of the SDS trial period were satisfied and the measure should not have passed the validity criterion. Furthermore, ASPE found that there was an association between higher costs and a beneficiary's dual eligible status for the MSPB measure. **Therefore**, **we urge CMS to work with NQF and the measure developer, Yale (under CMS contract), to test additional social-risk factors and ensure the measure meets scientific acceptability and move to risk-adjust the measure.**

Furthermore, we are aware of CMS making refinements to the physician-level MSPB measure used in the Merit-based Incentive Payment System (MIPS) program and seek clarification as to whether CMS plans on incorporating the changes to the physician measure into the hospital-level MSPB measure. Based on our initial review of the changes, we believe the refinements are improvements over the current measure and in effort to align physician and hospital measures we encourage CMS to potentially consider the changes. However, before incorporating the changes we urge CMS to release the revised specifications and provide the opportunity to comment.

Hospital Readmission Reduction Program

The AMA supports performance measures that seek to reduce preventable readmissions rates; however, we question whether additional reductions in scores can be achieved with the readmission measures and whether the measures in the HRRP are leading to unintended consequences. In a recent article published in the *Journal of the American Medical Association Cardiology* (*JAMA Cardio*), Gupta, et al. describe an association between implementation of the HRRP and an increase in mortality of fee-for service Medicare beneficiaries discharged after a heart failure admission.[9] In order to better understand the significance of the authors' findings within the larger body of literature on readmissions, and out of concern that a government-sponsored program might be leading to negative unintended consequences such as increased mortality, the AMA performed a literature search to evaluate whether the conclusions of Gupta and co-authors could be replicated. Due to the published literature using inconsistent data, such as not always using Medicare data, and because investigators used varying versions of the CMS readmission measures, our findings are inconclusive and raise additional questions that the AMA believes are important to explore.

In order for CMS to evolve the program and ensure that readmission penalties are not contributing to negative patient outcomes, there is an urgent need to address the questions outlined below. We recommend that CMS work in conjunction with the Agency for Healthcare Research and Quality (AHRQ) to answer the initial set of issues. We believe that the AHRQ is best suited for this work because it is the agency within HHS charged with enhancing the quality, appropriateness, and effectiveness of health care service. The AHRQ also has the acumen to answer questions around making improvements to the health care delivery system. The following are issues that should be explored to provide CMS and our health care system, including physicians and providers, better tools for discriminating between necessary or unnecessary admissions and to improve CMS' HRRP:

- There is a need to examine the data to determine if additional reductions in scores can be made using the existing measures in the HRRP since the readmission rates are now somewhat stable. Minimal improvements (decreases in rates) are now seen for most if not all of the readmission measures, but we do not know whether the rates have plateaued because there is no more room for improvement. Nor do we know if all of readmissions the measures capture are truly appropriate readmissions.

- To a certain degree, some level of readmissions is to be expected. However, we do not yet know with certainty what the appropriate target should be. There remains an urgent need to answer the

[9] Gupta, Ankar, et al. Association of the Hospital Readmissions Reduction Program Implementation With Readmission and Mortality Outcomes in Heart Failure. JAMA Cardiol. 2017. doi:10.1001/jamacardio.2017.4265. Published online November 12, 2017.

question so that the benchmarks and program use evidence-based optimal performance scores. These unknowns lead us to ask two questions:

  - Specifically, do the current measures in the program truly identify inappropriate readmissions at this point?
  - If CMS, physicians, and providers continue to try and drive down readmission rates even further, what additional unintended negative consequences for patients might be introduced?

- To what degree is the reported association of lower readmissions with higher mortality found over longer or shorter time periods such as, one year or one week, as compared to the first 30-days post discharge? Gupta and co-authors report that the inverse association was still evident at one year. To what degree are any positive or negative correlations related to all-cause mortality and/or readmissions versus the condition-specific outcome?

