

June 13, 2017

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 2018 Rates (CMS-1677-P; 82 Fed. Reg. 19796, April 28, 2017)

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) 2018 Proposed Rule for the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System. There are many proposals in the rule that the AMA has significant concerns about; however, there are also many proposals in this rule that the AMA strongly supports.

Issues included in the rule that the AMA is concerned about include:

- CMS' proposal to update the new Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey by replacing previous questions about pain management with new questions that address "Communication about Pain during Hospital Stay." 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 for accountability, and ensure pain management questions do not lead to unintended consequences. The AMA also has concerns with a number of individual measures used in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs.
- CMS' proposals to hold physicians accountable for hospital readmission rates, as it is unclear whether further reductions in readmission rates can be achieved with the current Hospital Readmissions Reduction Program measures.
- CMS' proposal to require accrediting organizations to post final accreditation survey reports and plans of correction on a public facing website. While the AMA supports increased transparency, accreditation survey data may be overwhelming for consumers and is unlikely to allow consumers to make better health care decisions.

- CMS' requirement that all participants use 2015 edition certified EHR technology (CEHRT) starting in 2018. CMS is making assumptions about the electronic health record (EHR) market that are inaccurate and is presuming implementation timelines that could place patient safety at risk.

Policies included in this proposed rule that the AMA supports include:

- CMS' proposal to refine the risk adjustment methodology used in the Hospital 30-Day, All-Cause, Risk-Standardization Mortality Rate following Acute Ischemic Stroke Hospitalization (Stroke 30-day Mortality Rate) measure to include stroke severity codes. However, we do still have concerns regarding the standardization of stroke severity indicators within the measure.
- CMS' proposals related to the Medicare and Medicaid Meaningful Use programs, including the reduction of the reporting period from a full year to 90-days and the exception for physicians who cannot meet Meaningful Use requirements because their CEHRT has been decertified.
- CMS' consideration of measuring and accounting for social risk factors in the Hospital Inpatient Quality Reporting and Value-Based Purchasing Programs. The AMA continues to believe that in order to ensure the quality of care furnished by physicians and hospitals is assessed as fairly as possible, social risk factors must be taken into account.
- CMS' request for information regarding how the restrictions on physician-owned hospitals affect health care delivery. The AMA believes physician-owned hospitals represent the type of coordinated care that is needed for the future of health care delivery, and that these facilities should be able to compete on equal footing with other hospitals in the delivery system.
- CMS' request for information on CMS flexibilities and efficiencies. The AMA believes areas where CMS could reduce the regulatory burden for physicians include prior authorization and utilization management, certification and documentation requirements, appropriate use criteria, increased transparency around electronic health record costs, program integrity issues and the "two-midnight" policy. (See Appendix A)

I. Hospital Inpatient Quality Reporting (IQR) Program

The AMA strongly opposes several of CMS' proposed changes to the Hospital IQR program, including the new "Communication about Pain" composite measure in the Hospital Consumer Assessment of HCAHPS survey. The AMA also has concerns with numerous Hospital IQR measures such as the Severe Sepsis and Septic Shock: Management Bundle Composite Measure and the redundancy of the claims based payment measures. The AMA supports CMS' proposal to update the risk adjustment methodology for the Stroke 30-Day Mortality Rate measure.

Updated Pain Management Questions in HCAHPS Survey

HCAHPS is a national, standardized, publicly reported survey of patients' perspectives of hospital care during a recent overnight stay. The survey is designed to produce comparable data on the patient's perspective on care that allows comparisons between hospitals on domains that are important to patients.

The original HCAHPS survey included three pain management questions, which are as follows:

- During this hospital stay, did you need medication for pain? (Yes, No)
- During this hospital stay, how often was your pain well-controlled? (Never, Sometimes, Usually, Always)
- During this hospital stay, how often did the hospital staff do everything they could to help you with your pain? (Never, Sometimes, Usually, Always)

The AMA and other stakeholders have repeatedly expressed our concerns that these 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 this proposed rule, CMS proposes to update the HCAHPS survey measures by replacing the 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 proposes 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)

The AMA strongly urges CMS not to adopt the new Communication about Pain composite measure. Instead, 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 for accountability. 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 notes in this proposed rule, the Communication about Pain composite measure was reviewed by the Measures Application Partnership (MAP) in December 2016. The AMA submitted comments urging the MAP not to support this 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 National Quality Forum (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 went ahead and proposed the new pain measurement questions in this proposed rule.

The need for additional time to develop and test pain management questions was further highlighted in a recent article by Dr. David Baker, Executive Vice President in the Division of Health Care Quality Evaluation at The Joint Commission.¹ 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 vital 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 that CMS states in the rule that the questions have been tested, have excellent reliability, and have internal consistency as composite, a Cronbach offer of 0.81. While the testing may indicate that it 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**

¹ 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>.

and answer options to see which questions provide the most accurate data without negatively affecting patient care.

Furthermore, the concerns AMA has repeatedly expressed regarding the earlier pain management questions were not addressed in the new questions CMS has proposed. 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.**

Excess Days in Acute Care After Hospitalization Measures (for acute myocardial infarction, heart failure and pneumonia)

As currently specified, the excess days measures overlap with the readmission measures since readmissions are one of the excess days categories. It is unclear why CMS is putting forward measures that would penalize hospitals twice, and we urge CMS to eliminate redundancy across measures. In addition, we have concerns with the lack of SDS adjustments within the measures. For additional information, please see the Readmission Reduction Program section.

Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)

While the AMA supports the intent of NQF 500, Severe Sepsis and Septic Shock: Management Bundle, we have significant concerns with the current specifications and urge CMS to remove the measure from the IQR program until issues with the measure can be resolved. There is emerging evidence that this composite may improve care and has the potential to misrepresent performance due to questionable reliability and validity results. Because of these limitations, we believe that use of the measure is leading to negative unintended consequences.

As noted in a recent article published in the *American Journal of Medical Quality*, the sepsis bundle as currently specified could lead to patient harm and other unintended negative consequences.² 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.³ If a physician provides the

² Pronovost et al. (2017) *Finding Balance: Standardizing Practice in Corseting Physician Judgment*. American Journal of Medical Quality.

³ 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*

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 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.⁴

The identification of potential unintended consequences of a composite that calls for multiple components also 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 2001.⁵ 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 higher costs associated with the hospitalization.⁶ Therefore, we urge CMS, the measure developer, and the NQF to reevaluate the sepsis management bundle given the evidence in recent studies of unintended consequences.

We are also extremely concerned with the lack of adequate evaluation of this composite's reliability and validity during recent NQF evaluation. 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, the current criteria in 2D also asks 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.

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.

⁴ Vail et al. (2017). *Norepinephrine Shortage and Mortality among Patients with Septic Shock.* JAMA 317 (14) 1433-1442.

⁵ Kalil et al. (2017). *Early Goal-Directed Therapy for Sepsis: A Novel Solution for Discordant Survival Outcomes in Clinical Trials.* Critical Care Medicine 45(4) 607-614.

⁶ 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.

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 measure into question, and ongoing concerns over the reliability and validity of the measure results, we urge CMS to remove the measure from the Hospital IQR program until these issues can be addressed.

