

June 24, 2019

The Honorable Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human 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 and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals (CMS-1716-P; 84 Fed. Reg. 19158, May 3, 2019)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to provide comments to the Centers for Medicare & Medicaid Services (CMS) regarding the Fiscal Year (FY) 2020 Proposed Rule for the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System. Our detailed comments are below.

In summary:

- The AMA continues to be encouraged by CMS' efforts in the proposed rule to reduce physicians' administrative burden. While we believe some proposals need to be refined, we support CMS' efforts to focus the program on interoperability and improved patient access to health information.
- The AMA is concerned with the newly proposed measures for the Inpatient Quality Reporting (IQR) program and believes CMS should not move forward with the measures until the issues are addressed. While the AMA agrees that it is useful to understand the rate of readmissions in the 30 days following hospital discharge particularly for quality improvement, we do not believe that there is sufficient evidence to attribute responsibility of these rates to hospitals and a measure on 30-day all-cause readmissions should not be included in any inpatient accountability program.
- There is also an urgent need to re-evaluate the Hospital Readmission Reduction Program (HRRP) as there is emerging evidence that the program and the associated measures may be leading to negative unintended patient consequences and no longer capturing the appropriate patient population due to the structure and timeframe of the measures.

- The AMA believes that the current approach to address the opioid crisis through quality measurement has been too narrowly focused on preventing and/or reducing opioid use in the absence of addressing the larger clinical issue—ensuring adequate pain control while minimizing the risk toward opioid addiction. Quality measurement must focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain.
- The AMA supports CMS' policies that establish a clear and predictable pathway to payment for innovative technologies. The AMA also supports increasing flexibility that incentivizes the development of innovative technologies, however, we urge CMS to take a measured approach to current policy as outlined below.
- The AMA supports CMS' efforts to reduce administrative burden with regards to graduate medical education as outlined in the proposed rule.
- The AMA encourages CMS to seek specialty and stakeholder input prior to implementation of reimbursement and policy changes related to Medicare Severity Diagnosis-Related Groups that have the potential to negatively impact patient access to care.

**Please see our detailed comments below on the following topics:**

- I. Promoting Interoperability Program;
- II. Hospital Quality Reporting Programs;
- III. Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures;
- IV. Hospital Readmission Reduction Program;
- V. Future Direction of the PI Program—Request for Information (RFI) on Potential Opioid Measures
- VI. PPS-Exempt Cancer Hospital Quality Reporting Program;
- VII. Long-Term Care Quality Reporting Program;
- VIII. Innovation;
- IX. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG); and
- X. Graduate Medical Education Issues

**I. Promoting Interoperability Program**

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

We further note the importance of regulatory alignment across agencies with respect to data access and urge CMS to ensure that the PI measures outlined in the proposal align with the PI measures within the PI component of the Merit-Based Incentive Payment System (MIPS) to minimize burden on hospitals, physicians, and Electronic Health Record (EHR) developers. Physicians should not have to manage

requirements of two different programs across practice settings, and vendors should not be forced to design technology for compliance with two different regulatory programs.

#### Proposals the AMA Supports

- **90-day reporting period in 2021:** The AMA has previously noted that practices, especially small practices with limited resources, often require a significant amount of time to upgrade their EHR technology, conduct tests and training, and change workflows after the EHR has passed certification. We value CMS' recognition that a 90-day reporting period will provide flexibility in reporting PI measures.
- **Optional Query of PDMP measure:** The AMA is committed to addressing the country's opioid epidemic. In last year's IPPS rule, we supported CMS' proposal to provide a bonus PI score in 2019 to hospitals who choose to utilize a PDMP when clinically appropriate and in accordance with state law, and urged the agency to continue rewarding the activity with bonus points in 2020. We appreciate CMS' recognition that the operationalization of this measure is complex and can be burdensome. Furthermore, we appreciate that by continuing to score this measure as a bonus for an additional year, CMS can keep the Provide Patients Electronic Access measure's value at 40 points in 2020, underscoring the agency's commitment to patient access while incentivizing clinicians to utilize the PDMP when clinically appropriate.
- **Attestation of Query of PDMP measure:** We support CMS' proposal to remove the numerator and denominator for this measure and applaud the change to an attestation ("yes/no") response. We agree with CMS that a "yes/no" attestation, rather than a numerator and denominator response, significantly reduces burden on physicians, which we know is a CMS priority. **We strongly urge CMS to apply this "yes/no" attestation reporting model to all PI program measures**, as discussed more fully below. We appreciate CMS' ultimate goal of reaching a state in which PDMP data is accessible and integrated into the clinical workflow so that physicians do not need to access multiple systems to find and reconcile PDMP information. However, we urge against further regulating the use of technology; rather, CMS should continue to promote the use of PDMPs through positive incentives and examine how to achieve such integration at no cost to health care providers.
- **Removal of the Verify Opioid Treatment Agreement measure:** The AMA supports CMS' proposal to remove the Verify Opioid Treatment Agreement measure. The AMA agrees that this measure was complicated, burdensome, and did not promote interoperability.

#### Additional Recommendations from the AMA

- **Use of health information technology (IT) beyond CEHRT:** The AMA continues to commend CMS' recognition, through the proposed Query of PDMP measure, that the use of health IT outside of CEHRT can be useful for physicians, improve patient outcomes, and enhance patient safety. Because increased interoperability and patient access will require new combinations of technologies and services, we continue to urge HHS to reevaluate regulations that prioritize the use of CEHRT over other non-certified digital health tools. Patients, physicians, and other care team members should be empowered to make decisions based on what works best for their needs, and not what regulatory boxes must be checked. Any new PI measures should utilize not only

CEHRT but also health IT that “builds on” CEHRT—a concept taken directly from CMS’ priorities in its call for new PI measures.<sup>1</sup>

- **PI simplification and burden reduction through attestation:** CMS seeks comment on how the PI program should evolve in future years. Most importantly, the PI program must pivot away from linking a physician’s successful participation to the prescribed use of an EHR. **The AMA accordingly urges CMS to only require hospitals to attest to meeting the program’s measures—i.e., hospitals should only be required to report “yes/no” on whether they had at least one patient in the numerator of each measure.** Each “yes” would be worth a certain amount of points. In addition to relieving reporting burden on hospitals, an attestation-based approach would help facilitate EHR development to be more responsive to real-world patient and physician needs, rather than designed simply to measure, track, and report, and could help prioritize both existing and future gaps in health IT functionality. Because EHRs capture what functionalities are used to perform tasks, EHR vendors can easily provide such information to CMS and ONC. This data capture mechanism also provides an audit trail for CMS to ensure that hospitals actually did have at least one patient in the numerator of each “yes” attestation. Hospitals should focus on meeting the PI program’s objectives rather than worry about measurement and documentation. **Shifting PI measure reporting to attestation will promote interoperability and reduce physician burden, which, as noted above, is one of the administration’s priorities.**

We also appreciate CMS’ emphasis on patient access and interoperability measures in the current PI programs. These two priorities will continue to receive a large emphasis from physicians as there will be multiple levers—with significant penalties—to ensure that patient access and health information exchange occur: MIPS information blocking requirements, ONC’s information blocking regulation, and the Health Insurance Portability and Accountability Act’s (HIPAA) patient right of access (The Office of Civil Rights’ Director Severino has already noted publicly that patient access enforcement will increase this year). These three levers provide enough motivation for physicians—and their affiliated hospitals—to use health IT. Continuing to measure on the current prescriptive PI measures will detract from clinical relevance, add burden, and focus PI participation on reporting and compliance rather than patient access and interoperability.

