American College of
Emergency Physicians®

ADVANCING EMERGENCY CARE

June 24, 2019

Re: CMS-1716-P

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

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 Proposed Rule

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Dear Administrator Verma:

On behalf of over 39,000 members, the American College of Emergency Physicians (ACEP) appreciates the opportunity to comment on the fiscal year (FY) 2020 Inpatient Prospective Payment System (IPPS) proposed rule. There are a few proposed policies and requests for information within the rule that, if finalized, would have a significant impact on emergency physicians and the patients we serve.

Proposed Add-On Payments for New Services and Technologies for FY 2020

Currently, CMS provides additional payment for new medical services and technologies under the IPPS. One of the requirements for this additional payment is that the new service or technology demonstrate a substantial clinical improvement over existing services. CMS has received questions from stakeholders on what data must be presented to meet this "substantial clinical improvement" requirement. Therefore, CMS is seeking comment on specific details and guidance stakeholders would find useful in understanding the Agency's approach to evaluating such data.

ACEP believes that these add-on payments for new technologies are critical to ensuring that hospitals have the capability to treat their most complex patients, especially those who come to the emergency department (ED) and then get admitted to the hospital. Without these payments, some products could be cost prohibitive for certain hospitals. Given the importance of these payments, we encourage CMS to provide greater clarity on the types of evidence that may be considered by the Agency in assessing substantial clinical improvement.

CMS also acknowledges that the new technology add-on payment (NTAP) program does not adequately reflect the costs of new technology,"[1] particularly in the context of "a new technology with an unprecedented high cost, such as the chimeric antigen receptor (CAR) T-cell therapies."[2] Accordingly, CMS proposes to change the new technology add-on payment amounts beginning in FY 2020 from 50 percent to 65 percent. If finalized, the maximum add-on payment would increase from $186,500 to $242,450. ACEP appreciates CMS' recognition that the current NTAP levels are insufficient and supports this increase to incentivize the development of new treatments.

Quality Reporting/Performance Programs

CMS is proposing a number of changes to the Hospital Inpatient Quality Reporting (IQR) Program, including adding the following two new opioid-related quality measures beginning with the calendar year (CY 2021) reporting period/FY 2023 payment determination: Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure (eCQM) and Hospital Harm – Opioid-Related Adverse Events eCQM.

Safe Use of Opioids – Concurrent Prescribing electronic clinical quality measure (eCQM)

As emergency physicians, we are on the front lines of the opioid epidemic, so we understand the benefits of medication-assisted treatment (MAT) and support the use of non-opioid alternatives for pain management. We also generally agree with the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, which recommends that clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible.[3] However, despite our support for these initiatives, we have concerns with the structure of the Safe Use of Opioids – Concurrent Prescribing eCQM. We previously raised these concerns during the measure development process[4] but believe that CMS has not adequately addressed them.

The Safe Use of Opioids – Concurrent Prescribing eCQM is a process measure that calculates the proportion of patients age 18 years and older prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (inpatient and ED including observation stays).[5] In the rule, CMS states that the agency recognizes "that there may be some clinically appropriate situations for concurrent prescriptions of two unique opioids or an opioid and benzodiazepine. Thus, we do not expect the measure rate to be zero; rather, the goal of the measure is to help systems identify and monitor patients at risk, and ultimately, to reduce the risk of harm to patients across the continuum of care."[6] While we appreciate that CMS acknowledges that it may be appropriate for some patients to have concurrent active prescriptions of two unique opioids or an opioid and benzodiazepine, we are concerned that even including the measure in the Hospital IQR may have some inappropriate, unintended consequences. First, CMS does not take into account the potential bias this measure could pose against emergency physicians, who may, through no fault of their

[1] 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 Proposed Rule, 84 Fed. Reg. 19373 (May 3, 2019).
[2] Ibid.
[3] Dowell, D., Haegerich, T. & Chou, R. (2016). CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. Morbidity and Mortality Weekly Report: Recommendations and Reports, 65. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[4] "Safe Use of Opioids—Concurrent Prescribing Public Comment Summary Report," https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Hospital-Inpatient-and-Outpatient-Process-and-Structural-Measure-Development-and-Maintenance.pdf.
[5] 84 Fed. Reg. 19477
[6] Ibid.