Claims Based Payment Measures

The AMA urges CMS to address the overlap between the clinical-episode based payment measures with the Medicare Spending per Beneficiary (MSPB) measure to eliminate any redundancy. The AMA also continues to have significant concerns that the payment measures have not been adequately assessed to address methodological issues, such as attribution. It is also unclear why CMS is pursuing implementation of the inpatient hospital episode groups when the physician community has just begun to develop definitions for the first set of episodes of care to be used in Merit-Based Incentive Payment System (MIPS), which include acute inpatient episodes. We also remain concerned over the lack of sociodemographic status (SDS) adjustment within the measures. The recent report from 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 measures examining costs for a specific condition could demonstrate similar results. Therefore, the AMA does not believe that the clinical-episode based measures should be used to adjust payment until these questions are resolved. We offer the following feedback on the individual payment and episode measures:

Medicare Spending Per Beneficiary

The Medicare Spending per Beneficiary (MSPB) measure is currently undergoing maintenance review at NQF and we continue to remain concerned about the reliability and validity of the measure. Therefore, we do not believe that the measure currently meets the 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 higher 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 since the last submission. 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 measures of quality.

The AMA also has significant concerns regarding the lack of responsiveness from the developer on the inclusion of SDS 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, a 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 pass the validity criterion.

We urge CMS to work with NQF and the measure developer, Yale (under CMS contract), to test additional SDS factors and ensure the measure meets scientific acceptability.

Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure

CMS is proposing to continue for FY 2019 and 2020 payment determination, a clinical episode-based payment measure, “Aortic Aneurysm Procedure Clinical Episode-Based Payment (AA Payment) Measure.” This measure is intended to capture Medicare payments for services related to the clinical episode for aortic aneurysm procedures. CMS is using this clinical episode-based measure to supplement the Hospital IQR Program's MSPB Measure.

This measure was uniformly opposed in comments during the MAP process and was not endorsed by the NQF. Therefore, the AMA opposes the inclusion of this measure in the Hospital IQR program until the aortic aneurysm clinical episodes are completed by the medical specialty societies as part of our efforts directed at the implementation of the cost measures for the MIPS.

Before this measure can be used to evaluate providers’ clinical effectiveness and efficiency, the clinical episodes to collect and organize the cost data for appropriate comparison need to be created. Individual clinical episodes would need to be created with the following characteristics, triggers, and end points:

- Location of the Aortic Aneurysm;
- Type or method of surgery that was performed;
- Type of device used;
- Emergent or Non-Emergent Aortic Aneurysm; and
- Patient’s status at discharge.

In addition, new technologies and devices continued to be developed in this area of medicine. Physicians must have the flexibility and access to select the appropriate device based on an individual patient’s needs.

Cholecystectomy and Common Duct Exploration Clinical Episode-Based Payment Measure

CMS is re-proposing for FY 2019 and subsequent years, a clinical episode-based payment measure for Cholecystectomy (Chole) and Common Duct Exploration (CDE). The measure includes a set of medical services related to a hospital admission for Chole and CDE, including treatment, follow-up, and post-acute care. The measure also assesses the payment for services initiated during an episode that spans the period immediately prior to, during, and following a beneficiary’s hospital stay. The MAP did not support this measure because although cost is important to the measure, data supporting variation in costs for this procedure were not provided. The AMA agrees with the MAP and makes the additional note that it is very difficult to define the severity of illness for Chole and CDE, making it a poor proxy for quality. Therefore, the AMA does not support the inclusion of the Chole and CDE Payment measure in the IQR program.

Spinal Fusion Clinical Episode-Based Payment Measure

CMS is again proposing for FY 2019 and subsequent years, a clinical episode-based payment measure, “Spinal Fusion Clinical Episode-Based Payment Measure.” This measure is intended to capture Medicare payments for services around spinal fusion in the inpatient setting. The spinal fusion measure is limited to fusions of the lumbar spine and accounts for the fusion approach and number of levels being fused,

however the measure fails to account for the patient's diagnosis. Therefore, we urge CMS to refrain from implementing the measure until further improvements can be made.

A lumbar fusion to treat disc degeneration is different than a lumbar fusion to treat spondylolisthesis, multiple recurrent herniated nucleus pulposus, and iatrogenic instability. Further, there may be important anatomic and clinical differences regarding the location of the lumbar fusion (L1-L2, L2-L3, L3-L4, L4-L5 and L5-S1). While current coding does not distinguish between the levels fused, some ICD-10-CM codes allow for an additional level of granularity by distinguishing the lumbosacral region (L5-S1) from the lumbar region (L1-L5). Future ICD-10-CM codes could serve to identify specific segments of the spine within each region and further refine the patient cohort. The measure currently looks to specified Medicare Severity-Diagnosis Related Group (MS-DRG) and Current Procedural Terminology® (CPT) codes to trigger an episode. Therefore, we recommend that CMS continue to use CPT codes to refine the patient populations assessed in this measure and the one being developed for MIPS. Using CPT definitions, as opposed to more heterogeneous MS-DRG-based patient groupings, will provide for more homogeneous patient populations and more accurate data. Inclusion of ICD-10-CM codes may further homogenize the patient population by adding diagnosis information. This is another opportunity to achieve greater specificity of patient populations within the episodes and subtypes.

As currently specified, the measure does account for some patient complexity variables by including MS-DRGs as part of the episode trigger and incorporating patient age and severity of patient illness. However, it does not appear to account for other important patient complexity variables such as sociodemographic factors, obesity, tobacco use, and population health variables which can significantly increase the complexity of obtaining a successful fusion. These factors are outside of the provider's control, add to the complexity of the case, impact how well a patient does during and after surgery, and should be accounted for within the risk adjustment of the measure. For more specifics on refining the measure, we urge CMS to work with the orthopedic and neurosurgical physician specialty societies.

Refinements to the Stroke 30-Day Mortality Rate (MORT-30-STK)

For the FY 2023 payment determination and subsequent years, CMS proposes a refinement to the CMS Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate following Acute Ischemic Stroke Hospitalization Measure by changing the measure's risk adjustment to include stroke severity. While the AMA believes the proposed refinements are an improvement to the current measure, we still have serious concerns with the measure specifications and implementation of the measure. First, there is still a lack of adjustment for tissue plasminogen activator/thrombectomy. In addition, while 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 (the attending physician, resident or nurse) at what point in time CMS will use. Therefore, we urge CMS to remove the measure from the program until the methodological issues can be resolved.

Possible New Quality Measures and Topics for Future Years

As part of the 2018 IPPS rule, CMS is inviting comment on the potential future inclusion of several measures into the Hospital IQR program. The AMA offers feedback on the following measures:

Quality of Informed Consent Documents for Hospital-Performed, Elective Procedures

The AMA recognizes the importance of informed consent but does not support inclusion of the measure into the Hospital IQR program because the measure focuses on documentation rather than the quality of communication and shared decision making around informed consent. The measure was also placed on the 2017 MAP Measure Under Consideration (MUC) list for review by the MAP Hospital Workgroup and did not receive support. We recommend that CMS work with the physician and provider community to address problems with the measure before proposing the measure into a program.

Safe Use of Opioids— Concurrent Prescribing

During the 2017 MAP cycle, CMS placed Safe Use of Opioids measure on the MUC list for review by the MAP Hospital Workgroup. Based on review by the workgroup and commenters, the MAP recommended that the measure be refined and resubmitted due to concerns that the measure was not precisely specified. The MAP recognized that there are many clinical conditions where concurrent prescriptions of opioids and benzodiazepines are appropriate. MAP also noted that patients may unintentionally suffer withdrawal symptoms if previously prescribed opioids and/or benzodiazepines are reduced and/or stopped prior to discharge. The AMA agrees with the MAP's assessment and recommends that CMS work with the provider and physician community to refine the measure before including the measure in the Hospital IQR program.