Additionally, given that technology continues to evolve, current PI measures are likely to become quickly outdated or will fail to include more innovative uses of the EHR. Creating broad categories of PI measures, coupled with an attestation approach, would provide flexibility to allow patients and physicians to efficiently test new uses of technology to see what does and does not work, while encouraging further innovation. For example, CMS could create an objective called “Chronic disease management enabled by digital medicine.” Measures could be developed that support physicians using not only emerging CEHRT functionalities, like APIs and patient-generated health data, but also could also promote the use of digital health tools, such as remote patient monitoring services. **We stress, however, that absent an attestation approach, any new objectives and associated measures should be optional to provide additional opportunities for hospitals and physicians to be successful in the PI program.**

In sum, an attestation-based approach would give physicians freedom to choose the technology they want to use, and how they want to use it, as long as it helps them support patient care and long-term wellness.

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<sup>1</sup> See 2019 Medicare Promoting Interoperability Program Call for Measures criteria, available at <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/CallForMeasures.html>

CMS should prioritize this attestation-based approach to reduce provider burden and get physicians back to practicing medicine.

- **Potential new measures (trusted exchange networks):** The AMA has previously submitted two proposals for new PI measures that: (1) Participate in a trusted exchange network (TEN) and (2) Search for or Directly Request Patient information from a TEN. Each of these measures would contribute significantly to the PI program's goals of interoperability and greater health information exchange.

By their very nature, participation in and query of a TEN advance CMS' goal of decreasing information blocking. They also can reduce the burden on both the clinician and the patient of relying on paper exchange and use of the fax machine. Furthermore, they have the potential to exponentially improve program efficiency as clinicians would not need to duplicate documentation or order unnecessary tests. They also help improve patient safety and outcomes by offering clinicians a more complete picture of the patient's health. While participation in public health registries and clinical data registries are current measures, this measure would encourage exchange of a broad swath of clinical information as opposed to specific quality measures. Again, because an EHR can automatically track when a TEN is used and queried, CMS should permit "yes/no" attestation of the measures.

Coupled with an attestation-based approach to reporting, these new measures would encourage greater TEN participation by clinicians, both by adopting a TEN and using it to search for or request patient records. Physicians may also become more familiar with TENs—whether regional, EHR-based, or—perhaps—through the Trusted Exchange Framework and Common Agreement (TEFCA). However, we note that some of the potential use cases outlined in ONC's draft TEFCA raised questions as to physicians' ability to willingly participate (or not participate) in TENs. Due to the sensitive nature of protected health information and the potential disruption to physician practices involved in implementing the technology required to participate in a TEN, the AMA underscores the importance of ensuring that physicians understand and can willingly elect to participate in information sharing via TENs. **We urge CMS to address issues of physician choice and voluntary participation when evaluating the use of TENs as a PI measure, and stress that absent an attestation approach, these new measures should be optional.**

- **Immediate access to health information:** In light of the proposal in its Patient Access and Interoperability proposed rule requiring certain health plans and payers (Payers) to make patient health information available through APIs no later than one day after receipt by the Payer,<sup>2</sup> CMS seeks comment on whether eligible hospitals and CAHs should make patient health information available to Payers "immediately." The AMA strongly opposes this problematic potential policy, which would have numerous downstream consequences, including whether such tactics will narrow a Payer's provider network. Narrow network plans have become increasingly common in private health insurance markets, including Medicare Advantage, and both the AMA and other physician groups have raised concerns that narrow physician networks create challenges for patients seeking care and pose potential patient protection issues.

Moreover, physician practices have limited resources, including administrative staff, and have developed procedures and workflows to turn claims around quickly. The faster physicians submit claims, the faster

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<sup>2</sup> 84 Fed. Reg. 7610 (March 4, 2019).

they are paid, so there is already a built-in incentive to submit claims quickly. Furthermore, payers have much more leverage in a physician-payer relationship than a physician—particularly a small physician practice—and they will point to comments like these to strong-arm physicians. **Requiring physicians to adjust their workflows to ensure that Payers “immediately” receive information—particularly given that Payers must only provide the information to their enrollees as soon as they receive it (i.e., not within a certain amount of time from the date of service)—would be an unwelcome intrusion upon a practice’s long-standing business operations, would require renegotiation of numerous contracts, and should not be permitted by an administration seeking to eliminate regulatory burden.**

- **Bonus for early adoption of standards-based APIs:** CMS seeks comment on whether the PI program should offer a bonus to participants who adopt certified FHIR-based APIs before ONC’s final rule compliance date. We note that ONC’s proposed changes to 2015 Edition CEHRT will be significant and it will be difficult for health IT developers to finalize the technology within the proposed timeframe. Obviously, a physician’s EHR adoption timeframe is, in large part, dependent on its health IT vendor’s development timeline. As such, the AMA commented that physicians should be given additional implementation time following the development timeline for the new certified FHIR-based APIs. We believe that few, if any, physicians would be able to take advantage of this potential early adoption bonus. That said, we do not believe there is harm in CMS offering a bonus to physicians who are able to adopt the technology before CMS’ required deadline and would support such a proposal.
- **Alternative EHI export measure:** CMS seeks comment on an alternative measure under the Provider to Patient Exchange objective that would require health care providers to use technology certified to the electronic health information (EHI) criteria to provide the patient(s) their complete electronic health data contained within an EHR (EHI Export for Patient Access). The AMA strongly supports patients’ right to have access to complete copies of their entire medical record in a computable format. We see the spirit of this new certification criterion as aligned with this right, however, there are several layers of ambiguity that will inhibit uniform implementation and widespread use of this functionality. For example, we note that patients requesting an EHI export will likely obtain vastly different payloads based on three factors: (1) the health IT developers certified to deliver the export; (2) the implementation decisions and customizations at each implementation; and (3) the institution’s interpretation of what constitutes EHI.<sup>3</sup> The result of these factors may add more confusion than benefit to patients. We also note that widespread use of this functionality will be inhibited because the task of making sense of the data falls largely on patients and families, not the developers or clinicians delivering the export. We therefore caution that the EHI Export for Patient Access needs refinement. **Until this refinement occurs, it would be premature for CMS to consider adding an EHI Export measure, unless it is optional, attestation-based, and scored as a bonus.**

In addition, we flag the following additional points for CMS’ consideration:

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<sup>3</sup> For a full technical discussion of our concerns, please see the AMA’s response to ONC’s 2015 Edition certification criterion proposal, available at <https://search.usan.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2019-5-31-Letter-to-Dr-Rucker-re-ONC-NPRM-Comments.pdf>, pp. 45-46.

*Export difference across developers*

Given that ONC does not propose specific transport, content, or syntax standards for EHI export (either Patient Access or Database Export), it is difficult to understand how ONC will judge conformance to this criterion. As we have seen in numerous other certification criteria, it is likely that developers are much more uniform in their conformance testing than in the real world, and it is very likely that this lack of specificity will deliver different exports for similar patients.

*Export differences based on implementation decisions and customizations*

ONC expects that EHI exports will encompass “all the EHI that the health IT system produces and electronically manages for a patient or group of patients.” Holding aside the ambiguity of “produces and electronically manages,” there is the simple fact that health care facilities have made implementation decisions and customizations that likely differ across sites, even when using the same developer, which will enable some systems to deliver data that other systems cannot.

*Export differences based on interpretation of EHI definition*

ONC defines EHI broadly. Generally, physicians have struggled to define the Designated Record Set (DRS) consistently, which by comparison is a more constrained concept. Given that the definition of EHI does not dictate which data must be delivered via Patient Access and Database Export, there is a high probability that institutional interpretations will create difference in what similar patients receive as part of this criterion.