- It is also worth examining whether trends exist based on unadjusted data and adjusted data. Most of the studies identified through our search of the literature, including Dharmarajan, et al. (2017), used risk-adjusted data. Most individual patient care decisions are not made with risk-adjustment in mind. To better understand the outliers (those who are readmitted), there is a need to investigate and determine whether there are small, but important associations between reduced readmissions rates with patient mortality. Therefore, are we masking the issue by only examining the adjusted rates? Examination of unadjusted and risk-adjusted rates could help address this concern.

- As highlighted in the IQR section, there is also a need to examine the timeframe of the readmission measures and whether 30 days post discharge is appropriate. There is emerging evidence that readmissions within seven days of discharge differ from those between eight and 30 days after discharge with respect to preventability.

Furthermore, as we have highlighted in our comments, we remain concerned with the lack of social risk factor adjustments within the readmission measure due to evidence that hospitals with larger populations of socio-disadvantaged patients perform poorly on the measures. We recognize that some of the measures have gone through NQF's trial period; however, we do not believe the appropriate risk-models were tested. The traditional approach of risk adjusting at the patient level may not be appropriate for measures where the measurement period includes care that is outside of the control of the hospital and a 30-day post-acute phase where the availability of community supports and other resources will directly impact a patient's care. We believe that there may be community-level variables that affect the risk of readmission during the 30 days following a hospital admission, but are not currently addressed. Measures that extend beyond the hospital stay or outside the locus of control of the measured entity should continue to have SDS adjustment addressed and analyzed at different levels (e.g., patient, hospital, and community). In addition, CMS should work with the developer to continue to explore new variables that are directly related to the community in which a patient resides, particularly given the ASPE report.

All our recommendations on areas of further study are intended to help CMS, physicians, providers, and patients better understand the impact our actions have on readmissions and outcomes. Examining the effects, expected and unexpected, of new and existing programs is exactly what it means to have a learning health system—one that evaluates, shares, and acts.

III. Hospital Requirements to Publicly List Standard Charges

The lack of complete, accurate, and timely information about the cost of health care services prevents health care markets from operating efficiently. As the health care market evolves, patients are increasingly becoming active consumers of health care services. Achieving meaningful price transparency can help lower health care costs and empower patients to make informed care decisions. The AMA supports price transparency and recognizes that achieving meaningful price transparency may help control health care costs by allowing patients to choose low-cost, high-quality care.

The AMA supports the following specific measures to expand the availability of health care pricing information that allows patients and their physicians to make value-based decisions when patients have a choice of provider or facility:

- Patient confusion and health literacy should be addressed by developing resources that help patients understand the complexities of health care pricing and encourage them to seek information regarding the cost of health care services they receive or anticipate receiving.

- All health care professionals and entities should be required to make information about prices for common procedures or services readily available to consumers.

- Physicians should communicate information about the cost of their professional services to individual patients, taking into consideration the insurance status of the patient (e.g., self-pay, in-network insured, out-of-network insured) where possible.

- Health plans should provide plan enrollees or their designees with complete information regarding plan benefits and real-time, cost-sharing information associated with both in-network and out-of-network provider services or other plan designs that may affect patient out-of-pocket costs.

- Health plans, public and private entities, and other stakeholder groups should work together to facilitate price and quality transparency for patients and physicians. Entities promoting price transparency tools should have processes in place to ensure the accuracy and relevance of the information they provide. All-payer claims databases should be supported and strengthened. EHR vendors should include features that assist in facilitating price transparency for physicians and patients.

The lack of transparency in health care pricing and costs is primarily the result of a health care financing system that depends largely on the complex arrangements between and among employers, third-party payers, providers, and patients. These arrangements can make it difficult to identify accurate and relevant information regarding costs associated with specific medical services and procedures. Price also varies depending on where the service is performed, which impacts cost and a patient's cost-sharing. The cumulative effects of each of these factors often make it difficult to provide accurate pricing information for an individual patient in the absence of an actual service claim.