Appropriate Documentation of a Malnutrition Diagnosis

During the 2017 MAP cycle, CMS placed the Appropriate Documentation of a Malnutrition Diagnosis measure on the MUC list for review by the MAP Hospital Workgroup. Based on review by the workgroup and commenters, the MAP did not support the measure for the Hospital IQR program. The measure also underwent review by NQF's Health and Well-Being Committee and did not pass the evidence criterion, which is a must pass criteria to receive NQF endorsement. Given there is a lack of scientific evidence to support the measure, we do not support CMS including the measure in any CMS program for future years.

II. Hospital Readmission Reduction Program

The AMA supports performance measures that seek to reduce preventable readmission rates but we question whether additional reductions in scores can be achieved with the readmission measures that are used in the Hospital Readmissions Reduction and IQR programs. The true benchmark or optimal performance rate for readmission measures is unknown, and based on the significant strides the provider and physician community has made to reduce readmissions, it is unclear whether there is still room for improvement. Specifically, we are concerned with the lack of performance data that demonstrates a change in scores over time. **Therefore, we recommend that CMS work with the physician and provider community to better refine “preventable or avoidable” readmissions, as well as identify appropriate benchmarks for the measures.**

We also remain concerned with the lack of SDS adjustments within the readmission measures due to evidence that hospitals with larger populations of socio-disadvantaged patients perform more 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 recent ASPE report.

III. Appropriateness of Social Risk Factors

In this proposed rule, CMS asks for feedback on the appropriateness of accounting for social risk factors in the Hospital IQR and Hospital Value-Based Purchasing (VBP) programs. CMS also notes that it is reviewing a report on the issue of measuring and accounting for social risk factors in CMS' value-based purchasing and quality reporting programs that was released in January 2017 by ASPE and the National Academies of Sciences, Engineering, and Medicine. **The AMA appreciates CMS' acknowledgement that social risk factors such as income, education, employment, disability, community resources, and social support play a major role in health.** However, it would be helpful if CMS also considered the role of social risk factors in physician programs, such as the Quality Payment Program (QPP). We believe social risk factors may have an even greater impact on QPP program results due to the more homogeneous patient population within the physician practice setting. Therefore, our comments and feedback focus on both hospital and physician programs.

In order to ensure the quality of care furnished by hospitals and physicians is assessed as fairly as possible and does not disincentivize care of high risk patients, social risk factors must be taken into account. The relationship between social risk factors and a patient's health, disability, and morbidity have been extensively documented. Social risk factors such as income, community services, social support, and geographic area of residence have a significant impact on beneficiaries' potential outcomes and ability to follow treatment plans, and must be accounted for in quality and value-based purchasing programs.

The AMA also supports CMS' review of different methods for accounting for social risk factors. While the AMA believes additional studies and testing must be undertaken to determine the most effective and least burdensome approach to accounting for social risk factors, we are encouraged that CMS is exploring a variety of options.

We offer the following feedback on the options CMS is exploring:

- 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 undertaken a two year trial period to review whether risk adjustment for selected social factors is appropriate for certain measures and that CMS will review the findings once the trial period concludes. As noted earlier, while the AMA is highly supportive of NQF's trial period, we do not believe that appropriate risk models were tested 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.
- CMS notes that one method, among many they are reviewing, is to “incentivize” providers to care for patients with social risk factors. The AMA agrees with this approach only if risk-adjusting for social factors cannot be done at the individual and/or program level and if compensation is provided through upfront payments that are not financed through withholds or reductions in payments to other physicians. For example, the AMA would be concerned if CMS used a methodology similar to what was used with the physician Value Modifier (VM) program. In the face of concerns and some evidence that practices with large percentages of high-risk patients might score poorly under the VM, CMS decided to add on to any bonus these practices earned in the quality tiering process. The approach provides retroactive help to practices that manage to score well despite having a high-risk patient population. However, the approach does not help physicians who cannot make up-front investments to improve their cost and/or quality scores to avoid penalties related to their care of patients with serious health conditions and socioeconomic circumstances.

Operational Considerations

The AMA also appreciates the opportunity to comment on the collection, appropriateness, and feasibility of accounting for social risk factors in CMS programs. While we recognize the need for social risk data to support statistically-sound risk adjustment methodologies, hospitals and physicians—particularly those in environments with constrained resources—already experience an overwhelming collection, documentation, and reporting burden. CMS must prioritize and balance the elements they collect, including the frequency with which they do so, to best support the provider's decision-making ability and the agency's efforts to capture the effects of social risk. Furthermore, physicians are often frustrated when required to complete tasks that do not fit into their normal workflow, or when they must repeat tasks multiple times for no discernable reason. As such, CMS should refrain from requiring hospitals and physicians to collect social risk data at prescribed intervals.

For instance, physicians may consider social risk factors, along with the patient's narrative, to inform and guide diagnosis and treatment. Health Information Technology offers the potential to capture and collect relevant patient data for use in clinical decision making. CMS could also leverage and collect data on existing factors that contribute to patient wellness which originates outside of the care setting. In addition to clinical information, behavioral, environmental, and socioeconomic data help provide a more complete picture of patients' health and likely response to treatment.

The recent ASPE and National Academies of Science, Engineering, and Medicine report found that the development of new data sources would be beneficial in identifying indicators of social risk.⁷ To ensure any additional data collection improves patient care without adding to physician burden, CMS must coordinate with physicians and health IT developers to identify and “grab” pertinent risk factor data in an automated fashion. This must be coordinated with the Office of the National Coordinator for Health IT’s (ONC) efforts to improve the computability and interoperability of health data and will require a reimagining of health IT certification priorities. The AMA is committed in assisting both CMS and ONC in this endeavor.

IV. Medicare and Medicaid Meaningful Use Programs

2015 Certified Electronic Health Record Technology

The AMA supports several of CMS’ proposals for the Meaningful Use (MU) program but opposes the requirement that all participants use 2015 edition CEHRT starting in 2018. CMS is making assumptions about the EHR market that are inaccurate and is presuming implementation timelines that could place patient safety at risk. **We, therefore, ask that CMS continue to allow the use of both 2014 and 2015 edition technology for the 2018 MU and Merit-based Incentive Payment System (MIPS) reporting periods.**

CMS notes in this proposed rule that, by its own estimates, over one-quarter of physicians will not have updated technology by the end of CY 2017. Indeed, numerous stakeholders, including the AMA, have noted the lack of 2015 edition certified products, the small number of vendors who have undergone certification, and how this scarcity is forcing physicians to make technology choices that may not be best for their practice or patient population. Unfortunately, CMS’ proposal maintains a deadline that the majority of EHR vendors have clearly failed to meet, leaving physicians without recourse.

We also believe that CMS’ vendor readiness assessments are overly optimistic for a number of reasons. First, certification is only the initial step in the timeline of having products deployed, implemented, and functioning. Practices, especially small organizations with limited resources, often require a significant amount of time to upgrade their technology, conduct tests, and change workflows after the EHR has passed certification. EHR implementation and upgrades are not standard processes but require physician offices to spend valuable staff time to prepare for the necessary software and hardware overhaul. In addition, such upgrades are often not done all at once but are conducted in phases to ensure that practices can continue to operate. This prolongs the implementation timeframe but ensures patient safety and allows issues to be resolved as they occur. Without the time to take these necessary steps, patient safety is downplayed simply to meet arbitrary deadlines and satisfy reporting requirements.

