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February 9, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Kate Goodrich, MD, MHS
Chief Medical Officer
Director, Center for Standards and Quality
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma and Dr. Goodrich,

On August 2, 2018, less than six weeks after the comment period closed on the proposed rule, CMS released the Hospital Inpatient Prospective Payment Systems (IPPS) final rule for 2019. On July 27, 2018, CMS released the Physician Fee Schedule and Quality Payment Program (PFS) proposed rules for 2019.

The Electronic Health Record Association’s comments were among more than 16,000 comments received on the proposed rules as published in the *Federal Register*. Very few of the concerns noted by the EHR Association and others were ultimately addressed in the final rules, and both of these regulations created many questions in the technical implementation of the required elements.

The EHR developer members of the EHR Association believe in the promise of Meaningful Measures and want to see them succeed. As important new priorities are rolled out, it is vital to ensure they are implemented in a way that is sensitive to the burden of measurement and poor clinician workflow.

Because of this, we've given extensive feedback to CMS on the new measures introduced in Promoting Interoperability (PI), specifically those related to:

- Prescription Drug Monitoring Programs (PDMP)
- Verifying Opioid Treatment Agreements
- New HIE Measure to support electronic referral loops by receiving and incorporating health information

We provided extensive commentary on both [the IPPS](#) and [the PFS](#) proposed rules and followed up with a series of questions after the Final Rules. Our requests began with an email request for certification clarification on August 21, 2018, and additional questions were raised in a joint CMS/EHRA monthly call on September 11, 2018.

Subsequently, a separate call to discuss PI was scheduled for October 18, 2018 and EHRA provided a list of questions to EHRA on October 8, 2018. Unfortunately CMS cancelled the call less than 24 hours ahead of the scheduled meeting and ultimately rescheduled for November 18, 2018.

In the interim:

- CMS provided written responses to EHRA questions on October 18
- EHRA responded, requesting additional clarification
- CMS provided updated written responses to some questions on October 24
- EHRA requested an escalation of our request for additional clarification, noting that the responses to-date were insufficient for programming EHRs; also, we requested a CMS contact for sharing concerns
- CMS provided updated responses to remainder of submitted questions on October 25
- At CMS' request, EHRA provided written suggestions to CMS

During the call between EHRA and CMS on November 18, 2018, EHRA again relayed our concerns about the technical feasibility and the need for clarifications in order to develop solutions that meet the requirements set forth in the rules. CMS representatives told us that further guidance would be released before the end of the year. We provided written follow up questions, which CMS responded to on November 24.

On December 27, 2018, CMS released PI specifications. On January 2, 2019, EHRA requested that a PI representative attend the joint EHRA/CMS monthly meeting on January 8 to address member questions regarding PI specifications, and on January 4, EHRA provided a list of those questions to CMS. During that call, EHRA asked again about escalation options regarding lack of clarification and insufficient guidance.

We are taking this next step in writing to you because we want to escalate two concerns:

- First, it has taken too long to clarify these measures. Our users are anxious to see their performance on new measures and we still do not have the necessary clarity to begin programming. We have spent too much time trying to clarify basic concepts we would expect a well-specified measure to make clear from the beginning, such as the definition of an opioid.
- Second, some of the clarifications we have received have negative implications for clinician workflow. We are concerned that the measures we implement this year may be the subject of clinician burden discussions next year.

We propose the following next steps to address both an urgent need for clarity on how development and certification will proceed as well as the long term need of re-specifying these measures to avoid burden and improving CMS processes so that future measures do not encounter the same problems:

1. Long term:
 - a. CMS must improve their processes to incorporate earlier feedback from stakeholders in the development of new measure specifications.
 - b. CMS must improve their responsiveness to feedback in the public comment window--many of the issues seen now were shared by stakeholders at that time and not addressed by CMS.
 - c. CMS must respond more quickly to questions after regulation is issued so that issues do not stretch for months after a final rule is published.
 - d. CMS must communicate more frequently and publically on when developers should begin work on measures and when CMS is continuing to offer guidance and specifications are in flux.
2. Short term:
 - a. CMS should publically clarify that (g)(2) certification to new measures is not expected in 2019, given their delay in clarifying questions from EHR developers.
 - b. To support flexibility for providers and developers in 2019, participating providers will have the option to claim the exclusions related to “unable to implement” even if their EHR offers an uncertified version of the measure in 2019. This would be applicable to the following new measures, which already have exclusions for this reason:
 - i. PDMP Query
 - ii. Verify Opioid Treatment Agreement
 - iii. Support Electronic Referral Loops by Receiving and Incorporating Health Information
 - c. CMS must work with stakeholders to resolve issues with the measure specifications for clarity and consistency of implementation. If measures are sufficiently specified by June 2019 then certification to criterion (g)(2) could begin. We think it would be reasonable for (g)(2) certified software to be expected to be used for 2020 90-day reporting periods.

We support an open and collaborative relationship with CMS to address the current frustrations and develop a way to work closely in future rulemaking. Thank you for your attention to this important concern.

Sincerely,



Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare



Sasha TerMaat
Vice Chair, EHR Association
Epic

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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.