*EHI export security considerations*

The EHI Export for Patient Access should be tied to “HIPAA compliant uses,” which would be physician access for treatment, payment, or operations for the purposes of continuity of care, and patient data access for whatever purpose they deem appropriate. We stress that until such time EHR vendors utilize an API orchestration to provide patients direct EHI export capabilities, the ability to request an EHI export be medical practice-facing. We have concerns with the potential of hundreds or thousands of users’ “requests” coming into an EHR for an export. This would severely bog down an EHR’s performance, putting patients at risk. Furthermore, externally-facing EHI export capabilities (i.e., download or export functions provided via patient portals), would expose an EHR to denial-of-service attacks (DoS). To be clear, patients could still request their ePHI from the medical practice, but the act of querying the EHR should be reserved for authorized users, administrators, and medical office staff. Until such time that EHR vendors have proven capable of supporting patient-facing EHI requests while also mitigating privacy and security issues, EHI Export should be protected from potential abuse or exploitation.

- **Patient matching:** CMS seeks comment on ways for ONC and CMS to continue to facilitate private sector efforts on a patient matching strategy. The absence of a consistent approach to accurately identifying patients has resulted in significant costs to the health care system. Patient identification errors often begin during the registration process and can initiate a cascade of errors, including wrong site surgery, delayed or lost diagnoses, and wrong patient orders. As data exchange increases beyond traditional medicine, patient identification and data matching errors will become exponentially more problematic and dangerous. Precision medicine and disease research will continue to be hindered if records are incomplete or duplicative. Accurately

identifying patients and matching them to their data is essential to coordination of care and is a requirement for health system transformation and the continuation of our substantial progress towards nationwide interoperability. The AMA shares the goals of CMS and ONC in increasing patient matching to improve patient safety, better coordinate care, and advance interoperability.

#### *Patient matching algorithms and software*

Before discussing the requirement of patient matching algorithms or software, the AMA believes that indicators surrounding proper validation should be first established as guidance and provide flexibility in allowing patient-matching technologies to mature. Indicators that are necessary for assessment and reporting include database duplicate rate, duplicate creation rate, and true match rate. The current lack of consensus, adoption, and transparency of such indicators makes communication, reporting, and cross-provider or cross-organizational comparisons impossible, impedes a full and accurate assessment of the extent of the problem, prohibits informed decision making, limits research on complementary matching methods, and inhibits progress and innovation in this area. Moreover, CMS needs to account for the fact that specific algorithms and software solutions are system, vendor, data, and organization dependent. Thus, any guidance or requirements should be algorithm agnostic.

#### *CMS identifier*

The AMA has concerns about requiring a CMS-wide identifier as being a step towards a government-issued unique patient identifier. CMS and ONC should be offering technical assistance to private-sector led initiatives that support a coordinated national strategy to promote patient safety by accurately identifying patients and matching them to their health information. A CMS identifier would go beyond such technical assistance and raises privacy concerns and risk that the identifier becomes a de facto ID for other potentially questionable purposes. Moreover, implementation and operation of a required identifier could be expensive and administratively burdensome. Furthermore, the presence of an identifier does not equate to a high assurance identity proofing process or a high assurance authentication process.

#### *Use of USCDI*

The AMA believes that CMS should coordinate with ONC to advance more standardized data elements for patient matching by leveraging the USCDI. Additionally, CMS and ONC should work together to establish guidance surrounding common issues that could be resolved by standardization, such as the following:

- Recording names with spaces, hyphens, or apostrophes;
- Listing addresses in single or separate fields (e.g., separately street names from the city and state);
- Including special characters in phone numbers; and
- Handling missing data for fields (e.g., SSN, email address).

#### *Verifying data sources for identity proofing*

The AMA believes that use of any potential data source for identity proofing and patient matching should only be used for those specific purposes. CMS should not support the use of identity proofing data sources for discriminatory reasons, eligibility determinations, or to limit medically necessary care.



- **Patient-generated health data (PGHD):** CMS seeks comment on a number of concepts related to PGHD, including how the PI program should be leveraged to reward physicians for obtaining, reviewing, and analyzing PGHD. We begin by noting that though the prospect of patient-generated data is evolving, there are still questions of whether patient-generated information is relevant, accurate, and meaningful, to say nothing of the issues related to information collection, usage, storage, privacy, and security.

Today's app landscape offers more opportunity than ever before for patients to generate and collect health data. Yet the information yielded through health-related smartphone applications can be of uncertain reliability (for example, one study showed a 30 percent error rate in assessing melanoma risk that could result in delayed diagnosis and associated patient harm)<sup>4</sup>. Moreover, patients may not be aware that the HIPAA Rules are inapplicable to apps, networks, and service providers that are neither covered entities nor business associates, thereby affording a significantly lower degree of regulatory protection to information collected, generated, or transmitted in this fashion. The AMA highlighted these concerns in its comments on CMS' Patient Access and Interoperability proposal and ONC's Information Blocking proposals, noting that a recent study published in the *Journal of the American Medical Association (JAMA)* found that many health apps created to track a user's progress in battling depression or quitting smoking are sharing the personal details they collect about an individual with third parties—like Google and Facebook—without the individual's knowledge or informed consent:

Transmission of data to third-party entities was prevalent, occurring in 33 of 36 top-ranked apps (92 percent) for depression and smoking cessation, but most apps failed to provide transparent disclosure of such practices. Commonly observed issues included the lack of a written privacy policy, the omission of policy text describing third-party transmission (or for such transmissions to be declared in a nonspecific manner), or a failure to describe the legal jurisdictions that would handle data. In a smaller number of cases, data transmissions were observed that were contrary to the stated privacy policies.<sup>5</sup>

**Not only do these practices jeopardize patient privacy and commoditize an individual's most sensitive information, but they also threaten patient willingness to utilize technology to manage their health—a goal frequently expressed by the administration. Until such concerns are addressed, physicians should not be required to encourage their patients to utilize apps to generate and collect PGHD or be penalized for failing to collect PGHD.**

We are also concerned that a PGHD measure would lead to mounds of information without proper context or data segregation. It is not clear how data would be tagged so that it is obvious to the physician where external data originated. Tagging is also an important feature to ensure information is not inadvertently mixed in with clinically generated data. There is a lack of educational resources that help patients, clinicians, and researchers understand the benefits of PGHD use. More guidance and best

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<sup>4</sup> Joel A. Wolf *et al.*, *Diagnostic Inaccuracy of Smartphone Applications for Melanoma Detection*, *JAMA Dermatology*, 149 no. 4 (2013): 422-426.

<sup>5</sup> Kit Huckvale *et al.*, *JAMA Netw Open*. 2019;2(4):e192542, *Assessment of the Data Sharing and Privacy Practices of Smartphone Apps for Depression and Smoking Cessation* (April 19, 2019), available at [https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730782?utm\\_source=For The Media&utm\\_medium=referral&utm\\_campaign=ftm\\_links&utm\\_term=041919](https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2730782?utm_source=For%20The%20Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=041919).

practices are needed to aid the incorporation of PGHD into clinical and research workflows and cultures.<sup>6</sup> Without data integration standards, vendors are likely to vary in the form PGHD are presented to the physician. While this variation could be seen as flexibility in system design, the simple fact is physicians will be challenged to ensure usability. We are concerned patient information could be entered simply as a “data dump” that is not actionable for physicians.