CMS’ focus on the 2014 upgrade is also a poor projection of the 2015 system change—the 2015 update requires 19 new certification requirements and includes more sophisticated functionalities, such as application program interfaces (APIs). The 2015 upgrade also contemplates many more privacy and security risks, requiring more training and changes to previous workflows to ensure protection of patient information. Physicians will need additional time, compared to that used for their 2014 upgrades, to

⁷National Academies of Sciences, Engineering, and Medicine, Accounting for social risk factors in Medicare payment. Washington, DC: National Academies Press, 2017.

understand and safely and effectively use the new capabilities; otherwise the benefits of these system changes will be compromised. Furthermore, the number of providers using EHRs has significantly grown since the 2014 upgrade. CMS, however, has not indicated that it has adjusted its timeframes to take into account the greater number of systems upgrades, the complexity of these changes, and the additional resources that will need to be spent to move to the 2015 version in a manner that does not compromise usability and patient safety.

To partially address the existing certification backlog, CMS proposes creating a shorter, 90-day reporting period for MU in 2018. **While we strongly support a 90-day performance period since it reduces administrative burden and provides flexibility in reporting MU measures, it does not resolve the problem with the certification deadline.** EHRs are not solely used for the MU program but are required to report quality measures and participate in various advanced payment models. For example, those wishing to report chronic care management codes, quality measures, or participate in the Comprehensive Primary Care Plus or Medicare Shared Savings programs will need to use certified EHRs and must comply with deadlines that span the full calendar year. Physicians are therefore trying to make purchasing decisions now to plan for all of their reporting requirements and cannot wait until the last months in the year to upgrade their systems. The 90-day change to MU fails to address these other competing deadlines.

Instead, allowing physicians to use 2014 edition technology recognizes the current state of the marketplace while still allowing new and improved features to reach doctors, hospitals and patients. Vendors can provide partial or modular upgrades, including APIs, without requiring a full edition replacement. ONC specifically adopted this modular approach when creating its certification requirements, encouraging vendors to focus on implementing those aspects that provide the greatest benefit to consumers. Practices often learn and implement best practices and useful policies from early adopters in their community, who essentially act as real world testing grounds and are in a position to provide feedback to health IT developers if products need patches or other fixes before widespread deployment. While this more paced approach to upgrading systems may lengthen implementation timeframes, it would allow practices to continue to operate and test new functionalities while monitoring for patient safety issues. A staggered approach would additionally provide an opportunity to incorporate elements from the strategy outlined by Congress in the 21st Century Cures Act to reduce EHR regulatory and administrative burden into certification requirements (e.g., testing CEHRT in real-world settings).

We therefore strongly urge CMS to defer the 2015 CEHRT requirement and ask that the agency make this policy change as soon as possible. The AMA believes CMS should not rely on hardship exemptions to address the delay in 2015 CEHRT at a later date. This places additional administrative burden on physicians, through no fault of their own, and creates uncertainty about CMS' own programs. Instead, CMS should resolve this issue now by providing physicians with the flexibility to keep their current technology and have sufficient time to appropriately and safely upgrade their EHRs.

Exception for Decertified EHRs

The AMA supports the provision in the 21st Century Cures Act that exempts physicians and other professionals from penalties if their EHR is decertified. **We, however, urge CMS to use at least a two-year exemption period and allow physicians to seek additional time if necessary before once again being subject to reporting requirements.**

Switching an EHR system is extremely time and resource intensive. It requires physicians to research, implement, test, and train staff before completing a system change. Recent examples, including Vanderbilt University Medical Center, suggest that this process requires over a year to complete since it often requires complex maneuvering between old and new computer systems while maintaining continuity for patients. Such system changes often require hundreds of staff, millions of dollars, and complete workflow redesigns that require the practice to reduce workloads in order to ensure patient access to care. We do not believe that during such a process physicians can be fairly judged on their performance with a new EHR system.

Furthermore, we do not believe that CMS should require a physician or practice to demonstrate and provide supporting documentation to qualify for an exemption. Such documentation creates administrative burden when the practice is undergoing significant disruption to patient care and provides no additional information—ONC will be aware of the systems that have undergone decertification. Rather, CMS should allow the practice to simply attest that it was using the decertified technology during the two-year period and not have to reapply during this timeframe. This would allow the practice to focus on changing its system and return to providing patient care with the understanding that if it does not secure a new system in the future it could face penalties under the MU or MIPS program requirements.

Exemption for Ambulatory Surgical Centers (ASCs)

The AMA appreciates CMS' proposal to exempt physicians practicing in ASCs from the MU penalties. To define an ASC-based physician, we support using the 75 percent threshold, rather than 90 percent. This will help align MU definitions with the MIPS program, which we believe will assist in understanding the new requirements and minimize confusion.

Clinical Quality Measures (CQMs) for the Medicaid MU program in 2017

CMS proposes to change the CQM reporting period for physicians who report CQMs electronically in the Medicaid MU program to 90-days. The AMA supports this proposal, and agrees that CMS should align the Medicare and Medicaid reporting and quality improvement programs wherever possible. However, the AMA urges CMS to also reduce the reporting period for physicians reporting CQMs by attestation to 90-days. Some states, such as California, require physicians to submit CQMs through attestation. Physicians should not be required to report CQMs for a full year versus 90-days based on state reporting requirements. CMS should allow all physicians participating in the Medicaid MU program, regardless of reporting method, to report CQMs for 90-days in 2017. Creating two different timelines adds unnecessary complexity to the program and will likely confuse physicians.

V. Accreditation Transparency

In this rule, CMS proposes to require accrediting organizations (AOs) with CMS-approved accreditation programs to post final accreditation survey reports and plans of correction (PoCs) on a public facing website designated by the AO. **While the AMA supports increased transparency in health care, we have concerns about CMS moving forward with this proposal at this time.** AOs currently do not make their survey reports and accompanying PoCs publicly available. Under the proposal, the information would be required to be posted 90-days after it is made available to facilities. The new proposal would apply to survey reports and PoCs of facilities that participate in Medicare based on their accreditation from a CMS-approved AO, including hospitals, psychiatric hospitals, critical access

hospitals, home health agencies, hospices, ambulatory surgery centers, outpatient physician therapy and speech-language pathology services, and rural health clinics. Advanced diagnostic imaging AOs would also be required to comply.

First, the statutory intent is clear that no AO surveys should be published unless an enforcement action was taken by the Secretary, which is contrary to CMS' proposal. Section 1865(b) of the Social Security Act states:

“The Secretary may not disclose any accreditation survey (other than a survey with respect to a home health agency) made and released to the Secretary by the American Osteopath Association or any other national accreditation body, of an entity accredited by such body, except that the Secretary may disclose such a survey and information related to such a survey to the extent that such survey and information relate to an enforcement action taken by the Secretary.”

While CMS' proposal would require the AO organizations themselves to post the surveys instead of CMS, the AMA believes that this would clearly still violate the intention of the statute that this information not be reported until an enforcement action was taken. In addition, the status of whether a facility is accredited is already published, and includes material defects of those facilities in pending status.

In addition, the current accreditation surveys provide an overwhelming amount of information for consumers to digest and interpret. Much of the information contained in these reports raises issues that could alarm prospective patients, yet are easily remedied during the accreditation process or during the resolution of a complaint. In addition, survey reports contain references to current malpractice cases along with personnel health and training information, which has previously been considered confidential information. CMS states that they believe posting AO survey reports and PoCs would provide a more comprehensive picture of the health care system. The AMA respectfully disagrees, and believes that without proper aggregation and context of the AO survey data, data from AO surveys and PoCs could be easily misinterpreted.

It is also unrealistic to expect an AO to publish the information 90-days after it is made available to facilities and include proper analysis, design and testing so that it can be easily understood and useful to consumers. Furthermore, it is unclear whether a facility's full corrective action plan would have to be posted and there are varying degrees of severity within a corrective action plan that can easily be misinterpreted.

