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July 10, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS- 1735-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes for and Fiscal Year 2021 Rates; etc.

Dear Administrator Verma:

Thank you for soliciting feedback on the Centers for Medicare & Medicaid Services' (CMS) proposed regulations to update hospital payment and health information technology-related policies. The use of electronic health record (EHR) systems can both improve safety and contribute to medical errors. Health care faces unprecedented challenges during the COVID-19 outbreak, so it is vital that in CMS' fiscal year 2021 payment rule the agency strikes the right balance between supporting hospitals and encouraging improvements to their practices. While we understand the need to provide flexibility during this upcoming fiscal year, CMS in future rulemaking should consider opportunities to strengthen the Medicare and Medicaid Promoting Interoperability program by addressing aspects of EHR use that contribute to medical errors. Specifically, CMS should consider opportunities that advance the adoption of best practices in EHR use to improve care quality and patient safety.

The Pew Charitable Trusts is a non-profit research and policy organization with several initiatives focused on improving the quality and safety of patient care, facilitating the development of new medical products, and enhancing the coordination of care. Pew's health information technology initiative focuses on advancing the interoperable exchange of health data and improving the safe use of EHRs.

In this proposed rule, CMS updates payment policies for hospitals and seeks comment on the Medicare and Medicaid Promoting Interoperability program, through which the agency encourages health care facilities to use EHRs in different ways. In last year's hospital payment policy regulations, CMS specifically sought input on how to encourage the safe use of EHRs. Since then, additional research has demonstrated the connection between EHR use and patient safety, and offers direction on opportunities for CMS to address these issues.

EHR use continues to affect patient safety

EHR safety challenges can arise due to system usability, which refers to whether clinicians can efficiently and effectively interact with the technology. Usability challenges can result from the initial design of systems, how they are customized by facilities, unique workflows, user training, and other factors.¹ Usability-related safety problems can emerge from confusing interfaces to complete tasks, the need to develop workarounds, an overabundance of unnecessary alerts, and many other issues given the central role that EHRs increasingly have in helping clinicians order procedures, review health information, and obtain decision support.² For example, research published in 2018 showed that EHR usability contributed to approximately a third of 9000 medication errors examined across just three health care organizations that care for children; 609 of these usability related events reached the patients.³ In one case involving the birth of newborn twins, clinicians could not create a record for one of the infants, which delayed a necessary blood transfusion. Ordering a transfusion for the sibling provided a life-saving workaround that added time and opportunity for error.⁴ In another case, a clinician entered a child's weight in pounds when the EHR was configured in kilograms, doubling the child's weight and resulting in the patient receiving twice the appropriate medication dose.⁵

Another recent study found a wide variation in the safety of different EHR systems implemented in facilities.⁶ Using the Leapfrog Computerized Physician Order Entry (CPOE) tool, which assesses the EHR's ability to alert clinicians to medication-related safety issues, researchers studied data on safety from 8657 hospitals over a 10-year period (2009-2018). The researchers found that, despite progress, often EHR use still could contribute to medical errors. For example, EHRs failed to detect safety issues up to a third of the time.

These issues can both detrimentally affect care for Medicare beneficiaries and increase costs due to complications associated with medical errors.

CMS has opportunities to improve EHR safety

CMS recognized the importance of addressing EHR safety in the fiscal year 2020 hospital payment rule. Specifically, CMS requested input on how the agency could encourage adoption of the Safety Assurance Factors for EHR Resilience (SAFER) Guides—which document a series of best practices for health care organizations to self-assess their medical record systems—or alternatives by providers.

While rewarding the use of SAFER Guides in the Promoting Interoperability Score will likely lead to increased adoption, there are additional steps the agency can take to advance EHR safety. For example, Pew and MedStar Health's National Center for Human Factors in Healthcare recently collaborated to identify best practices that hospitals should adopt to monitor and address technology-related problems. To identify those practices, Pew and MedStar reviewed hospital accreditation requirements, and conducted interviews with hospital administrators, health IT usability and safety experts, and informaticists—system specialists and engineers. The findings, to be published this summer, focus on ways to incorporate these best practices into requirements

from The Joint Commission, which accredits approximately 80 percent of U.S. hospitals.⁷ Those same best practices, though, could also inform future Promoting Interoperability requirements.