Even if basic pricing information were widely available, there are additional barriers to achieving meaningful price transparency in health care. For example, an ideal price transparency system would allow patients to access relevant and accurate information prior to receiving care. This would enable

patients to anticipate their potential costs in advance, and to choose among providers to seek the best value care. Yet, anticipating the need for health care services is often difficult. The urgent nature of some medical care, the inability to predict the particular course of treatment that might be indicated or identified subsequent to the initial complaint, and the intensity and scope of service required often leave patients without time or ability to evaluate their options prior to receiving care.

IV. Burden Reduction

We applaud the ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. We agree with the CMS proposal to no longer require a written inpatient admission order to be present in the medical record as a specific condition of Medicare payment. With physician certification and recertification claims, the AMA also supports the proposal to remove the requirement that a physician statement must specify the location in the medical record for the supporting information. While this proposed rule is focused on the inpatient prospective payment system, this regulatory change to physician certification and recertification also impacts all other sections in 42 CFR Part 424, Subpart B including partial hospitalizations and other Part B medical and health services. The AMA appreciates the efforts of CMS and looks forward to working with CMS to identify additional areas where physicians are being denied payment due to technical discrepancies.

V. Graduate Medical Education (GME) Issues

Proposed Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

Under CMS' proposed rule, beginning July 1, 2019, new urban teaching hospitals may form a Medicare GME affiliated group and therefore be eligible to receive both decreases and increases to their full-time equivalent (FTE) caps. Previously only increases were allowed. It is our understanding that the current definition of a new teaching hospital is any hospital that built its FTE cap after 1996. However, stakeholders have received conflicting information from CMS that for a "new" urban teaching hospital to be eligible to receive both decreases and increases to its FTE cap, it must have an established FTE cap after 1996 and thus no longer be involved in the five-year cap building process. Thus, a new urban teaching hospital could be one that is actually a decade or more old. The AMA urges CMS to clarify its definition of new urban teaching hospitals that may form a Medicare GME affiliated group and therefore are eligible to receive both decreases and increases to their FTE caps under the proposed rule.

Medicare Hospital Cost Reports

CMS proposes that a Medicare hospital cost report filed on or after October 1, 2018, will be rejected if the Intern and Resident Information System data do not contain the same total counts of Direct Graduate Medical Education (unweighted and weighted) and Indirect Medical Education FTE residents that are reported on the Medicare hospital cost report. The AMA believes that the proposed cost report changes will create significant administrative burden for these important teaching hospitals. As you know, there are over 1,000 teaching hospitals that directly employ 2.7 million people and are among the largest employers in their communities. Cost reports should not be rejected, and funding for teaching hospitals delayed, because of minor discrepancies in numbers or estimated data submissions. If the cost report contains all required information we believe it should be considered complete and be accepted by the Medicare Administrative Contractor. The AMA disagrees that the requirement to have the numbers match

up at the time of the cost report submission will ensure that medical residents are not double counted and therefore urges CMS not to finalize this change within the proposed rule.

VI. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare and Medicaid Participating Providers and Suppliers

CMS requests comments on how it could use the CMS health and safety standards required for providers and suppliers participating in Medicare and Medicaid (i.e., Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long Term Care Facilities) to "further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers."

CMS notes that it might consider revisions to CoPs for hospitals such as: "requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested."

In general, we do not believe that a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information is necessary in the context of other current and forthcoming policies. We are concerned that compliance fears and costs associated with new standards could hinder investments and actions to enhance interoperable data exchange. Further, health care stakeholders have not had sufficient time to evaluate the impact of forthcoming regulations and enforcement around information blocking, the impact of the PI program, and the operations of TEFCA and U.S. Core Data for Interoperability (USCDI)—each of which will affect interoperability going forward.

Alternatively, we strongly suggest CMS examine fundamental issues that continue to hinder interoperability and identify the appropriate methods to address these issues. This concept is further explored below. CMS should address priority elements of health information exchange and consider actions to promote the electronic availability of pertinent clinical information, rather than focusing on pure "data exchange."