Instead of moving forward with the publication of additional information, CMS should instead focus on improving the accuracy and usability of the data that is currently available to consumers through public reporting websites such as Hospital Compare and Physician Compare. As the AMA has noted previously, physicians continue to find inaccuracies in the data published on Physician Compare. In addition, the data review and correction process continues to operate on an unrealistic timeline and remains burdensome for physicians and their staff.

VI. Request for Information on Physician-Owned Hospitals

The AMA appreciates the opportunity to provide comments on physician-owned hospitals. We believe physician-owned hospitals provide quality care to patients and needed competition to the health care

industry. The AMA supports competition between and among health care providers and facilities as a means of promoting the delivery of high quality, cost-effective health care. Providing patients with more choices for health care services stimulates innovation and incentivizes improved care, lower costs, and expanded access.

Appropriate Role of Physician-Owned Hospitals in the Delivery System

The AMA believes physician-owned hospitals should be allowed to compete equally with other hospitals in the delivery system. Limiting the role of physician-owned hospitals only reduces access to high quality health care for patients. Physician-owned hospitals are a benefit to patients and their communities and represent the type of coordinated care that is needed for the future of health care delivery. These hospitals provide: tens of thousands of jobs nationally; a local economic engine through property taxes and higher-wage jobs; and patient access to the best quality health care available. Furthermore, the presence of physician-owned hospitals has not had an impact on the financial viability of surrounding hospitals showing no effect on inpatient volumes, revenues, or profits.

Physician-owned hospitals can also serve the role of adding much-needed competition into the hospital market. Hospitals continue to merge and consolidate. For example, in 2017, four large health system mergers have already occurred.⁸ Hospital mergers and consolidation generally results in higher prices. This is true across geographic markets and different data sources. When hospitals merge in already concentrated markets, the price increases can be dramatic, often exceeding 20 percent.⁹

Thus, the appropriate role of physician-owned hospitals includes having physician-owned hospitals act as a true competitor with other hospitals. Competition forces traditional hospitals to improve and innovate. This benefits patients and the health care system as we work to improve care. In addition, in physician-owned hospitals, physicians—who are fundamentally responsible for the existence of the hospital and the maintenance of its standards—can manage hospital costs through innovation and improved efficiency, which increases value. Physician-owned hospitals already are more likely to have operating rooms that they use more efficiently than traditional hospitals.¹⁰ Physician-owned hospitals are also more engaged in general medical and surgical care than other hospitals.¹¹ Accordingly, by allowing physician-owned hospitals to compete with other hospitals, the delivery system benefits by increasing competition and patient choice.

Current Scope of and Restrictions on Physician-Owned Hospitals Affect Health Care Delivery

CMS also requested information on the current scope of and restrictions on physician-owned hospitals that affect health care delivery. In short, the **restrictions have a negative effect on health care delivery and patient choice.**

⁸Dave Barkholz, *Hospital Mega-Mergers Hit Fast and Furious in Q1*, Modern Healthcare (Apr. 29, 2017), available at <http://www.modernhealthcare.com/article/20170429/MAGAZINE/170429835>.

⁹Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation – Update*, Robert Wood Johnson Foundation (June 2012) available at http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261.

¹⁰Elizabeth Plummer & William Wempe, *The Affordable Care Act's Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, Health Affairs 35, no. 8 (2016) available at <http://content.healthaffairs.org/content/35/8/1452.full.pdf+html>.

¹¹*Id.*

The restrictions on physician-owned hospitals have effectively eliminated the formation of new hospitals and additional choices for patients to receive quality care. For example, the restrictions resulted in freezes on the construction and expansion of 45 partially completed physician-owned hospitals.¹² In Texas for example, 13 physician-owned hospitals were formed after enactment of the Affordable care Act (ACA), however because of the restrictions; they did not accept any Medicare or Medicaid patients.¹³ Currently, all of these physician-owned hospitals have either been sold or are part of bankruptcy filings.

The restrictions on physician-owned hospitals are without merit and have no valid justifications. Physician-owned hospitals provide better or same quality care at the same costs as other hospitals and do not cherry pick or lemon drop patients.

Quality and Cost

Physician-owned hospitals provide better or same quality care at the same costs as traditional hospitals. Several studies have shown high levels of quality care and patient satisfaction in physician-owned hospitals. Recently, the *British Medical Journal* found that physician-owned hospitals performed comparably with other hospitals on both disease specific and composite measure of mortality, congestive heart failure, readmissions for myocardial infarction, and pneumonia. Furthermore, physician-owned hospitals had similar costs and payments for episodes of care for these services. Studies have also shown that these hospitals provide more net community benefits through uncompensated care and taxes than not-for-profit competitors as a share of total revenues.

High Risk Beneficiaries

There is no evidence that physician-owned hospitals treat fewer high risk beneficiaries. In fact, a comprehensive, peer-reviewed study of all physician-owned hospitals published in the *British Medical Journal* found that physician-owned hospitals see the same patients as hospitals without physician ownership and are not leaving their competitors with sicker, lower-income patients. The lead author—Daniel Blumenthal, MD, a clinical fellow at Massachusetts General Hospital—said, “By and large, physician-owned hospitals have virtually identical proportions of Medicaid patients and racial minorities and perform very similar to other hospitals in terms of quality of care.”¹⁴

Accordingly, physician-owned hospitals should play an integral role in the delivery system as a true competitor with no restrictions. The inability of physician-owned hospitals to address the growing demand for high quality health care services in their community is bad for our entire health care system and does nothing but penalize patients who should have the right to receive care at the hospital of their choice.

VII. Request for Information on CMS Flexibilities and Efficiencies

CMS included a request for information on regulatory, subregulatory, policy, practice, and procedural changes that would reduce unnecessary burden for physicians and patients. Please see Addendum A,

¹²D M Blumenthal, *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, *British Medical Journal* (2015) available at <https://doi.org/10.1136/bmj.h4466>.

¹³Elizabeth Plummer & William Wempe, *The ACA's Effects on the Formation, Expansion, and Operation of Physician-Owned Hospitals*, *Health Affairs* 35, no. 8 (2016) available at <http://content.healthaffairs.org/content/35/8/1452.full.pdf+html>.

¹⁴D M Blumenthal, *Access, quality, and costs of care at physician owned hospitals in the United States: observational study*, *British Medical Journal* (2015) available at <https://doi.org/10.1136/bmj.h4466>.

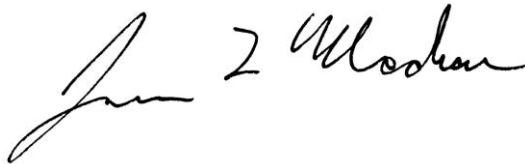
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attached to this letter, for a list of areas the AMA believes CMS should address in order to reduce the regulatory burden for physicians, while also simplifying the health care system and ensuring patients receive optimal care.

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 2018 IPSS/LTC Proposed Rule. If you have any questions please contact Margaret Garikes, Vice President of Federal Affairs, at 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and a stylized "M".

James L. Madara, MD

Attachment

Appendix A: AMA Suggestions for Regulatory Relief

Prior Authorization and Utilization Management

According to a recent AMA survey of 1000 practicing physicians, a medical practice completes an average of 37 prior authorization (PA) requirements weekly per physician, taking a physician and their staff an average of 16 hours, or the equivalent of two business days, to process. In response to this waste of resources and the resulting delays in care, the AMA and more than 100 other organizations representing physicians, hospitals, pharmacists, medical groups, and patients have endorsed 21 Prior Authorization and Utilization Management Reform Principles that are intended to serve as best practices and reasonable reforms for utilization management (UM) programs. The AMA urges all entities engaged in UM—including the Centers for Medicare and Medicaid Services (CMS)—to follow these principles.