Lastly, we worry about security issues associated with PGHD and seek clarification on how CMS intends to mitigate these issues. For instance, PGHD could be incorporated into an EHR in a variety of ways. It could be hand keyed into a portal by a patient, sent through secure email, or uploaded into the EHR as a file attachment. Each method could open an EHR up to external threats or cyber-attacks. In one of many scenarios, a physician’s EHR allows patients to upload patient-generated data into the EHR through a portal. In this instance, if a patient felt it was necessary to share their data collected through a wearable or remote monitoring device, more than likely the data would be encapsulated into a file for ease of transfer. By selecting and uploading the file from their local computer, the patient may inadvertently introduce a virus or other malicious software into the physician’s EHR. We are very aware of the well-documented threats large medical centers and payers are facing when it comes to cyber-attacks. An infected file uploaded from a patient’s computer could devastate a health system or medical practice’s medical information. Worse still, a compromised EHR could expose the personal medical history of tens of thousands of individuals to the outside world. This level of data breach is drastically different from someone’s credit card number being stolen given the sensitive nature of health care information. As with other industries, it will take time for best practices to develop and evolve to protect EHRs. **Based on these numerous concerns we recommend that CMS refrain from adopting PGHD-related measures at this time. Alternatively, CMS should consider taking the following enabling actions:**

- Prompt collaboration with industry to strengthen model practices, consumer education, and outreach that support the private and secure capture, use, and sharing of PGHD.
- Increase funding for programs that aim to understand the outcomes of PGHD use as part of advanced health care models.
- Provide guidance that assists physicians in understanding the intersection of medical malpractice and liability laws with legal issues related to the use of PGHD.
- **SAFER Guides:** The AMA supports CMS’ concept related to offering points towards a PI program score to hospitals that attest to performance of an assessment based on ONC’s SAFER Guides. In fact, the AMA proposed this concept as an Improvement Activity in the Merit-based Incentive Payment System with a recognition that it would help physicians identify recommended practices to optimize the safety and safe use of EHRs. We continue to believe that the SAFER Guides offer value to practices, and we appreciate CMS’ suggestion that points would be rewarded based on an attestation approach.

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<sup>6</sup> Office of the National Coordinator for Health Information Technology. Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health Data in Care Delivery and Research through 2024. (2018). Available at: [https://www.healthit.gov/sites/default/files/onc\\_pghd\\_practical\\_guide.pdf](https://www.healthit.gov/sites/default/files/onc_pghd_practical_guide.pdf).

## II. Hospital Quality Reporting Programs

We appreciate the opportunity to comment on future measure proposals in the Inpatient Quality Reporting (IQR) program. The AMA offers the following feedback on the proposed measures:

- *Safe Use of Opioids—Concurrent Prescribing eCQM*

The AMA does not support inclusion of this measure in the IQR program due to our ongoing concerns that this measure will not truly drive improvements in care, is not aligned with the Centers for Disease Control and Prevention (CDC) guideline, and may result in unintended negative consequences for patients, hospitals, and physicians.

Specifically, as we stated in previous comments, the measure as currently defined lacks the precision needed to ensure that only those patients as defined by the clinical recommendations are included in the denominator. Considering the *New England Journal of Medicine* article by Dowell and colleagues<sup>7</sup> published on April 24, 2019, the AMA believes that no measure addressing opioid use should be implemented in any federal program until each is reviewed against the guideline to ensure consistency with its intent. Specifically, the CDC clarified that guideline is intended to apply to primary care clinicians who treat adult patients for chronic pain. Measures that call for hard limits and lead to abrupt tapering or discontinuation of opioids for those already receiving these medications are not consistent with the guideline recommendations. In addition, the CDC clarified in a letter to three specialty societies on February 28, 2019 that the recommendations do not apply to those patients receiving active cancer treatment, palliative care, and end-of-life care as well as those with a diagnosis of sickle cell disease. On review of the latest available specifications, the denominator population must be refined to ensure that the right population of patients is captured consistent with the evidence. Without further refinement, the AMA believes that there is a significant risk for the performance of hospitals and their physicians to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of these concurrent medications, then that is an indication of good patient care but the measure must precisely define the patients for which it is appropriate. We do not believe that this measure as specified is an appropriate goal as it may leave patients without access to needed therapies.

- *Hospital Harm—Opioid Related Adverse Events*

The AMA cautions CMS on implementing this eCQM in light of the potential unintended negative consequences it may have in the absence of balancing measures related to appropriate use of naloxone and ensuring that patients receive adequate pain control during their hospitalization, which was identified

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<sup>7</sup> Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. *N Engl J Med*. 2019 Apr 24. doi: 10.1056/NEJMp1904190. [Epub ahead of print] Dowell D. Clarification letter to NCCN, ASCO, and ASH on the CDC's Guideline for Prescribing Opioids for Chronic Pain. February 2019. Available at: <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf>. Accessed on June 7, 2019.

during the recent Measures Application Partnership review. Testing was only completed within two electronic health record (EHR) vendor systems, which does not truly enable us to have a broad understanding of the validity of the data elements outside of those two systems. Additional testing in other EHR vendor systems is needed prior to finalization. We also question whether the information provided as a result of this measure is truly useful for accountability and informing patients of the quality of care provided by hospitals. Specifically, our concern relates to the relatively limited amount of variation discovered during testing of the measure with variation across the five hospitals ranging from 0.12 percent to 0.52 percent. We do not believe measures that currently only identify such small differences in performance allow users to distinguish meaningful differences in performance. This measure is currently under review by the National Quality Forum and its implementation should not be finalized until their evaluation is completed and these concerns are addressed.

- *Hospital Harm—Severe Hypoglycemia eCQM*

The AMA cautions CMS on implementing this eCQM in light of lack of adequate evidence supporting the inclusion of the low glucose value (<40 mg/dL) and the need for a balancing measure assessing the rate of hyperglycemia, which was identified during the recent Measures Application Partnership review. Testing was only completed within two electronic health record (EHR) vendor systems, which does not truly enable us to have a broad understanding of the validity of the data elements outside of those two systems. Additional testing in other EHR vendor systems is needed prior to finalization. We also question whether the information provided as a result of this measure is truly useful for accountability and informing patients of the quality of care provided by hospitals. Specifically, our concern relates to the relatively limited amount of variation discovered during testing of the measure with variation across the six hospitals ranging from 1.05 percent to 3.56 percent. We do not believe measures that currently only identify such small differences in performance allow users to distinguish meaningful differences in performance. This measure is currently under review by the National Quality Forum and its implementation should not be finalized until their evaluation is completed and these concerns are addressed.

At this time, the developer has not provided sufficient data to demonstrate that the measure will capture only those patients for whom concurrent prescribing is not appropriate nor has CMS provided adequate evidence to demonstrate that use of this measure will drive improvements in patient care without also creating potentially negative unintended consequences. The AMA supports addressing the opioid crisis through quality measurement in addition to other avenues but strongly believes that any measures that are used by CMS in federal programs must also demonstrate that it does not compromise patient care.

- *Hospital Harm—Pressure Injury eCQM*

The AMA cautions CMS on implementing this eCQM due to the ongoing challenges with capturing present on admission and stage II pressure injuries within electronic health record (EHR) systems, which was identified during the recent Measures Application Partnership (MAP) review. This concern was validated in the testing provided to the National Quality Forum (NQF) where pressure ulcer information was more likely to be captured in a free text clinical note rather than a discrete field in one of the three systems tested. While we believe that this documentation can be improved over time, it leads us to conclude that additional testing in other vendor systems is needed prior to finalization of this measure. Testing in only three EHR systems is not sufficient. In addition, the MAP requested that the CMS examine whether additional exclusions are needed to capture patients undergoing treatments that may not

be appropriate to receive evidence-based pressure injury reducing interventions such as extracorporeal membrane oxygenation (ECMO); yet, the current version under review by NQF does not appear to address this concern. We also question whether the information provided as a result of this measure is truly useful for accountability and informing patients of the quality of care provided by hospitals. Specifically, our concern relates to the relatively limited amount of variation discovered during testing of the measure with variation across the 24 hospitals ranging from 0.00 percent to 1.46 percent. We do not believe measures that currently only identify such small differences in performance allow users to distinguish meaningful differences in performance. This measure's implementation should not be finalized until the NQF evaluation is completed and these concerns are addressed.