<u>Clear Regulatory Goals</u>

Evolving health information technology and sources of data have become central components of managing patient care and have the potential to enhance and refine physicians' understanding of patient health. Patient information, including social determinants of health and genomic data, will further add digital definition to patients' stories. We also expect the expansion of consumer health applications to add patient generated health data to the already complex domain of clinical data—offering new methods for patients to engage with their physicians.

However, systems today are unable to reliably and completely capture and exchange clinically meaningful and essential information. Despite the large amounts of health data being gathered today, it is not always meaningful, organized, or structured in a way that can easily be used, accessed, or shared by

people and systems. Health care data is fragmented, incomplete, incompatible, and often not in forms easy to exchange and aggregate. Furthermore, critical information on patient function, status, goals, social determinants of health, as well as patient and device-generated data is often inaccessible by clinicians and health systems. Current technical standards mostly specify how to exchange data, not what the right information to exchange is, and physician data entry burden is increasing to the point of becoming unsustainable.[10]

While industry adoption of EHRs has increased, the amount of health data captured and the expectation that EHR adoption would transform health care has failed to materialize. This is due to the fact that federal regulations have driven EHR design and use. CMS and ONC have historically focused their regulatory policy on measuring a physician's use of technology. To date, this approach has heavily influenced EHR development by focusing EHR design on documentation, reporting and regulatory compliance. Due to the misplaced emphasis on data capture and reporting, rather than data exchange, most patient health information is still "locked" inside the physician's office—only today it is in an EHR rather than a paper chart. Physicians and patients alike are eager to remove barriers that block access and exchange of EHR health information.

The AMA is encouraged that CMS is refocusing its efforts on promoting interoperability and access to information. **To ensure this momentum does not stall, the AMA urges CMS to further leverage appropriate regulation that advances outcomes and goals.** Rather than simply requiring data to be exchanged, CMS should eliminate regulation that drives health IT development and use, and instead focus on regulation that emphasizes patient care goals and the availability of the pertinent data to support those goals. **For instance, CMS should establish a focused interoperability strategy with the goal of clinical necessity, rather than exchanging data simply for reporting requirements.** We further recommend that this approach examine the burden of data collection and aspire to return time back to physicians to provide patient care. This course correction is necessary to reduce physician burden and to improve the quality of data for both physicians and patients.

Information Blocking

Both the AMA's and ONC's own report to Congress have identified that health IT vendors engage in information blocking—activities interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.[11] The AMA has received numerous complaints from physicians of health IT vendors blocking information through financial, technical, and contractual means. Through the Quality Payment Program (QPP), CMS already requires physicians to attest they will not engage in information blocking activities. However, to resolve information blocking problems, vendors must be held accountable as well.

While we understand that HHS' Office of Inspector General (OIG) and ONC are developing rulemaking to implement information blocking requirements, EHR vendors continue to create barriers to access patient information. These barriers interfere with and materially discourage physician and patient access to information. Our members report that some EHR vendors refuse to enter into negotiations for the

[10] Sinsky, Christine A. et al, Professional Satisfaction and the Career Plans of US Physicians. Mayo Clinic Proceedings, Volume 92, Issue 11, 1625-1635

[11] Office of the National Coordinator for Health Information Technology, Report to Congress: Report on Health Information Blocking, Washington, DC: Department of Health and Human Services, (April 2015), Available at https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf, Accessed June 2018.

transfer of patient information to clinical data registries. While some EHR vendors have negotiated with physicians and third-party software companies, other EHR vendors tack on large fees to send data from the EHR to clinical data registries or to even connect to a health information exchange (HIE). For instance, Cerner and Epic charge fees of $30,000 and $20,000 (respectively) for sending data abstraction from their EHR to clinical data registries, and Allscripts charges $1,000 to $1,500 per clinician for reporting under the MIPS Program.[12] We are also aware of vendors requiring physicians to purchase intermediary software systems, owned by the EHR vendor, just to enable data exchange. While certified EHR vendors are required to acknowledge the existence of fees, they are not required to publish the actual dollar amount, or even list a range of costs. In the spirit of transparency, and to better inform health IT consumers, we urge CMS and ONC to establish a method to collect, list, and publicize actual fees EHR vendors charge customers. **In addition, CMS should use this information to make publicly available the real-world cost estimations for physicians and hospitals to participate in all EHR-related reporting programs' measures and objectives.**