One critical area addressed in the principles is prior authorization (PA) process automation to improve efficiency and reduce costs for providers and payers by requiring payers to adopt the HIPAA-mandated transaction for medical services PA (X12 278) and the National Council for Prescription Drug Programs' (NCPDP) standard electronic transactions for pharmacy PA. Beyond the need for automation, UM requirements are overused and bluntly applied to all physicians, regardless of adherence to evidence-based guidelines. PA requirements now cover a wide range of services, including imaging, psychiatric hospital admissions, inpatient versus outpatient status and various surgical conditions. Rules may vary depending on whether the service is being provided on an inpatient versus an outpatient basis. Increasingly, tools intended as flexible guidelines instead are used as arbitrary standards, leading to denials for appropriate use. The problems are particularly pervasive in prescription drug coverage where physicians may be forced to rewrite prescriptions just to achieve a small, temporary discount from a particular company or to take advantage of a short-term strength-related discount on the same drug the patient is already taking at a different strength. Patients' confusion over changes in their medications' appearance and directions can lead to significant and sometimes life-threatening clinical outcomes.

Recommendations:

- CMS should require Part D plans to accept and respond to pharmacy PA and step therapy override requests through the NCPDP electronic PA transactions;
- CMS should accelerate automation of medical services PA by (a) issuing a rule for an electronic clinical attachment standard and (b) enforcing health plan compliance with the X12 278;
- CMS should ensure that all UM requirements are based on accurate and up-to-date, publicly available clinical criteria and never cost alone;
- CMS should require all MA and Part D plans to publicly disclose to both patients and physicians in a searchable electronic format all drugs and medical services that are subject to coverage restrictions (PA, step therapy, formulary restrictions, quantity limits) and provide this information to vendors to be displayed in electronic health record systems;
- CMS should require a 60-day grace period for UM requirements when a patient changes MA and Part D plans, align PA approvals with the duration of the prescribed/ordered treatment, and prohibit plans from requiring patients to retry therapies failed under previous plans;
- MA and Part D plans should abide by PA decisions and pay for any services approved in a PA request by performing eligibility and all other medical policy coverage determinations as part of the PA process and not revoking or restricting coverage for authorized care provided within 45 business days from the date the authorization was received;
- Except where there is evidence of widespread misuse, PA should not be required for drugs that are standard treatment for the patient's condition and/or have been previously approved for treatment of an ongoing/chronic condition;

- CMS should ensure that any “peer-to-peer” reviews utilize physicians from the same specialty/subspecialty as the ordering physician; and
- CMS should restrict PA requirements to “outlier” providers whose prescribing or ordering patterns differ significantly from their peers after adjusting for patient mix.

Social Security Number Removal Initiative (SSNRI)

The Medicare Access and Chip Reauthorization Act (MACRA) included a provision requiring CMS to remove the Social Security Number (SSN) from Medicare cards due to concerns of identity theft –the Social Security Number Removal Initiative (SSNRI). The new identification cards (ID) will be sent out in phases over a 12-month period beginning April 1, 2018. While we understand the importance of protecting Medicare beneficiaries from identity theft by replacing SSNs with new Medicare Beneficiary Identifier (MBI) on Medicare ID cards, we have had concerns about the size and characteristics of this vulnerable population and the need for CMS to handle this change efficiently and effectively. We appreciate CMS’ recent decision to address our earlier concerns about insufficient outreach and the lack of a look-up database to make it possible for providers to find or confirm a beneficiary’s MBI after the transition period ends.

Recommendations: CMS should work with the AMA and other physician organizations to:

- Implement its newly-announced MBI look-up database; and
- Effectively message information about the SSNRI to beneficiaries and providers.

Certification and Documentation

Medicare documentation requirements are a major imposition that delays care with redundant requirements for verifying physician orders and voluminous medical records where the salient patient information is buried in reams of purposeless, formulaic language. Physicians are also expected to keep other providers honest by certifying and recertifying the need for virtually any other service the patient requires—from power wheel chairs, to repeat orders of glucose strips, colostomy bags for patients with chronic ongoing conditions, to physical therapy plans, to home health and hospice services. All durable medical equipment (DME) and home health orders must be signed by hand by the physician and no stamps are allowed. All DME prescriptions require an in-person visit within a prescribed period of time for certification (even if it is for replacement of stolen or broken equipment). The task is further complicated when, for example, every home health agency uses a different form to confirm the physician’s involvement and new paperwork is required every time a patient switches to a new glucose monitoring system requiring different strips than the prior one. We need a more targeted approach that focuses on providers and suppliers who are repeat offenders, who could be identified through contractor claims analysis rather than imposing volumes of certificates signed by physicians. We need to standardize forms and eliminate the requirements for physicians to recertify patient conditions every year when it is a permanent chronic condition, non-acute. Authorization for supplies should be generic so that physicians are not required to fill out a new form every time a patient switches brands.

Recommendation:

- CMS should create a stakeholder workgroup to address CMS’ program Integrity needs while simplifying the bureaucratic requirements.

Unique Device Identifier (UDI) and Claims

The UDI for medical devices aims to improve post-market surveillance and patient safety. While the AMA strongly supports the incorporation of the UDI on medical devices, there is some debate about the most appropriate place to capture this information. CMS and FDA have called for including part of the UDI in the next claims form template update—slated for 2021. However, new certification requirements

that will allow EHRs to capture and transmit the full UDI will be implemented throughout 2018. The AMA views EHRs and registries as the most appropriate method to capture and manage the UDI. Capturing UDI information in administrative claims represents a significant cost to providers, as well as the industry as a whole, and claims information does not follow a patient as they switch insurers. The claims form changes would also not require the capture of the full UDI, instead capturing only the device identifier (“DI”) portion and excluding the product identifier portion. Both the PI and DI are key in providing the complete picture about a medical device when safety issues arise. Capturing this information in a patient’s EHR, allows the full medical device information to follow patients, and their longitudinal medical history, regardless of changes in insurance.

Recommendation:

- CMS should not require the capture of the device identifier portion of the UDI on administrative claims forms. The full UDI should be captured instead within a patient’s electronic medical record and managed by EHRs and appropriate registries. Registries that collect data from electronic health records could gather this UDI data from the EHRs in the aggregate to support comparative studies and post market surveillance.

Appropriate Use Criteria (AUC)

Protecting Access to Medicare Act (PAMA) enacted a new mandate which would require physicians ordering diagnostic imaging services to consult appropriateness use criteria in order for the physician who provides the imaging to be paid. Ordering physicians do not have to follow the criteria but after three years, so-called “outliers” who diverge from the criteria most often will be subject to preauthorization when ordering these services. This was supposed to begin in 2017 but due to complexity and necessity to build a complicated new infrastructure, CMS delayed the start date and is now saying that the AUC mandate could potentially begin on January 1, 2018. The AMA does not believe that the infrastructure will be ready by the start date of January 1, 2018. Nor do we believe that either CMS or physicians have the bandwidth to implement both AUC and MACRA at the same time. For example, CMS identified 8 clinical areas that would be used to identify outlier physicians and that must be included in all approved clinical decision support mechanisms. We think that this is too big a first-year burden—especially for primary care physicians and that it is unnecessary to require Clinical Decision Support Mechanisms (CDSMs) used by specialties to include criteria for services the specialty rarely or never orders. We also think that the requirements for what must be documented in the CDSM are extremely complex and will exacerbate the existing problems physicians are having with EHRs.