- *Cesarean Birth (PC-02) eCQM (NQF #0471e)*

The AMA does not support finalizing this eCQM due to the concerns raised during the recent Measures Application Partnership (MAP) review, which includes the lack of a precise denominator. The denominator does not exclude high-risk conditions such as pre-eclampsia/eclampsia and the need for risk adjustment has not been explored. The MAP voiced additional concerns related to more robust feasibility testing, the need for balancing measures and assessment of potential unintended consequences. In addition, while the chart-abstracted version of the measure is endorsed, the eCQM version of the measure was submitted to the National Quality Forum (NQF) for endorsement and did not pass the Scientific Methods Panel review due to concerns over the lack of risk adjustment and small sample sizes. Therefore, the concerns increase the potential for the measure to misrepresent hospital performance and the developer has yet to address the concerns. The measure should not be implemented and finalized until these concerns are addressed and received endorsement by NQF.

- *Hybrid Measure- Hybrid Hospital Wide Readmissions (HWR)*

While the AMA agrees that it is useful to understand the rate of readmissions in the 30 days following hospital discharge particularly for quality improvement, we do not believe that there is sufficient evidence to attribute responsibility of these rates to hospitals and a measure on 30-day all-cause readmissions should not be included in any inpatient accountability program. During previous reviews of the evidence provided by CMS, no research demonstrating that hospitals can directly or indirectly impact readmissions within 30 days has been provided. This lack of evidence paired with the continued omission of social risk factors in the risk adjustment model leads us to have significant concerns regarding the use of any measure that holds hospitals responsible for 30-day readmissions. If CMS must continue to include such a measure in the IQR, then the AMA supports the shift to the Hybrid Hospital-Wide, All-Cause Readmissions measure given the improved c-statistic in the risk adjustment model.

### **III. Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures**

The AMA supports the expansion of the confidential reporting of stratified data to the five additional measures in the spring of 2020. We believe that these reports have potential to provide supplemental information to physicians and hospitals on the quality of care they deliver to Medicare beneficiaries and may be useful for quality improvement efforts at the point of care. We caution CMS on any future proposals to make these reports available to the public as hospitals are just beginning to gain familiarity with them and additional experience must be gained. In addition, the differences in the results between these confidential reports and the stratified methodology used by the HRRP could lead to confusion and

may yield conflicting information that may not contribute to informing patients and the public. **We recommend that CMS study these differences, the potential impact on decision-making each may have, and what efforts should be made to harmonize these approaches if and when they are made public.**

We continue to urge CMS to improve data capture to better allow for more robust risk-adjustment related to social determinants of health. Specifically, there is a need to move toward harmonization of assessment tools (including LCDS PAC), and definition of explicit linkages between data capture/representation and terminology standards to allow data aggregation and analysis across populations and systems. For example, Piloting of SDoH programs through the CMS Innovation Center (e.g. Gravity Project use case, United Health Group/AMA ESRD transportation use case) to measure improvement in outcomes, advance best practices in providing interventions and develop mechanisms that pay for data capture, analysis and resulting action. Data derived from assessment surveys, and the algorithms used to analyze those data, should be free of bias that exacerbates health disparities.

#### **IV. Hospital Readmission Reduction Program**

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

While the AMA agrees that it is useful to understand the rate of all-cause readmissions in the 30 days following hospital discharge particularly for quality improvement, we do not believe that there is sufficient evidence to attribute responsibility of these rates to hospitals. According to a recent study in the *Annals of Internal Medicine*, the preventability of readmissions might change over the post-discharge time frame.<sup>8</sup> As the authors highlight, readmissions within seven days of discharge differ from those between eight and 30 days after discharge with respect to preventability. Early readmissions were more likely to be preventable and amenable to hospital-based interventions. Late readmissions were less likely to be preventable and were more amenable to ambulatory and home-based interventions. Therefore, post-seven-days hospital discharge there is potentially little influence a hospital has over a patient being readmitted to a hospital.

The Hospital-wide, All-cause Readmission measure (HRW) is also duplicative of the current set of condition-specific measures. During previous reviews of the evidence provided by CMS on the measure, no research was presented that demonstrated that hospitals can directly or indirectly impact readmissions within 30 days across the broad patient populations treated. This lack of evidence paired with the continued omission of social risk factors in the risk adjustment model leads us to have significant concerns regarding the use of this measure that holds hospitals responsible for all-cause, 30-day readmissions. 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

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<sup>8</sup> Graham, Kelly. Et al (2018). Preventability of Early Versus Late Hospital Readmissions in a National Cohort of General Medicine Patients. *Ann Intern Med*. Doi. 10.7326/M17-1724

impact a patient's care. We believe that there may be community-level variables that affect the risk of readmission during the 30 days following a hospital admission, but are not currently addressed. Measures that extend beyond the hospital stay or outside the locus of control of the measured entity should continue to have SDS adjustment addressed and analyzed at different levels (e.g., patient, hospital, and community). In addition, CMS should work with the developer to continue to explore new variables that are directly related to the community in which a patient resides, particularly given the ASPE report. **As a result, we believe that our concerns fall under Factor 2—measure does not align with current clinical guidelines or practice. The AMA recommends that CMS revisit inclusion of the HWR measure in the HRRP.**

Examining the effects, expected and unexpected, of new and existing programs is exactly what it means to have a learning health system—one that evaluates, shares, and acts. Therefore, the AMA continues to highlight the following areas of exploration in order to provide CMS and our health care system, including physicians and providers, better tools for discriminating between necessary or unnecessary admissions and to improve CMS' HRRP:

- There is a need to examine the data to determine if additional reductions in scores can be made using the existing measures in the HRRP since the readmission rates are now somewhat stable. Minimal improvements (decreases in rates) are now seen for most if not all of the readmission measures, but we do not know whether the rates have plateaued because there is no more room for improvement. Nor do we know if all of readmissions the measures capture are truly appropriate readmissions.
- To a certain degree, some level of readmissions is to be expected. However, we do not yet know with certainty what the appropriate target should be. There remains an urgent need to answer the question so that the benchmarks and program use evidence-based optimal performance scores. These unknowns lead us to ask two questions:
  - Specifically, do the current measures in the program truly identify inappropriate readmissions at this point?
  - If CMS, physicians, and providers continue to try and drive down readmission rates even further, what additional unintended negative consequences for patients might be introduced?
- To what degree is the reported association of lower readmissions with higher mortality found over longer or shorter time periods such as, one year or one week, as compared to the first 30-days post discharge? Gupta and co-authors<sup>9</sup> report that the inverse association was still evident at one year. To what degree are any positive or negative correlations related to all-cause mortality and/or readmissions versus the condition-specific outcome?
- It is also worth examining whether trends exist based on unadjusted data and adjusted data. Most of the studies identified through our search of the literature, including Dharmarajan, et al. (2017), used risk-adjusted data. Most individual patient care decisions are not made with risk-adjustment in mind. To better understand the outliers (those who are readmitted), there is a need to investigate and determine whether there are small, but important associations between reduced readmissions rates with patient mortality. Therefore, are we masking the issue by only examining

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

the adjusted rates? Examination of unadjusted and risk-adjusted rates could help address this concern.

All our recommendations on areas of further study are intended to help CMS, physicians, providers, and patients better understand the impact our actions have on readmissions and outcomes and to improve the quality of care provided to patients.