Additionally, we foresee information blocking becoming a major obstacle in the newly emerging area of EHR applications (apps). ONC's 2015 Edition Certification Final Rule and the 21st Century Cures Act contemplate the importance of application programing interfaces (API) and their potential to empower both physicians and patients with access to data using apps. Many emerging apps are based on SMART (Substitutable Medical Apps & Reusable Technology), an open, standards-based technology platform that enables innovators to create apps that seamlessly and securely run across the health care system. SMART apps based on the FHIR (Fast Healthcare Interoperability Resources) standards framework are designed to be interoperable across EHRs and easily installed or removed. However to realize the full potential of APIs and apps, EHR vendors must configure their software to use the same version of the FHIR standard. When vendors use slightly different versions of technical standards, or tweak standards to make them unique, interoperability breaks.

Essentially, "fitting a round peg into a slightly round hole" allows vendors to assert they are conforming to a standard while still stretching the standard's flexibility to fit their own business needs—effectively curbing data access, use, and exchange. The AMA is concerned that, without the appropriate transparency, testing, and assurances, EHR vendors will extend current interoperability issues into their next generation products. While we recognize CMS has limited influence on EHR vendor conformance to standards, we believe this issue will negatively impact the potential benefits of API-enabled EHRs. Furthermore, clinicians have little influence or capability to fix these interoperability issues and should not be held liable for issues outside their control. **Therefore, we urge CMS to establish "hold harmless" exceptions for physicians and hospitals when EHRs are suspected of or found to be information blockers. This should include instances when EHR vendors knowingly and willfully introduce uniqueness in their API development that is found to detract from, rather than improve, patient and physician access to data.**

[12] Letter from the Physician Clinical Registry Coalition to James A. Cannatti III, J.D., Senior Counselor for Health Information Technology, Office of Inspector General, U.S. Department of Health and Human Services, Kathryn Marchesini, J.D., Chief Privacy Officer Office of the National Coordinator for Health Information Technology, U.S. Department of Health and Human Services, (February 8, 2018), Available at https://www.registrycoalition.net/wp-content/uploads/2018/02/PCRC-Letter-re-Information-Blocking-by-Electronic-Health-Record-Vendors-D0765240-2.pdf, Accessed June 2018.

Access to All Relevant Information Without Burden

Patients and physicians need access to all relevant patient information to support wellness and high quality care. While studies have evaluated EHR usability issues, research has primarily focused on the burden of entering data or documenting information in the EHR.[13,14] A physician or hospital's inability to pull information out of an EHR or to extract entire medical records, caused by vendor claims of data ownership, business interests, or technical limitations, is also a major impediment to data access.[15]

EHRs often contain most of the information that makes up a patient's electronic medical record, yet accessing a complete record—particularly from the patient's point of view—is overly complicated. The HIPAA privacy rule defines the designated record set as a group of patient medical and billing records maintained by or for a covered entity—which may include enrollment, payment, claims, adjudication, and any additional information used in whole or in part to make care-related decisions. The digitization of medical records should have reduced the friction of collecting and organizing this data. From a practical sense, EHRs and health IT should ultimately provide secure electronic access and use of the designated record set in order to facilitate each patient's longitudinal health record. The 21st Century Cures Act reinforces this concept.[16]