own, discharge a patient from the ED who has concurrent (previous) prescriptions of two unique opioids or an opioid and benzodiazepine written by another provider unrelated and prior to the current ED visit. In many cases, emergency physicians see patients with acute conditions who we have never seen before. We do not choose our patient population, and per the Emergency Medical Treatment & Labor Act (EMTALA), are required to care for all patients who present for care. We are also not primary care physicians and do not have control over the medications that the patients have been prescribed prior to arrival to the ED. We deliver episodic care and are not in a position to disrupt an established physician-patient relationship that the patient has with their primary care physician, and as such are not in a position to stop medications that patients are being prescribed by their primary care physician. Therefore, performance on this measure is largely outside of the control of emergency physicians, especially when they present to the ED with active opioid and benzodiazepine prescriptions. In all, emergency physicians should not be held accountable and penalized for medications that they do prescribe and should not be held responsible for modifying a treatment regimen that was established prior to the patient's ED visit. **We strongly believe that this measure may pose a patient safety risk. The presence of the measure in the Hospital IQR Program could incentivize providers to abruptly cease a patient's established medications during emergent situations, which could potentially result in the undertreatment or mistreatment of pain or development of withdrawal syndromes which may include acute seizures.**

Another challenge for emergency physicians is that we do not always have access to a list of a patient's medications. In an ideal world, we should know the patient's medications, but our experience is that often the patients themselves do not know them. Most of the information available from the electronic health records (EHR) represents the last inpatient visit, and medications may, and do, change with subsequent outpatient visits. As we have stated in the past, we are eager to work with hospitals toward the goal of interoperable EHRs that will open the door to more comprehensive patient information sharing across sites of care. Linking disparate EHRs will allow us to make more informed decisions and will significantly enhance timely communication with patients, community physicians, and other caregivers.

Finally, we are concerned that CMS did not adequately address our previous request during the measure development phase to exclude patients with sickle cell disease from the measure. These patients generally require a baseline opioid with additional, often different, opioids for break-through pain. We had suggested in our previous comments that the measure be limited to large quantities of medications. This would provide the option for emergency physicians to continue a patient's multiple opioid or opioid/benzodiazepine regimen for five days.[7] In the rule, CMS decides to include patients with sickle cell disease in the measure denominator because: "expert opinions from clinicians recommended continuing to include patients for whom concurrent prescribing may be clinically necessary because experts stated that these populations are at highest risk of adverse drug events due to concurrent prescriptions and should continue to be monitored by clinicians throughout the continuum of care."[8] However, we believe CMS should go further in the final rule by specifically describing how this measure should be appropriately applied and interpreted in cases where patients with sickle cell disease are being discharged from the ED. In general, we continue to receive reports that individuals with sickle cell disease and their medical providers are unable to obtain access to appropriate medication because of opioid prescribing policies regarding duration and dosage. We are extremely concerned about these issues and encourage CMS, along with other offices within the Department of Health and Human Services (HHS), to take

[7] "Safe Use of Opioids—Concurrent Prescribing Public Comment Summary Report," https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Hospital-Inpatient-and-Outpatient-Process-and-Structural-Measure-Development-and-Maintenance.pdf
[8] 84 Fed. Reg. 19476.

additional action to raise awareness about the challenges that individuals with sickle cell disease continue to face.

Hospital Harm – Opioid-Related Adverse Events eCQM

The Hospital Harm – Opioid-Related Adverse Events eCQM measure would help "hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm, such as respiratory depression, which can lead to brain damage and death." [9] This outcome measure assesses, by the hospital, the proportion of patients who had an opioid-related adverse event during admission to an acute care hospital by assessing the administration of naloxone. ACEP understands that the measure focuses specifically on in-hospital opioid-related adverse events, rather than opioid overdose events that happen in the community and may bring a patient into ED.

While we appreciate that this measure is not meant to disincentivize the appropriate use of naloxone in the community and the ED, we do believe that a potential unintended consequence of this measure is that it would discourage the *in-hospital* use of naloxone. ACEP strongly agrees with CMS that naloxone "is a lifesaving emergent therapy with clear and unambiguous applications in the setting of opioid overdose," [10] and we do not think that CMS should be finalizing a measure that could in any way discourage its use in any clinical or community setting.