Recommendations:

- CMS should delay the start date at least until January 1, 2019;
- CMS should reduce, simplify and phase-in requirements; and
- CMS should expand use of hardship exemptions as the AUC requirement is implemented.

Increase Transparency Around EHR Costs

Physicians have already made significant investments in their EHRs, yet vendors often require additional, yearly fees to connect those EHRs to registries, information exchanges, and public health agencies. The Office of the National Coordinator for Health Information Technology (ONC) already requires vendors to state that extra charges may be required; however, the dollar figures are not made public. Most EHR vendors overly generalize costs and are not upfront with physicians when selling their products. This drastically affects small and solo physician offices. These fees are often both a surprise and overly excessive—acting as a roadblock to the exchange of vital patient data while limiting the interoperability between EHRs.

Recommendation:

- ONC should require vendors seeking certification to publicly provide detailed examples of fees (including dollar figures) typically charged to physicians and options available to enable data sharing.

Prohibit Vendor Data Blocking

While CMS' implementation of MACRA requires physicians to attest to a multipart attestation on data blocking, vendors currently do not face any limits on data-blocking activities. In the vast majority of cases, the vendors implement cost, technical, or contractual limitations to block the flow of patient data.

Recommendation:

- ONC should implement a vendor data-blocking attestation requirement as part of all current and future health information technology certification editions.

Prioritize ONC's Efforts Around Interoperability Use Cases

Interoperability across EHRs, mobile devices, registries and patient-specific health IT products is a top priority for physicians. Current product development efforts, based on federal regulations, have resulted in health IT accommodating measurement and reporting, rather than enabling the free flow of data. Today, accessing and moving data comes at a major cost for physicians and disrupts patient care. We need a health IT environment that is focused on and responds to the needs of physicians, patients, and researchers. This will require the administration to convene clinical experts, technology vendors, standards developers, and other stakeholders to identify barriers and find solutions.

Recommendations:

- ONC should leverage priority use cases outlined in the 21st Century Cures Act and convene stakeholders to assess the common needs of physicians, patients, and researchers;
- ONC should then provide a detailed summary of findings to the Health Information Technology Advisory Committee as a starting point for use case prioritization;
- ONC should prioritize technical (syntax), semantic (machine usable), and process (human usable) interoperability; and
- ONC should also ensure interoperability solutions are scalable and can be replicated with minimal cost, time, and effort.

Refocus ONC's Certification Program

Currently ONC certifies that EHRs are able to meet a low-bar of requirements directly attached to CMS' reporting program. In order to further the interoperability goals outlined above, ONC needs to improve its certification program.

Recommendation:

- ONC should refocus its certification program to test and validate an EHR's ability to conform to interoperable standards, features, functions, and capabilities described and sold by the vendor and should reflect the real-world needs of patient care.

Clarify Data Entry Requirements

Medicare rules allow physicians to delegate entering in certain data elements of a patient record to ancillary staff, which allows the physician to focus on providing patient care. The physician still signs off on the entire record to ensure its accuracy but is not burdened with keying in specific elements of the record. It is not clear if all the data entry can be delegated to ancillary staff. Specifically, Medicare rules do not explicitly indicate if physicians can delegate data entry for the History of Present Illness or Chief

Complaint. Several Medicare Administrative Contractors currently interpret CMS regulations to prohibit the physician from delegating data entry for these elements.

Recommendation:

- CMS should clarify that such information may be recorded in the medical record by non-physician staff.

Electronic Prescribing of Controlled Substances

Take-up rates for electronic prescribing of controlled substances (EPCS) have been very low, largely due to barriers imposed by the Drug Enforcement Agency (DEA). There is a need for the DEA to provide greater flexibility for EPCS, particularly around prescriber identity proofing and authentication.

Recommendation:

- DEA should allow for lower-cost, high-performing biometric devices, such as fingerprint readers on laptop computers and mobile phones, to be used for authentication.

Costs of Interpretation and Translation Services

Physicians are required to provide translators for Medicare and Medicaid patients with hearing impairments or limited English proficiency. Accommodations amount to an unfunded mandate that the AMA has long opposed as an unfair burden imposed upon physicians, especially those who are operating small businesses.

For example, qualified interpreters for those with hearing impairments can cost up to \$150 per hour, with a one- or two-hour minimum, plus transportation costs. The practice may also still incur a fee if the patient cancels without sufficient advance notice. We believe these costs should be taken into account as part of the cost of delivering care and should be fully reimbursed by the patient's health insurance plan.

Recommendation:

- The Office of Civil Rights should revise the definition of "qualified interpreter to an individual with limited English proficiency" to allow the use of an adult accompanying an individual with limited English proficiency to interpret or facilitate communication.

Protecting Access to Medicare Act (PAMA)

PAMA included numerous provisions aimed at reducing payments for clinical testing services paid on the Clinical Laboratory Fee Schedule. Included in PAMA are new requirements for laboratories, including physician office-based labs, to report private payor pricing data on tests offered by that lab. Data collected will be used by CMS to re-price tests on the Clinical Laboratory Fee Schedule, with new rates scheduled to take effect on Jan 1, 2018. There are significant concerns about the impact of PAMA on the pathology and laboratory practices, as well as other physician office-based labs. Reporting accurate private payor pricing data has proven to be exceptionally difficult for all labs and there is widespread concern that a substantial number of pathology, laboratory, and physician office-based laboratories will find the new rates unsustainable for their current practice characteristics and will be unable to withstand the expected reductions in reimbursement for these tests.

Recommendations:

- CMS should delay implementation of PAMA by one year to resolve significant substantive and operational issues;
- CMS should allow more time for laboratories to be able to fulfill CMS data collection requirements, for CMS data collection systems to function at adequate capacity to more accurately capture private payor data on which the clinical laboratory fee schedule will be based;

- CMS should revise current burdensome data collection requirements by reducing the number of data elements required as well as the period for which data must be reported. CMS should revise the method of collecting and assessing data from physician office-based laboratories to ensure data captured and resulting prices are reflective of testing services provided in this market segment; and
- CMS should reassess and consider redefining the definition of “applicable laboratory” so that private payor payments upon which the clinical laboratory fee schedule will be based is reflective of the market.

In-office Drug Compounding

In an attempt to crackdown on unsafe drug compounding practices, the Food and Drug Administration (FDA) has proposed new standards for compounding facilities that may severely limit the ability of physician to prepare sterile drugs for administration to patients in office settings. In its draft guidance “Insanitary Conditions for Compounding Facilities,” FDA has included physician offices that “compound” sterile drug products in the definition of a compounding facility. The guidance lays out a number of requirements that compounding facilities must meet in order to be considered “sanitary” failure to meet these requirements could lead to FDA action for compounding in insanitary conditions. Those requirements include onerous equipment requirements, essentially requiring that all sterile preparations take place in an ISO Class 5 cleanroom. We have significant concerns about both the inclusion of physician offices in this guidance and the continued inclusion of in-office preparation of sterile drug products by a physician for administration to patients in the definition of compounding. These types of activities are considered the practice of medicine and are not pharmacy compounding activities under the purview of FDA.

Recommendation:

- The FDA should exempt physician preparation of sterile drug products for administration to patients in an office-setting from its definition of compounding so that this draft guidance is not applicable to those activities, and/or remove the reference to “physicians’ offices” from its draft guidance “Insanitary Conditions for Compounding Facilities.”