However, many EHRs only provide a subset of this information—limiting access and exchange of the patient's designated record set. Health IT vendors can provide data beyond the required minimum, but have historically not gone above and beyond ONC certification requirements. Today, the data that is "exposed" by an EHR is often a subset of what most would consider a complete medical record. For example, the CCDS is a grouping of 20 data classes that is meant to act as a "floor" of data for certified EHRs. Yet, ONC has identified at least 50 additional data classes that should be made available electronically.[17]

The AMA views the discrepancy between what is legally required, i.e., the designated record set, versus what EHRs provide, i.e., the CCDS, as having major implications for health care. First, lack of access to the full record limits the physician's ability to see a complete picture of their patient's story, reduces their ability to use supportive health IT tools (e.g. clinical decision support systems), and contributes to physician burden by requiring re-documentation for quality measurement, reporting, or clinical registry reporting. Additionally, there are growing concerns that physicians may be held accountable or considered "data blockers" if patients cannot access their entire designated record set via new features like APIs and apps of their choice.

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[13]Arndt B, Beasley J, Watkinson M, Temte J, Tuan W, Sinsky C, Gilchrist V, Annals Journal Club: Tethered to the EHR: Primary Care Physician Workload Assessment Using EHR Event Log Data and Time-Motion Observations Ann Fam Med September/October 2017, 15:419-426; doi:10.1370/afm.2121

[14]Sinsky C, Colligan L, Li L, Prgomet M, Reynolds S, Goeders L, et al, Allocation of Physician Time in Ambulatory Practice: A Time and Motion Study in 4 Specialties, Ann Intern Med, 2016;165:753–760. doi: 10.7326/M16-0961

[15]AMA Board of Trustees Report 11-A-16. Principles for Hospital Sponsored Electronic Health Records (Resolution 825-I-14), (Nov. 2015), Available at https://www.ama-assn.org/sites/default/files/media-browser/public/hod/i15-bot-reports.pdf, Accessed June 2018.

[16]21st Century Cures Act, H.R. 34, 114th Cong. (2015).

[17]The Office of the National Coordinator for Health Information Technology, Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process, (Jan. 2018), Available at https://www.healthit.gov/sites/default/files/draft-uscdi.pdf. Accessed June 2018.

Patients are also disadvantaged by this inconsistency. While many stakeholders (including the AMA) have expressed support for APIs in the 2015 Edition EHRs, we are concerned that, in practice, many updated and new EHRs will underwhelm patients. We foresee issues where APIs will only provide access to a curtailed medical record, or provide access to more information only if using specific applications favored by the health IT vendor. Furthermore, we also question what—if any—efforts are underway to educate patients about the security, privacy, and usability of this data.

Importantly, not only should a complete record be accessible, but also the data contained therein must also be consistent, understandable, and usable. For this to occur, data must be in a recognizable electronic package (data structure or syntax) and maintain a consistent meaning (data semantics). Just as the English language is built from words and grammar, the translation from data to knowledge can only occur if the meaning of data is consistent. However, levels of semantic interoperability vary greatly in the health care system. Physicians agree that the current level of interoperability is inadequate to support the necessary changes, reforms, and innovations desired in health care.[18] As a practical matter, the more data exchanged that lacks both semantic and syntactic interoperability, the less useful it is to physicians and patients.

This leads to another piece of the interoperability puzzle that the industry must address: data mapping. Mapping is needed so transmitted data can be used by the receiving EHR rather than just viewed. For example, if a patient has a problem identified as "hypertension," a simple interface can move this text to another system where it can be viewed. However, to be useful in automated alerts and care planning, mapping must translate this information so that it has the same "meaning" in the receiving system. To create the appropriate meaning, the "hypertension" text typically must be put into the correct part of the receiving EHR's database so that EHR "knows" the patient has this condition. Additionally, problems like hypertension often are comprised of many different attributes, all of which should be captured, stored and transmitted in a common format. While this example may seem simple, the proprietary nature of EHRs, and the lack of an agreed upon medical data model, makes this difficult—even with the increased use of standardized codes.