Proposed Public Display of the Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure Beginning with CY 2020

CMS proposes to begin public reporting of the *Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy* measure in CY 2020. ACEP appreciates that this measure intends to address current issues with "outpatient chemotherapy patients having unmet needs and gaps in care, which, if addressed, could reduce admissions and ED visits and increase patients' quality of life." [11] However, we want to make sure that these high-risk patients are not in any way disincentivized from going to the ED when they feel that they have a medical emergency. We also do not want outpatient providers to be discouraged from sending their patients to the ED when appropriate.

Promoting Interoperability Programs

For CY 2021, CMS proposes an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and critical access hospitals [CAHs]) in the Medicare Promoting Interoperability Program attesting to CMS. ACEP supports a 90-day reporting period both for hospitals/CAHs and providers under the Promoting Interoperability (PI) Category of the Merit-based Incentive Payment System (MIPS).

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[9] 84 Fed. Reg. 19478.
[10] Ibid.
[11] "Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy," https://cmit.cms.gov/CMIT_public/ReportMeasure?measureRevisionId=672.

Query of PDMP Measure

In last year's rule, CMS had finalized that the Query of PDMP measure would be optional and available for bonus points for CY 2019 but required in CY 2020. However, based on feedback from health IT vendors and hospitals, CMS is now proposing to make the Query of PDMP measure optional in CY 2020 and eligible for five bonus points. While ACEP believes that PDMPs play an important role in identifying high-risk patients, we agree that CMS should move slowly to allow sufficient time for PDMPs to become fully integrated into clinicians' EHRs and their workflow. We support effective and interoperable PDMPs that push prescription data to emergency physicians, rather than requiring them to separately sign into and pull the data from the PDMP. Currently, not all states have optimally functional PDMPs, resulting in highly variable usability and trustworthiness. Some states have not made commitments to make their PDMPs state-of-the-art, and as a result, they are cumbersome, may not contain real-time data, and the information can be unreliable. In addition, patients may cross state lines for care, and not all states are part of InterConnect, which shares interstate information about dispensed prescriptions.

ACEP appreciates that CMS is making this measure optional again in 2020. Going forward, we believe that, under only certain conditions, it would be appropriate for CMS to require a hospital or CAH to query a PDMP for at least one Schedule II opioid that is electronically prescribed. These conditions include having the Office of the National Coordinator (ONC) consider adopting new EHR certification criteria that require EHRs to integrate PDMPs into their existing capabilities. Furthermore, CMS should require all PDMPs to be interoperable and to include certain standards, such as privacy and security protocols that protect patient sensitive information.

Requests for Information (RFIs)

RFI on a Metric to Improve Efficiency of Providers within EHRs

CMS is seeking comment on a potential metric to evaluate health care provider efficiency using EHRs under the Promoting Interoperability Program. In general, ACEP believes that it is the responsibility of EHR vendors to make their products more efficient and easier for providers to use. With respect to emergency medicine, emergency physicians do not have control over the specific EHR vendor or product their hospital is using and how the hospital choses to implement the overall system. Therefore, EHR vendors should do more to integrate EHRs into emergency physicians' clinical workflow and to improve the usability of data that is retrieved from the EHR. CMS should also take specific actions to increase the efficiency of health care provider interactions with EHRs. The agency could provide incentives to hospitals through the Promoting Interoperability Program or alter its current scoring methodology to build in an efficiency measure that rewards hospitals for investing in new technologies, such as instituting a single sign-on for all of their IT systems.

EHRs contain vast amounts of data, and we need better tools to be able to utilize that data efficiently and effectively to serve our patients better. The ability to find information quickly is most critical when emergency physicians and other emergency medical service (EMS) providers respond to both man-made and natural disasters. During disasters, we must have access to real-time data regarding all of the available health care resources in the affected region. However, unfortunately emergency physicians do not always know where or how to find this essential information. ACEP surveyed its members in May 2018 and found that over a quarter of emergency physicians did not have complete access to real-time data when responding to a natural or man-

made disaster or mass casualty incident.[12] This is not acceptable, and we strongly encourage the Administration to help improve providers' access to clinical data and information on available health care resources during these devastating events.

