June 25, 2018

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

[File code CMS-1694-P Submitted electronically via http://www.regulations.gov]

Dear Ms. Verma:

On behalf of the undersigned organizations, we appreciate the opportunity to comment on the potential future inclusion of the Hospital Harm—Opioid-Related Adverse Events electronic clinical quality measure (eCQM) in the hospital inpatient quality reporting program. This potential new measure is described within the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS) proposed rule governing the *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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims.*

The undersigned organizations are part of a broader National Patient Safety Collaborative ("Collaborative") that brings together prominent, national patient safety organizations to collectively work on mutually identified safety concerns and to provide each organization the opportunity to increase the impact of its work. As part of this mission, we support the development of measures to better understand, manage, and prevent adverse events and outcomes. Participation in the Collaborative is voluntary and members may focus on specific issues that fall within their own organization's mission. The undersigned members of the Collaborative with missions that fall within the scope of the proposed bills have provided their comments below.

In light of the nation's existing struggle with opioid addiction, we are supportive of testing an eCQM to address opioid-related adverse events. As you note in the proposed rule, reporting to The Joint Commission's Sentinel Event database indicates that the vast majority of opioid-related adverse drug events are due to preventable causes, such as wrong dose medication errors and improper patient monitoring. With appropriate risk adjustment and exclusions, naloxone administration could be a suitable proxy for opioid-related adverse events.

The undersigned organizations appreciate the use of clinical data, as opposed to administrative claims, for comparative quality metrics because it provides a much more accurate picture of hospital quality than administrative claims, which are not intended for use in quality measurement. We also observe that the majority of data elements that would be required under the proposed rule are routinely captured in the clinical workflow and are available in structured, extractable fields in the

EHR systems. That said, the complexity of the data elements and measure logic could be challenging to implement across hospitals. There is considerable burden required to map the necessary data elements from the EHR to the appropriate format, and some vendors are not properly equipped to collect and transmit such data through the CMS portal.

The undersigned organizations recommend that the measure be introduced as voluntary until it has been proven valid, reliable, feasible and of value through testing. Very few measures should automatically be mandatory, and it is our opinion that this measure is best used for quality improvement until it is better tested. Introducing the measure as voluntary would also allow time to show the measure is compatible with EHR vendors, which is necessary to ensure electronic reporting is viable for all hospitals, and would grant providers sufficient time to prepare for reporting.

We appreciate your consideration of our comments, and we extend our willingness to be a resource in preventing adverse events and improving patient safety. We welcome the opportunity to assist you with your efforts, and are pleased to answer any questions you may have. Please do not hesitate to contact us or have your staff contact Brigid Russell, Associate Director of Federal Relations for The Joint Commission, at 202-783-6655 or brussell@jointcommission.org or Gerard Castro, Project Director for Patient Safety Initiatives for The Joint Commission, at 630-792-5972 or gcastro@jointcommission.org.

Sincerely,

Ronni P. Solomon, JD
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ECRI Institute

Patricia McGaffigan, RN, MS, CPPS
Vice President, Safety Programs;
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Institute for Healthcare Improvement

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Mark R. Chassin, MD, FACP, MPP, MPH
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UNDERSIGNED MEMBERS OF THE NATIONAL PATIENT SAFETY COLLABORATIVE

For nearly 50 years, ECRI Institute, a nonprofit organization, has been dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best, all to enable patient care improvement. ECRI has more than 5,000 members and clients, including hospitals, health systems, public and private payers, U.S. federal and state government agencies, health clinics, patients, policymakers, ministries of health, associations, and accrediting agencies worldwide.

The Institute for Healthcare Improvement (IHI) is an independent not-for-profit organization based in Boston, Massachusetts. Believing that everyone should get the best care and health possible, IHI is a leading innovator, convener, partner, and driver of results in health and health care improvement worldwide. For more than 25 years, IHI has partnered with visionaries, leaders, and front-line practitioners around the globe to spark bold, inventive ways to improve the health of individuals and populations.

The Institute for Safe Medication Practices (ISMP) is the only 501c(3) nonprofit organization devoted entirely to preventing medication errors. During its more than 30-year history, ISMP has helped make a difference in the lives of millions of patients and the healthcare professionals who care for them. ISMP is known and respected as the gold standard for medication safety information, and runs the only national voluntary practitioner medication error reporting program.

The Joint Commission is an independent, not-for-profit organization founded in 1951, which seeks to continuously improve health care for the public in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. The Joint Commission accredits and/or certifies more than 21,000 health care organizations and programs in the United States that span the continuum of care including most of the nation's hospitals. In addition to hospitals, our programs encompass ambulatory, office-based surgery, behavioral health, home care, hospice, and long-term care settings in addition to advanced diagnostic and laboratory entities. The Joint Commission plays a significant role in health care delivery in these settings.