Some of the best practices identified encompassed topics broadly applicable to health IT system use and implementation. Other practices identified focus on the use of clinical decision support (CDS) functions, which are tools that doctors, nurses, and other health care providers use to guide their care. For example, Pew and MedStar identified the following opportunities to advance best practices:

- *Order sets*: Hospitals should have a process for a regular review of order sets that includes a committee with clinical and health IT expertise that meets regularly to assess their content and structure.
- *Governance*: Hospitals should have a clear, documented, organizational governance structure in place for making decisions about health IT.
- *Training*: Hospitals should have a clear process for training that maintains regular in-person courses, online materials, or other procedures for staff.
- *Hazard identification*: Hospitals should conduct regular safety reviews of EHRs using a self-assessment, such as through the Leapfrog CPOE tool.
- *Hazard reporting*: Hospitals should have a patient safety event reporting system and process in place for noting whether errors are associated with health IT use.
- *Hazard analysis and resolution*: Hospitals should have a committee that regularly reviews identified hazards and works to address them by engaging internal information technology staff and/or the EHR vendor.
- *Health IT awareness*: Hospitals should maintain processes to update affected providers about EHR safety risks and solutions.
- *CDS for recognized high risk clinical scenarios*: Hospitals should have CDS in place for scenarios, such as high-risk drug-drug interactions or drug allergy issues to reduce adverse safety events.
- *CDS functionality and maintenance*: Hospitals should have a process—like the Leapfrog CPOE tool—for assessing CDS, reviewing results, and improving CDS based on the information.
- *Review of CDS use*: Hospitals should have an electronic visual dashboard that shows CDS dismissal rates for high-risk conditions, and the data should be reviewed by a hospital committee that will also develop action plans to address identified challenges.

Additional information on each of these best practices will be published later this summer and shared with CMS.

As CMS examines how to advance EHR safety, the agency has several other opportunities to advance best practices in technology use to reduce medical errors. First, CMS could incorporate EHR safety measures into the Promoting Interoperability Program as considered by the request for information in last year's hospital payment rule. CMS could, for example, require hospitals to document their EHR safety practices and attest to doing so. The aforementioned best practices should serve as guidance on those practices.

Similarly, CMS could collaborate with The Joint Commission to encourage adoption of EHR safety-focused best practices. For example, CMS could encourage The Joint Commission to embed these best practices into its hospital accreditation program and develop associated standards.

Conclusion

The use of EHRs introduces dual opportunities to enhance safety and contribute to patient harm. Hospitals' adoption of best practices for how they customize, implement, and monitor these health IT systems can help mitigate patient safety risks. As CMS considers future updates to the Promoting Interoperability program and other hospital requirements, the agency should prioritize patient safety by focusing on the use of EHRs.

Thank you for the opportunity to comment on these proposed regulations. Should you have any questions or if Pew can be of assistance, please contact me at (202)540-6333 or bmoscovitch@pewtrusts.org.

Sincerely,



Ben Moscovitch
Project Director, Health Information Technology
The Pew Charitable Trusts

¹ The Pew Charitable Trusts, "Improving Patient Care Through Safe Health IT," (2017), <https://www.pewtrusts.org/en/research-and-analysis/reports/2017/12/improving-patient-care-through-safe-health-it>.

² The Pew Charitable Trusts, "Ways to Improve Electronic Health Record Safety," (2018), <https://www.pewtrusts.org/en/research-and-analysis/reports/2018/08/28/ways-to-improve-electronic-health-record-safety>.

³ Raj M. Ratwani et al., "Identifying Electronic Health Record Usability and Safety Challenges in Pediatric Settings," *Health Affairs* 37, no. 11 (2018: 1752-1759, <https://doi.org/10.1377/hlthaff.2018.0699>).

⁴ Ibid.

⁵ Ibid.

⁶David C. Classen, et al, "National Trends in the Safety Performance of Electronic Health Record Systems From 2009 to 2018," *JAMA Network* (2020), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2766545?utm_source=STAT+Newsletters&utm_campaign=cfb0704901-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-cfb0704901-149709245

⁷Centers for Medicare & Medicaid Services, "CMS to Strengthen Oversight of Medicare's Accreditation Organizations," news release, Oct. 4, 2018, <https://www.cms.gov/newsroom/press-releases/cms-strengthen-oversight-medicare-accreditation-organizations>.; The Joint Commission, "About the Joint Commission," <https://www.jointcommission.org/about-us/>.