The lack of consistency regarding how data are displayed in EHRs also makes it hard for us as emergency physicians to search for what we need and find it in a timely manner. For example, some information can be stored in the EHR as a scanned image rather than as structured data, making it almost impossible at times to find the data we are looking for. Finally, we need to improve the way patient information is collected and entered into EHRs to better integrate it into the clinical workflow. A lot of the data we are forced to collect and screenings we are required to perform are not necessary and do not add clinical value. Also, as referenced above, we believe that a lot of the documentation and provider entry that we currently do is duplicative. We support the use of non-physician aids to put in orders and data and also encourage the use of scribes and dictation to reduce physician burden further. Going forward, we would like to see more advancements in technical innovations that would further automate the collection process of structured data (such as voice recognition technology and connected devices) and make it even easier for providers to enter usable information into EHRs.

RFI on the Provider to Patient Exchange Objective

Building off proposals in both the CMS Interoperability and Patient Access Proposed Rule[13] and the Office of the National Coordinator (ONC) for Health Information Technology Interoperability and Information Proposed Rule[14], CMS is seeking comment on whether eligible hospitals and CAHs should make patient health information available immediately through the open, standards-based application programming interface (API), no later than one business day after it is available to the eligible hospital or CAH in their CEHRT. ACEP is extremely concerned about the impact that imposing tight deadlines on hospitals may have on hospital-based providers, such as emergency physicians. **ACEP believes that if CMS instituted this requirement, hospitals would impose short, unrealistic turn-around times for hospital-based clinicians to provide the information.** Quick deadlines could lead to mistakes and inaccurate information being put on the API. These issues would be exacerbated in the emergency care setting. A large proportion of emergency care involves the acute diagnosis, treatment, and stabilization of diffuse and undifferentiated clinical conditions. For example, two of the most common patient presentations are "chest pain" and "abdominal pain." These initial symptoms have a large range of ultimate diagnoses and require a large variety of patient-specific lab tests, radiology exams, and other interventions. Due to the unpredictability of emergency care, sorting out claims for individual cases is a complex and timely process. **We therefore strongly recommend that CMS does not require hospitals to make patient health information available through the API no later than one business day after it is available to the hospital in their CEHRT**. While we understand the need to get information to consumers as quickly as possible so that they can make more informed decisions about their health care, what is even more important is that the information they are receiving is accurate.

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[12] ACEP New Release, "Most Emergency Physicians Report Hospitals Lack Critical Medicines; Not "Fully Prepared" for Disasters, Mass Casualty Incidents," May 22, 2018, http://newsroom.acep.org/2018-05-22-Most-Emergency-Physicians-Report-Hospitals-Lack-Critical-Medicines-Not-Fully-Prepared-for-Disasters-Mass-Casualty-Incidents

[13] Medicare and Medicaid Programs: Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers Proposed Rule, 84 Fed. Reg. (March 4, 2019

[14] 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, 84 Fed. Reg. (March 4, 2019).

Similar to the CMS and ONC Interoperability proposed rules, CMS also seeks comments on ways for ONC and CMS to continue to facilitate a workable and scalable patient matching strategy so that the lack of a specific unique patient identifier (UPI) does not impede the free flow of information. As emergency physicians, we recognize the critical importance of being able to quickly identify our patients and track them across different health care settings. When it comes to treating patients with acute medical needs, minutes and even seconds matter. Therefore, the inability to know who our patients are, and what other services they may have previously received, really impacts our ability to provide the best possible care. To underscore the problem, in 2016, Harris Health System in Houston reported it had 2,488 records with the name "Maria Garcia;" of those, 231 shared the same birthdate, suggesting some of them refer to the same individual.[15] Notably, if all health care organizations collected certain pieces of demographic data uniformly, patient-match rates would increase significantly.

Therefore, in general ACEP supports efforts to create a patient identifier or tracking system. We are cognizant however, about privacy and security concerns around creating a patient identifier. An identifier could become as sensitive as a person's social security number, so creating safeguards to protect it is essential. Further, if the patient identifier is based on a patient's date of birth, former address, or any other background piece of information about the patient, even that has its potential issues. Some patients, especially those who have suffered a trauma, may not know or be able to easily recall this information, which could lead to confusion and potential medical errors.