Furthermore, EHRs typically do not identify components of the office note in the same manner. For instance, when a physician sees a note drafted in a Cerner EHR shown in an Epic EHR the information gets rearranged, misconstrued, or lost. This is because information stored in Cerner's terminologies and logic is not machine-readable by Epic's technology. For the information to interoperate between the two systems, the information must be translated into a standard terminology while, at the same time, preserving all the exchanged information's content and context. Providers spend hours documenting and searching for needed information when they lack access to interoperable and usable digital information.

To address this issue, the AMA has launched the Integrated Health Model Initiative (IHMI). The IHMI is a digital platform for stakeholder collaboration and clinical review to build a unified data model to organize data in an interoperable fashion. Utilizing the IHMI, different computer systems will be able to exchange data with unambiguous, shared meaning and be fully comprehensive across systems and clinical environments—enabling a true longitudinal patient health record independent of the data's originating source.

[18] Stanford Medical, How Doctors Feel About Electronic Health Records National Physician Poll by The Harris Poll, (June 2018), Available at http://med.stanford.edu/content/dam/sm/ehr/documents/EHR-Poll-Presentation.pdf. Accessed June 2018.

The IHMI will also support improvements in quality measurement. Currently, EHRs do not uniformly calculate eCQMs across different vendors and practices due to the lack of specificity within the ONC's CEHRT program. Incorporation of data requires the development, maintenance, and refinement of administrative code sets such as the ICD, Current Procedural Terminology® and clinical vocabulary standards such as SNOMED Clinical Terms,® Logical Observation Names and Codes® (LOINC), and RxNorm. Creating standards and mapping tools will facilitate working across these different codes and ensure consistency when data is exchanged. The AMA, through its IHMI, is participating in activities to support ontological structures that will provide pathways for better data collection and analytics.

We recognize that CMS alone cannot incentivize the health IT market to expose or standardize information. However, more needs to be done to increase access to all appropriate medical information—for both patients and physicians. Access to granular data that is available, consistent, and retains the same meaning is a crucial element in improving health and lowering costs—and is ultimately the foundation of interoperability. This will require a coordinated approach involving clear objectives with a singular focus, planning and prioritization. **The AMA strongly recommends that CMS establish a plan, in conjunction with stakeholders and other federal agencies, to focus interoperability efforts on promoting data consistency and access. This must include balancing policy goals with a sensible timeline. CMS should align future reporting programs around clinically led efforts—like the IHMI—that aim to advance terminologies, data elements, coding, and common data models to promote interoperability.**

Health Data Cybersecurity

The AMA is deeply concerned that our nation's health care providers and patients have been insufficiently prepared to meet the cybersecurity challenges of an increasingly digital health care system. Cybersecurity is a national priority and physicians, other health care providers, and patients need tools to secure sensitive patient information in the digital sphere. As clinical adoption of digital medicine tools accelerates with new innovations, and in light of increased public and commercial insurer coverage of digital medicine tools and services, there is increased urgency to advance policies that remedy vulnerabilities in cybersecurity.

The health care community must recognize that cybersecurity is not only a technical issue, but also a patient safety issue. The AMA recently completed a first of its kind cybersecurity survey of 1,300 physicians.[19] The top three cybersecurity concerns that physicians identified were interruption to EHR access, EHR security (including compromised patient data), and general patient safety concerns. This survey underscores the importance of considering the potential harm to patients and interruption to their care when making the cost-benefit analysis of data security, privacy, and interoperability.