Medicare Advantage (MA) Star Ratings

As the Star Ratings program has expanded and plays a larger financial role on health plans’ bottom lines, the administrative demand has simultaneously increased on physicians and impeding clinical care and thus does not provide a beneficiary benefit. A large percentage of the measures within the MA Star Ratings program are based completely on physician action and compliance. In order for health plans to increase their HEDIS scores and earn greater incentives from CMS, plans are requiring practices as part of their clinical data submission requirements to submit data on all patient lab results and tests and the plans state it is due to the Star Ratings HEDIS requirements. Many of the measures, particularly the HEDIS *Effectiveness of Care* measures, have more to do with physician quality than assessment of a health plan. The *Effectiveness of Care* measures are really targeting clinical quality, which is a physician or facility issue—and therefore physicians and facilities have the data. Without a better focus the MA ratings program is just one more burden on physicians and does not provide beneficiaries with the best information they need to determine the most appropriate and high quality Medicare Advantage or drug plan.

Recommendations:

- CMS should refine Star Ratings to better measure the quality of plans and things over which the plan has control and the supporting data (for example, access);

- CMS should require health plans to allow practices to respond *at-will* at a time of their choosing, at a minimum allow for at least 90 days to respond, support use of electronic methods of data submission, and adequately compensate physicians for the time and burden;
- CMS should allow for more general exclusions for patients with specific conditions, comorbidities or allergies from measures to ensure patient and clinical differences are accounted for and do not interfere with clinical decision making; and
- Denominators of quality measures should be appropriately defined to ensure patients for whom the treatment may not be appropriate are excluded from measurement.

Data Requests to Support MA Risk Adjustment Scores

MA plans routinely demand medical records from physician practices as a means of identifying information plans use to support increases in payments from CMS that are tied to the health status of plan enrollees. Only a small fraction of these requests are linked to CMS audits of MA risk adjustment data. Plans generally provide no compensation for staff time required to pull records and make copies. Physicians frequently complain that charts are demanded for large numbers of patients and that the same practices are repeatedly subject to these demands, often for the same patients. MA plans frequently subcontract the chart audits to third parties so the medical practice has no idea which plan is making these demands, and misleading statements are made that the audits are required by CMS when they are not. Although having more complex patients involves more physician work, physicians do not receive any additional compensation from MA plans that have higher risk adjustment scores. Instead, those practices that are able to help plans increase their scores are likely to face repeated demands for risk information in the future, adding to their regulatory burdens.

Recommendations:

- CMS should accept physician attestations to support MA beneficiaries' diagnoses instead of requiring documentation from medical records;
- Once beneficiaries have been diagnosed with a permanent condition (i.e., multiple sclerosis, quadriplegia, arthritis), this diagnosis should follow them from year-to-year and not have to be re-designated each year; and
- To eliminate ambiguity as to the authority, regulation, policy, and MA plan contract that is the basis for medical record requests, CMS should require all MA plans to use a standard letter.

Program Integrity

Physicians are facing an increasing amount of pre-payment and post-payment scrutiny from a variety of government entities and contractors including CMS, Medicare Administrative Contractors, Recovery Audit Contractors (RAC), Unified Program Integrity Contractors (UPIC) (combining program safeguard, zone program integrity, and Medicaid integrity contractors), Quality Improvement Organizations, Comprehensive Error Rate Testing (CERT), and Supplemental Medical Review Contractors. The amount of reviews and types of reviewers is confusing, adds unwarranted physician burden and unnecessary costs, and disrupts and distracts from delivering care. Further, some contractors are auditing and attempting to recoup against services that Medicare does not require or are not adhering to CMS requirements surrounding the approval of Local Coverage Determinations (LCD). Physicians need a single transparent, consistent, and fair review process to reduce administrative burden.

Recommendations:

- CMS should develop a uniform approach for reviewers in notifying physicians of a review, requesting records, informing physicians of the specific reason why a claim is denied, and conspicuously stating a physician's appeal rights and avenues;
- CMS should apply consistent and clear Medicare and Medicaid payment and coverage policies including having contractors follow the proper notice and comment process regarding LCDs;

- HHS should eliminate duplicate review of claims among different Federal government reviewers;
- CMS should clarify the function and scope of authority of the contractors;
- CMS should establish an internet portal for consolidating information on program integrity efforts including contractor sampling and extrapolation methodologies;
- CMS should publish data on an annual basis about contractor activities including the number of denials and appeals, net denials (defined as total denials minus denials overturned on appeal), each contractor's appeal rate, and common coding and billing errors and omissions (e.g., error type, omission type, physician specialty, contractor, and region);
- CMS should also increase its physician education efforts on how to avoid common coding and billing mistakes and work with physician practices to address internal deficiencies that may have led to a high volume of coding and billing errors;
- CMS should refine reviews using predictive analytics to focus on claims that are at high risk for improper payments;
- CMS' reviews need to capture and consider specialty, patient mix, and site of service;
- CMS' reviews should also be reviewed by a practicing physician of the same specialty;
- CMS' contractors should face a financial penalty when denials are overturned on appeal; and
- CMS should consider replacing financial penalties with corrective action plans.

Recovery Audit Contractors (RACs)

RAC auditors retain a percentage of the amount they recover for the government with little regard for the burden and accuracy of the audits. These audits are a great source of frustration for the physician community.

Recommendations:

- CMS should retain the current RAC medical record request limits to ensure audits are not overly burdensome;
- CMS should allow for settlements for Part B claims to ease appeal backlog;
- CMS should repeal the contingency fee structure of the RAC audits;
- CMS should implement meaningful financial penalties and fines for RACs who make errors;
- CMS should require RACs to reimburse the costs (including interest) to physicians who win on appeal of a RAC audit;
- CMS should require RACs to reimburse for medical records (hospitals are now partially reimbursed for medical records; physicians are not); and
- RAC audits should be reviewed by a practicing physician of the same specialty or subspecialty and in the same jurisdiction.

Loosen Stark and Anti-kickback Restrictions

Physicians are barred from participating in innovative and cost-saving care models due to outdated regulations, including Anti-Kickback and complicated Stark prohibitions. These models may require the use of EHR software and technology in order to be viable and effective. While safe harbors exist in this area, they are temporary and limited in scope. In addition, physicians are inadvertently subjected to large fines or penalties for Stark technical violations (e.g., missing or out-of-date paperwork).

Recommendations:

- Create new exceptions or safe harbors for Stark and Anti-kickback to facilitate coordinated care and promote cost reductions including extending existing waivers from the Medicare Shared Savings Program's ACOs to other individuals and entities implementing alternative payment models outside this program;

- HHS should amend and revise the definition of “fair market value” to account for new payment models that are based on value and outcomes rather than productivity (e.g., allowing incentive payments for efficient and better care rather than on the number of hours or RVUs worked);
- Make permanent the existing safe harbors for EHR software and technologies and should broaden the definition of “electronic health record” beyond clinical diagnosis and treatment. The definition should include such things like information sharing and cybersecurity and allow for flexibility as technology evolves; and
- HHS should also focus more on educating physicians on technical violations (and work with the U.S. Department of Justice and the Office of Inspector General so that technical violations are not subject to any Stark penalty).

2 Midnight/Observation Care

The “2-Midnight” rule has had significant unintended negative consequences that burden Medicare beneficiaries. It remains an artificial construct reflecting a flawed approach that gets in the way of the physician-patient relationship and unnecessarily increases the administrative burden of admitting physicians. The Medicare Payment Advisory Commission voted unanimously on a draft recommendation to withdraw the “2-Midnight” rule as it detracts from admission criteria that depend upon clinical judgment.

Recommendations:

- CMS should rescind the 2-midnight rule in favor of clinical judgement for determining a patient’s inpatient/observation status; and
- CMS should count time spent in a hospital as an outpatient toward the three-night requirement for Medicare coverage of SNF services.