In addition, we ask CMS to consider the concept of an "error reporting registry" to track patient mismatches and common mistakes that may or may not be Health Insurance Portability and Accountability Act (HIPAA) violations. This registry could help inform further process improvements and necessary updates to both the API and provider processes pertaining to patient record matching. A simple, straightforward way for providers and patients to report instances of information blocking under any variety of circumstances, including faxing, would be of great benefit, particularly to smaller providers.

Beyond patient identification, the number of administrative roadblocks that currently exist to get information about our patients is equally as concerning. We often see patients who have received care from another ED, hospital, or provider, sometimes the same day. When a patient comes to the ED, emergency physicians can rarely see any of the information from the previous healthcare encounter. When we reach out to the other ED, hospital, or provider to ask what happened to avoid duplication of workup and make sure nothing is being missed, we are referred to a medical records office instead of the treating provider and are told that we need to have the patient sign a consent form for release of information and that they cannot be given information over the phone. When health care providers have the opportunity to talk directly to each other, they almost always share all the relevant information that is necessary to treat individual patients. Breaking down the barriers that inhibit or delay these types of conversations from taking place could improve clinical workflow and our ability to provide effective patient care while still preserving patient privacy and data security.

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[15] Giuseppe Lippi et al., "Patient and Sample Identification: Out of the Maze?" Journal of Medical Biochemistry 36 (2017): 1-6, http://dx.doi. org/10.1515/jomb-2017-0003; Harris Health System, "Harris County Hospital District Puts Patient Safety in the Palm of Your Hand" (April 5, 2011), https://www.harrishealth.org/en/news/pages/patient-safety-biometric-palm-scanner.aspx.

CMS is seeking comment on how to further mitigate the specific safety risks that may arise from technology implementation. Specifically, CMS seeks feedback on ways that the Promoting Interoperability Program may reward hospitals for engaging in activities that can help to reduce errors and other patient safety issues associated with EHR implementation. **First and foremost, ACEP strongly believes that physicians should never be penalized for reporting medical errors caused by poor EHR usability. Efforts in some states such as Rhode Island to punish doctors for reporting mistakes that are meant to draw attention to risks in their EHR systems are unjustifiable.[16]** Studies have shown that poor EHR usability has led to certain types of medical errors, as physicians, nurses, and other clinicians use these systems to care for patients, and there is increasing evidence showing the association between usability issues and safety. For example, a study in Health Affairs examining 9,000 health information technology and medication safety events in three pediatric hospitals showed that inadequate usability contributed to approximately a third of the errors, many of which resulted in patient harm.[17]

In August 2018, the Pew Charitable Trusts, MedStar Health's National Center for Human Factors in Healthcare, and the American Medical Association conducted a literature review and convened a multidisciplinary expert panel composed of physicians, nurses, pharmacists, EHR vendors, patients, and health information technology experts. This information led to the development of:

- Recommendations on how to advance usability and safety throughout the EHR software life cycle, which can be used as the foundation for a voluntary certification process for developers and EHR implementers; and
- Criteria are detailing what constitutes a rigorous safety test case and the creation of sample test case scenarios based on reported EHR safety challenges.[18]

We urge CMS to review the findings of this report and work with ONC to incorporate its recommendations, as appropriate.

We appreciate the opportunity to share our comments. If you have any questions, please contact Jeffrey Davis, ACEP's Director of Regulatory Affairs at jdavis@acep.org.

Sincerely,

Vidor E. Friedman, MD, FACEP
ACEP President

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[16] Allen, A. "Rhode Island docs alarmed by subpoenas they link to EHRs," Politico (30 Jan. 2019) https://www.politico.com/story/2019/01/30/medical-misconduct-subpoenas-ehr-1107689.
[17] Ratwani, R. et al. "Identifying Electronic Health Record Usability And Safety Challenges In Pediatric Settings," Health Affairs, Vol. 37, NO.11 (Nov. 2018).
[18] The Pew Charitable Trusts, American Medical Association, & Medstar Health, "Ways to Improve Electronic Health Record Safety: Rigorous testing and establishment of voluntary criteria can protect patients," (Aug. 2018), https://www.pewtrusts.org/-/media/assets/2018/08/healthit_safe_use_of_ehrs_report.pdf.