V. **Future Direction of the Promoting Interoperability Program—Request for Information (RFI) on Potential Opioid Measures**

The AMA appreciates the opportunity to comment on the future direction of the PI program and potential opioid measures. The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. Therefore, we offer the following feedback on the National Quality Forum (NQF) and CDC measures:

*NQF Quality Measures*

- *Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940)*

The AMA disagrees with the fundamental premise of a measure that focuses only on daily dose and duration of therapy involving prescription opioid analgesics because on its own it is not a valid indicator of quality patient care. In fact, since the CDC Guideline for Prescribing Opioids for Chronic Pain<sup>10</sup> was issued, there have been many reports of patients who have been successfully managed on opioid analgesics for long periods of time, and in whom the benefits of such therapy exceed the risks, of being forced to abruptly reduce or discontinue their medication regimens. Such involuntary tapers are associated with sometimes extremely adverse outcomes, including depression, anxiety and emergence of other mental health disorder, loss of function and the ability to perform daily activities, and even suicide. There has been considerable discussion of these unintended consequences at meetings of the HHS Interagency Pain Management Best Practices Task Force.

This measure as currently defined lacks the precision needed to ensure that only those patients as defined by the clinical recommendations are included in the denominator. In light of the *New England Journal of Medicine* article by Dowell and colleagues<sup>11</sup> published on April 24, 2019, the AMA believes that no measure addressing opioid use should be implemented in any federal program until each is reviewed against the guideline to ensure consistency with its intent. Specifically, the CDC clarified that the guideline is intended to apply to primary care clinicians who treat adult patients for chronic pain. Measures that call for hard limits and lead to abrupt tapering or discontinuation of opioids for those already receiving these medications are not consistent with the guideline recommendations. In addition, the CDC clarified in a letter to three specialty societies on February 28, 2019, that the recommendations do not apply to those patients receiving active cancer treatment, palliative care, and end-of-life care as well as those with a diagnosis of sickle cell disease.<sup>12</sup> On review of the latest available specifications, the

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<sup>10</sup> Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49. DOI: <http://dx.doi.org/10.15585/mmwr.rr6501e1>.

<sup>11</sup> Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. *N Engl J Med*. 2019 Apr 24. doi: 10.1056/NEJMp1904190. [Epub ahead of print]

<sup>12</sup> <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf>.



denominator population must be refined to ensure that the right population of patients is captured consistent with the evidence. Without further refinement, the AMA believes that there is a significant risk for the performance of hospitals and their physicians to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

Identifying those patients for whom the daily prescribed morphine milligram equivalents (MME) are considered high may serve as an indicator of whether a patient is at risk of overdose and should be co-prescribed naloxone, but it alone is not an appropriate marker of the quality of care provided. The CDC recommendations allow physicians to document a clinical rationale or justification when suggested dose levels are exceeded; yet, the existing measures that focus on MME do not capture if a justification exists, nor do they provide a well-defined and targeted denominator. CMS should explore more appropriate methods to assess a patient's chronic pain such as the Pain Assessment Screening Tool and Outcomes Registry (PASTOR) and use those patient-reported data on areas as the basis for performance measures. This tool utilizes the Patient Reported Outcomes Measurement Information System (PROMIS) and through the use of Computer Adaptive Testing, key domains such as sleep disturbance and physical function can be assessed in a targeted and patient-directed way.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of significant doses of these medications, then that is an indication of good patient care but the measure must precisely define the patients for which it is appropriate. We do not believe that this measure as specified is an appropriate goal as it may leave patients without access to needed therapies.

In addition, the AMA has significant concerns with the proposed inclusion of this measure in the Promoting Interoperability Program because it was developed with the intention of determining the quality of care provided by prescription drug health plans, and not for hospitals. The measure as currently specified requires access to health plan medical and pharmacy claims and member enrollment information; hospitals are less likely to have access to these data sources and we do not believe that re-specifying this measure for electronic health record reporting is appropriate nor would it produce valid results.

Currently, the developer has not provided sufficient data to demonstrate that the measure will capture only those patients for whom high dosage prescribing is not appropriate nor has CMS provided adequate evidence to demonstrate that use of this measure will drive improvements in patient care without also creating potentially negative unintended consequences. The AMA supports addressing the opioid crisis through quality measurement in addition to other avenues but strongly believes that any measures that are used by CMS in federal programs must also demonstrate that it does not compromise patient care and produces valid and reliable results.

- *Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950)*

The AMA has significant concerns with the proposed inclusion of this measure in the Promoting Interoperability Program because it was developed with the intention of determining the quality of care provided by prescription drug health plans, and not for hospitals. The measure as currently specified

requires access to health plan medical and pharmacy claims and member enrollment information; hospitals are less likely to have access to these data sources and we do not believe that re-specifying this measure for electronic health record reporting is appropriate nor would it produce valid results. Comprehensive assessment of the feasibility of collecting and reporting these data at the hospital level must be determined. For example, it is unclear whether hospitals can access data to confirm that prescriptions were not received outside of their system. Ensuring that hospitals can collect the data needed to satisfy the measure requirements is necessary to inform and allow thorough evaluations of the reliability and the validity of the performance scores.

In addition, this measure as currently defined lacks the precision needed to ensure that only those patients as defined by the clinical recommendations are included in the denominator. In light of *the New England Journal of Medicine* article by Dowell and colleagues<sup>13</sup> published on April 24, 2019, the AMA believes that no measure addressing opioid use should be implemented in any federal program until each is reviewed against the guideline to ensure consistency with its intent. Specifically, the CDC clarified that guideline is intended to apply to primary care clinicians who treat adult patients for chronic pain. Measures that call for hard limits and lead to abrupt tapering or discontinuation of opioids for those already receiving these medications are not consistent with the guideline recommendations. In addition, the CDC clarified in a letter to three specialty societies on February 28, 2019 that the recommendations do not apply to those patients receiving active cancer treatment, palliative care, and end-of-life care as well as those with a diagnosis of sickle cell disease.<sup>14</sup> Furthermore, based on our review of the latest available specifications, the denominator population must be refined to ensure that the right population of patients is captured consistent with the evidence. Without further refinement, the AMA believes that there is a significant risk for the performance of hospitals and their physicians to be inaccurately represented. More importantly, there is a substantial risk that patients for whom these medications may be warranted will not receive appropriate therapies, leading to potential adverse outcomes, including depression, loss of function and other negative unintended consequences.

The AMA believes that quality measurement needs to focus on how well patients' pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. If pain can be well controlled and function improved without the need of these medications, then that is an indication of good patient care but the measure must precisely define the patients for which it is appropriate. At this time, the developer has not provided sufficient data to demonstrate that the measure will capture only those patients for whom prescribing is not appropriate nor has CMS provided adequate evidence to demonstrate that use of this measure will drive improvements in patient care without also creating potentially negative unintended consequences. The AMA supports addressing the opioid crisis through quality measurement in addition to other avenues but strongly believes that any measures that are used by CMS in federal programs must also demonstrate that it does not compromise patient care and produces valid and reliable results.

- *Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951)*

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<sup>13</sup> Dowell D, Haegerich T, Chou R. No shortcuts to safer opioid prescribing. *N Engl J Med*. 2019 Apr 24. doi: 10.1056/NEJMp1904190. [Epub ahead of print]

<sup>14</sup> Dowell D. Clarification letter to NCCN, ASCO, and ASH on the CDC's Guideline for Prescribing Opioids for Chronic Pain. February 2019. Available at: <https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2019-CDC-Opioid-Guideline-Clarification-Letter-to-ASCO-ASH-NCCN.pdf>. Accessed on June 7, 2019.

As the AMA outlined in our comments on the individual NQF measures (2950 and 2951), this rolled-up measure lacks consistency with the CDC guideline recommendations and questions the validity of the results when derived from electronic health record data. In addition, after reviewing the performance scores provided during the NQF endorsement of the health plan version of the measure, we question whether this measure has adequate variation in scores to enable meaningful comparisons in performance. The testing results demonstrated that less than a 2.5 percent difference existed between the minimum and maximum rates for the Medicare population and less than 5.5 percent difference existed for the Medicaid population. If similar rates were to be found when applied to hospitals, we believe that it will be difficult to distinguish better versus worse care. In addition, this measure must be adequately specified and tested across inpatient facilities prior to its implementation. Given the ongoing concerns with this measure, the AMA does not support its inclusion in the PI Program.