Physician practices spend a substantial amount of money on cybersecurity. For example, as noted in the AMA's cybersecurity study's qualitative review, a nine-physician practice spent $250,000 per year and a 50+ physician regional medical center spent $440,000 per year. We further note that only one in five small physician practices have an in-house security official. Thus, small practices need extra help in navigating cybersecurity challenges to help them prepare for cyber attacks and ensure patient data remains confidential as it is exchanged. **CMS must consider the added complex interplay of agency**

[19] AMA, *Medical Cybersecurity: A Patient Safety Issue*, (Dec. 2017), Available at https://www.ama-assn.org/about/medical-cybersecurity-patient-safety-issue, Accessed June 2018.

policies and their impact on physicians and interoperability. For instance, the OCR, the OIG, ONC, and the Food and Drug Administration have differing perspectives on and authority over security.[20] Absent alignment across the federal government on these issues, health IT developers, health systems, and physicians will increasingly encounter conflicting guidance, which stymies innovation and adoption**.**

Finally, cybersecurity impacts the entire health care ecosystem. Technology has increased connectivity and collaboration in all facets of the health care delivery system. Indeed, the AMA's cybersecurity survey shows that 85 percent of physicians believe it is "very" or "extremely" important to share data to provide efficient, quality care but are concerned about how to share it securely. This integration is increasingly important as the industry moves towards value-based care and provides more care outside the four walls of a brick-and-mortar health care practice.

The AMA encourages CMS to reframe its view of data security from punitive requirements to an opportunity for positive incentives to encourage cybersecurity activities that will protect practice continuity and patient information. **We strongly urge CMS to introducing positive incentives in Medicare programs that promote good cyber hygiene.** For example, the AMA has recommended that CMS adopt Improvement Activities in the QPP related to good cyber hygiene.

Additionally, the AMA recently requested that the OIG create a safe harbor that allows for the sharing of cybersecurity items and services with detailed suggestions into the structure of a potential safe harbor, including definitions, scope, donors, recipients, value of technology, and appropriate safeguards similar to the current EHR safe harbor and Stark exception.[21] Overall, the AMA stresses that any cybersecurity anti-kickback safe harbor or Stark exception be easy to understand, interpret, and enforce so that donors and recipients can readily distinguish permissible activities from those that violate the Anti-Kickback Statute. This concept is reflected in the HHS Cybersecurity Task Force Report Recommendation 1.5, which "strongly encourage[s] Congress to evaluate an amendment to [the Stark Law and Anti-Kickback Statute] specifically for cybersecurity software that would allow health care organizations the ability to assist physicians in the acquisition of this technology, through either donation or subsidy."[22] While OIG has the regulatory authority to create an anti-kickback safe harbor, CMS must show no program or patient abuse in creating Stark exceptions. We understand this Stark standard is difficult for CMS to meet and has caused other proposed regulatory Stark exceptions to fail. **Thus, we urge CMS to consider methods similar to those that allowed for an EHR Stark exception-to extend their legislative interpretation to include cybersecurity services and technology.**

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[20]Letter from the Hon. Greg Walden, Hon. Frank Pallone Jr., H. Comm. on Energy and Commerce, Hon. Patty Murray S. Hon. Lamar Alexander, S. Comm. on Health, Education, Labor, and Pensions to The Hon. Alex Azar Sec'y US Dep't of Health and Human Services, (June 5, 2018), Available at https://energycommerce.house.gov/wp-content/uploads/2018/06/20180605HHS.pdf, Accessed June 2018.

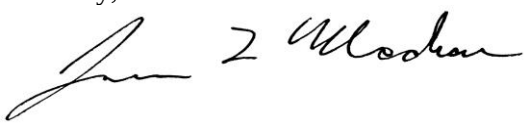
[21]AMA, *Letter to OIG in Response to Solicitation of Safe Harbors*, (Feb. 2018), Available at https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-2-26-Letter-to-Levinson-re-Draft-OIG-Annual-Solicitation.pdf, Accessed June 2018.

[22]Health Care Industry Cybersecurity Task Force, *Report on Improving Cybersecurity in the Health Care Industry* (June 2017), Available at *https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf*, Accessed June 2018

Conclusion

We greatly appreciate this opportunity to share the views of the AMA regarding the proposals, issues, and questions which CMS has raised in the 2019 IPPS/LTC Proposed Rule. If you have any questions, please contact Margaret Garikes, Vice President of Federal Affairs, at 202-789-7409.

Sincerely,



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