- *CDC Quality Improvement (QI) Opioid Measures*

As the AMA highlighted in our comments on the NQF measures, the AMA believes that the current approach to address the opioid crisis through quality measurement has been too narrowly focused on preventing and/or reducing opioid use in the absence of addressing the larger clinical issue—ensuring adequate pain control while minimizing the risk toward opioid addiction. Quality measurement must focus on how well patients’ pain is controlled, whether functional improvement goals are met, and what therapies are being used to manage pain. As a result, while we are supportive of these CDC measures due to their alignment with the original guideline intent, we believe that they are too narrowly focused. Therefore, we recommend that CMS should develop measures that examine adequate pain control with appropriate therapies of which opioids may be an option. Until such time that these broadly applicable measures are available, we do not support continued inclusion of these narrowly focused measures.

We also would like to highlight that many of the CDC measures, specifically the long-term opioid therapy measures are duplicative of the NQF measures and continue to have the same concerns that are highlighted earlier in our comments on the NQF measures.

## **VI. PPS-Exempt Cancer Hospital Quality Reporting Program**

### *Pain Management Measures and Measurement Concepts for the Cancer Patient Population*

The AMA appreciates the opportunity to provide comment on measurement concepts that evaluate pain management for cancer patients and supports CMS’ proposal to remove the pain management questions from the HCAHPS survey that is used in the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Cancer pain affects millions of Americans and an estimated 40 percent of cancer survivors continue to experience persistent pain as a result of treatment such as surgery, chemotherapy, and radiation therapy.<sup>15,16,17</sup> Persistent pain is also common and significant in patients with a limited

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<sup>15</sup> National League of Cities and National Association of Counties. A Prescription for Action: Local Leadership in Ending the Opioid Crisis. Washington, DC; 2016. [http://opioidaction.org/wp-content/uploads/2017/01/NACo-NLC-JointOpioidReport\\_FINAL\\_12.15.16.pdf](http://opioidaction.org/wp-content/uploads/2017/01/NACo-NLC-JointOpioidReport_FINAL_12.15.16.pdf). Accessed November 21, 2017.

<sup>16</sup> Kong LJ, Lauche R, Klose P, et al. Tai Chi for Chronic Pain Conditions: A Systematic Review and Meta-analysis of Randomized Controlled Trials. *Sci Rep*. 2016;6:25325. doi:10.1038/srep25325

<sup>17</sup> Lee MS, Pittler MH, Ernst E. Tai chi for osteoarthritis: a systematic review. *Clin Rheumatol*. 2008;27(2):211-218. doi:10.1007/s10067-007-0700-4

prognosis, as often encountered in hospice and palliative care. As part of the Trump Administration's efforts to address gaps or inconsistencies for managing chronic and acute pain they have convened The Pain Management Best Practices Inter-Agency Task Force.<sup>18</sup> The report they developed specifically looked at patients with cancer-related pain and patients in palliative care and found there are large gaps in care when it comes to managing these individuals' pain and we recommend that CMS look to these recommendations when developing quality measures around this issue. More specifically, CMS should prioritize two gaps and their associated recommendations:

- The task force identified a gap in quality of pain care when patients' cancer-related or palliative care is managed by practitioners who may not be trained to recognize or treat persistent pain associated with cancer or other chronic medical problems with limited prognosis. It recommended that clinicians assess and address pain at each patient encounter, and evaluate, treat and monitor causes of pain such as recurrent disease, second malignancy or late onset treatment effects.
- A second gap identified by the task force affects patients with persistent pain associated with cancer and/or cancer treatment or other chronic medical problems with limited prognosis in palliative care, who often receive less optimal care with restricted treatment modalities. It recommended that, when clinically indicated, multimodal and multidisciplinary treatment should be part of cancer-related pain management and palliative care.

The identified gaps and associated recommendations are well suited for quality measure development. We encourage CMS to work with the American Society of Clinical Oncology (ASCO), American Society for Radiation Oncology (ASTRO), and PCPI because they are centrally involved in MIPS measures that assess whether pain is quantified and if yes, is there a plan of care for all patients with a cancer diagnosis. The measures are several years old and most likely in need of an update and testing to determine whether appropriate for the PPS-Exempt Cancer Hospital Quality Program. Causes of pain such as recurrent disease, second malignancy or late onset treatment effects should be evaluated, treated, and monitored and measures evaluating current performance on these topics should be developed.

## **VII. Long-Term Care Quality Reporting Program**

- *Social Determinants of Health and Standardized Patient Assessment Data*

The AMA is encouraged to see CMS propose a new category of standardized patient assessment data elements data on social determinants of health (SDoH). The new category will allow for better risk-adjustment in the Long-Term Care Quality Reporting Program and allow providers to better address patients' needs. However, we believe the proposal is a first step because collection of the information is reliant on paper questionnaires and ICD-10 codes. Over time we encourage CMS to move to electronic capture of this information to allow for more robust and granular data. Therefore, the AMA recommends CMS move towards harmonization of assessment tools across settings (including LCDS PAC), and definition of explicit linkages between data capture/representation and terminology standards to allow data aggregation and analysis across populations and systems. CMS should also consider piloting of SDoH programs through the CMS Innovation Center, such as the current efforts being spearheaded by the Gravity Project. For example, through the Gravity Project, the AMA in conjunction with the United

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<sup>18</sup> Pain Management Best Practices Inter-Agency Task Force, <https://www.hhs.gov/ash/advisory-committees/pain/index.html>

Health Group is piloting a transportation use case to measure improvement in outcomes, advance best practices in providing interventions and develop mechanisms that pay for data capture, analysis and resulting action. Out of caution, CMS must also ensure data derived from assessment surveys, and the algorithms used to analyze those data, should be free of bias that exacerbate health disparities. The AMA welcomes the opportunity to work with CMS on piloting innovative solutions for capturing SDoH data and explain our ongoing efforts on improving SDoH data.

### **VIII. Innovation**

- *RFI Substantial Clinical Improvement Criterion: Add-On Payment and Transitional Device Pass-Through Payment Amount*

CMS proposes to modify how the Agency analyzes and appraises “substantial clinical improvement” for determining which medical technology merits IPPS add-on payments and OPPS transitional pass-through payments. The AMA strongly supports CMS policies that establish a clear and predictable pathway to payment for innovative technologies. CMS should adopt policy changes that advance the quadruple aim. Developers and manufacturers should be incentivized to pursue technological advances that demonstrably improve patient health outcomes, lower costs, result in better population health, and improve the experience of physicians and the extended health care team. The foregoing should underpin the assessments of all new technologies. Why? Demographic changes including the overall aging of the U.S. and global populations, are projected to increase the demand on federal health care programs. At the same time it is projected that there will be proportionately fewer working people contributing to the Medicare trust fund per beneficiary. The result will be fewer human and financial resources available to meet an increased demand for health care services.

As a result of the foregoing, the AMA appreciates that CMS is seeking information to provide greater clarity and predictability with regard to applications that meet the criterion for substantial clinical improvement. As the add-on payments represent an additional cost to federal funding, the AMA urges CMS to ensure that clinical benefit is clearly established. To that end, CMS should consider as evidence of clinical benefit not only the results of randomized, prospective clinical trials<sup>19</sup> but other well-defined and rigorous processes and sources. In certain instances real world evidence (RWE) would be appropriate, but it would not be appropriate to only rely on the use of real world data. The RWE methods employed as well as the data sources will have to be carefully considered.<sup>20</sup> The Food and Drug Administration (FDA) has defined RWE as “information on health care that is derived from multiple sources outside typical clinical research settings, including EHRs, claims and billing data, product and disease registries, and data gathered through personal devices and health applications.” And, the FDA has issued guidance: “Use of Real-World Evidence to Support Regulatory Decision Making for Medical Devices” that should guide

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<sup>19</sup> While randomized clinical trials (RCTs) have been considered the gold standard, RCTs have imitations which include being conducted in highly selected populations (that are not diverse or representative) and specialized environments that require intensive monitoring to ensure adherence to study protocol, neither of which may represent everyday clinical practice. *Real-World Evidence - What Is It and What Can It Tell Us?* Sherman RE, Anderson SA, Dal Pan GJ, Gray GW, Gross T, Hunter NL, LaVange L, Marinac-Dabic D, Marks PW, Robb MA, Shuren J, Temple R, Woodcock J, Yue LQ, Califf RM *N Engl J Med.* 2016 Dec 8; 375(23):2293-2297; and, *Participation in cancer clinical trials: race-, sex-, and age-based disparities.* Murthy VH, Krumholz HM, Gross CP *JAMA.* 2004 Jun 9; 291(22):2720-6.

<sup>20</sup> Dhruva SS, Ross JS, Desai NR. *Real-World Evidence: Promise and Peril For Medical Product Evaluation.* *P T.* 2018;43(8):464–472.

CMS approaches to RWE. In addition, the National Evaluation System for health Technology (NEST) has been established to “efficiently generate better evidence for medical device evaluation and regulatory decision-making.”<sup>21</sup> The stated purpose of NEST is to “generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices.” CMS should also carefully consider the policies, methods, and protocols developed by NEST related to RWE. In addition, the AMA supports CMS consideration of evidence developed through rigorous methods with regard to off-label uses. However, the AMA continues to strongly urge CMS to heavily weight results published in peer-reviewed journals as yet-another means of ensuring that the evidence has been more fully considered within the medical commons.

- *Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices*

CMS proposes to eliminate the substantial clinical improvement criteria for medical technology participating in the FDA Breakthrough Device Program. While the AMA supports increasing flexibility that incentivizes the development of innovative technologies, removing the clinical improvement criteria would not necessarily advance the quadruple aim. To the extent that CMS does not adopt expanded evidentiary requirements for establishing substantial clinical improvements, it might be appropriate to eliminate the substantial clinical improvement criterion for medical technologies that have received FDA Breakthrough Device program status. However, in lieu of waiving this requirement, the AMA strongly urges CMS to instead, as discussed in the above section, expand the evidence relied upon to assess substantial clinical improvement. Furthermore, the AMA would not support waiving this requirement in the context of a 510(k) clearance, but it could be appropriate for a de novo classification and pre-market approval if CMS has not modified the substantial clinical improvement criteria and related policies. Specifically, it would not be appropriate to consider a product “new and not substantially similar” to an existing technology if the medical device receives a 510K clearance based on a predicate device.

- *Proposed Revision of the Calculation of the Inpatient Hospital New Technology Add-On Payment*

CMS seeks comments on a proposal to increase the value of the IPPS new technology add-on payment. Currently, CMS caps the add-on payment amount at 50 percent and reportedly this may not be a sufficient incentive for the use of new technology given the clinical integration challenges some of these technologies present. The AMA supports modifying the current payment mechanism to increase the amount of the maximum add-on payment amount to 65 percent, but would have concerns if the amount was increased above 65 percent without information demonstrating uptake remains anemic.

#### **IX. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS-DRG) – Extracorporeal Membrane Oxygenation (ECMO)**

Several physicians and specialty medical societies brought to the AMA’s attention changes to Medicare reimbursement for ECMO and modifications to the relevant ICD-10-PCS codes. We have major concerns that these changes were made without sufficient opportunity for public comment and without objective information supporting the change. Transparency and public comment must be the cornerstone of policy

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<sup>21</sup> [FDA: National Evaluation System for Health Technology \(NEST\)](#) Accessed January 17, 2019.

changes such as this one. The AMA strongly believes that CMS should seek specialty and stakeholder input prior to implementation of reimbursement and policy changes that have the potential to negatively impact patient access to care.

## **X. Graduate Medical Education Issues**

- *Medicare GME for Teaching Hospitals and Payments to CAHs*

CMS proposes a change relating to how full-time equivalent (FTE) resident time may be counted when residents train at critical access hospitals (CAHs). Under current Medicare policy, a CAH is not considered a “nonprovider setting,” which prohibits IPPS hospitals from claiming on their cost reports any time residents spend at CAHs, even if the IPPS hospitals incur the stipend and benefit costs for residents during their training at the CAH. Some CAHs are unable to support residency training programs. “In order to support the training of residents in rural and underserved areas” (p.19447), CMS is proposing to permit IPPS hospitals to count the time residents spend training at CAHs, so long as the nonprovider site requirements are met. The AMA supports CMS’ proposal to provide flexibility by counting the time residents spend training at CAHs; we believe this change will expand access to care in rural and underserved areas. We trust that, as stated in the proposed rule (p.19448), once the proposal is finalized, “CMS will work closely with HRSA and the Federal Office of Rural Health Policy to communicate the increased regulatory flexibility to CAHs as well as existing residency programs and the options it affords for increasing rural residency training.”

- *Allow Flexibility for IPPS Hospitals Within Their Cap-Building Period to Count All Residents for Cap-Calculation Purposes*

The AMA also encourages CMS to allow IPPS hospitals currently within their cap-building period to count the time residents previously spent training at CAHs at any point during their cap-building period. This would apply for cap-calculation purposes only and would not require CMS to reopen previous years’ cost reports. There are many teaching hospitals that are several years into, or at the end of, their cap-building period that have struggled to accommodate rotations to CAHs as a result of this restriction. Permitting these hospitals to count FTEs that would have otherwise been counted toward their cap development under the proposed policy would allow for additional training in rural and underserved areas each year.

- *Regulations to Allow for Electronic Submission of Applications for Reclassification from urban to Rural Status*

Current requirements under 42 CFR §412.103(b)(3) state that for reclassification from urban to rural status applications must be mailed to the CMS Regional Office by the requesting hospital and may not be submitted by facsimile or other electronic means. CMS is proposing to eliminate the restriction on submitting an application by facsimile or other electronic means so that hospitals may also submit applications to the CMS Regional Office electronically. The AMA applauds this proposal in an effort to reduce burden and promote ease of application.

- *Cancellation Requirements for Rural Reclassifications*

Currently, 42 CFR § 412.103(g)(2) requires that, for a hospital that has been classified as a rural referral

The Honorable Seema Verma

June 24, 2019

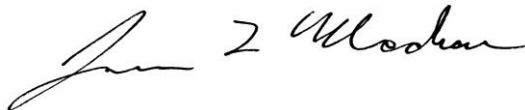
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center (RRC) based on rural reclassification under 42 CFR §412.103, cancellation of a rural reclassification is not effective until the hospital that is classified as an RRC has been paid as rural for at least one 12-month cost reporting period, and not until the beginning of the federal fiscal year following both the request for cancellation and the 12-month cost reporting period. CMS proposes to remove the 12-month requirement and instead apply uniform cancellation requirements that would allow hospitals to cancel reclassifications 120 days before the end of the federal fiscal year. The AMA supports these proposed changes to the cancellation requirements, and applauds CMS' efforts to reduce administrative burden.

### **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 2020 IPPS/LTC Proposed Rule. If you have any questions please contact Margaret Garikes, Vice President of Federal Affairs, at [margaret.garikes@ama-assn.org](mailto:margaret.garikes@ama-assn.org) or 202-789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive, flowing style.

James L. Madara, MD