EHRA
HIMSS ELECTRONIC HEALTH RECORD ASSOCIATION

33 West Monroe Street, Suite 1700
Chicago, IL 60603

@EHRAssociation | ehra.org

October 1, 2020

Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma,

On behalf of the nearly 30 member companies of the Electronic Health Record (EHR) Association, we are pleased to offer our comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the *Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies*, etc., which was published in the Federal Register on August 17, 2020.

The EHR Association's member companies serve the vast majority of hospitals, post-acute, specialty-specific, and ambulatory healthcare providers using EHRs across the United States. Our core objectives focus on collaborative efforts to accelerate health information and technology adoption, advance information exchange between interoperable systems, and improve the quality and efficiency of care through the use of these important technologies.

Following are several of the primary points we make within the body of our comment document:

CMS's 2021 Physician Fee Schedule proposed rule would require provider adoption of 2015 Edition Cures Updates for the purposes of Certified EHR Technology (CEHRT) compliance by August 2, 2022 for Promoting Interoperability and IQR participants. Because the EHR Association has concerns with the proposal's interpretation of the timing of the expected readiness for both health IT developers and providers, we highly recommend CMS consider extending the flex period through the end of calendar year 2023. By adopting an amended timeline within the CMS programs described, it would establish a more straightforward deadline and allow for more sufficient time for Cures Updates to be implemented by providers.

On the subject of the MVP pathway, the EHR Association agrees with the proposal to create a similar

MVP pathway specific to APMs. However, we believe that this proposal contradicts the rationale for delaying the MVP pathway due to provider burden associated with COVID-19 and also having to learn new reporting requirements. We recommend introducing both the MVP and APP models at the same time to allow providers to understand their options and have more time to prepare for this change.

Although we understand the proposal based on the potential historical data discrepancies due to COVID-19, we believe that solely basing MIPS scoring on performance benchmarks potentially penalizes providers by not allowing them to forecast and estimate their performance throughout the performance year. Therefore, we recommend that the better of performance benchmarks and historical benchmarks should instead be used for scoring.

On a related COVID-19 note, we have been pleased that the declaration of a public health emergency has allowed CMS to greatly expand reimbursable services that can now be rendered via telehealth. These changes have been welcomed by our healthcare customers at a time when patients were unable or unwilling to visit their doctor's office in person, and have offered measurable benefit to patients that need care and access to their providers, even while safely remaining at home. The healthcare industry has thus also had an opportunity to test the efficacy and clinical validity of the telehealth model on a scale previously unachievable, and the results have been overwhelmingly positive. We encourage CMS to permanently codify telehealth expansion as a core part of the healthcare system's new delivery model.

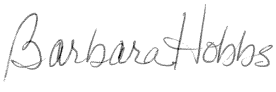
Our detailed responses to the proposed PFS regulation follow. Thank you for this opportunity to share the perspective of our members. We look forward to continuing to work with CMS and other stakeholders to advance widespread secure data exchange and to reduce clinician burden.

Sincerely,

Hans J. Buitendijk
Chair, EHR Association
Cerner Corporation

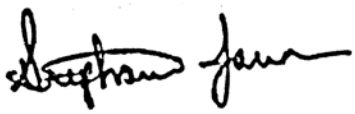
David J. Bucciferro
Vice Chair, EHR Association
Foothold Technology

HIMSS EHR Association Executive Committee



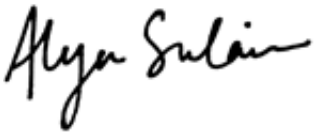
Barbara Hobbs
MEDITECH, Inc.

Cherie Holmes-Henry
NextGen Healthcare

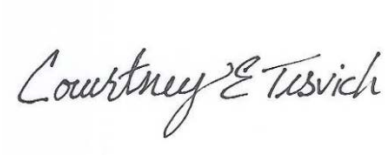


Stephanie Jamison
Greenway Health

Rick Reeves, RPh
CPSI



Alya Sulaiman, JD
Epic



Courtney E. Tesvich, RN
Nextech

About the HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 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

Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management.

The EHR Association supports this update, which will lower physician burden.

We are also proposing that the Category 3 criteria and basis for considering additions to the Medicare telehealth services list would be temporary, to expire at the end of the calendar year in which the PHE expires.

We support lessening provider confusion by making the criteria in Category 3 permanent as part of Category 1.

Whether the permanent addition of specific, individual services or categories of services to the Medicare telehealth services list supports quick responses to the spread of infectious disease or other emergent circumstances that may require widespread use of telehealth.

We are supportive of this recognition that the use of telehealth is beneficial for infectious disease and emergency circumstances.

What is the impact on the health care workforce of the inclusion of one or more services or categories of services on the Medicare telehealth services list (for example, whether the health care workforce and its capabilities to provide care are expanded).

This proposal offers flexibility, which can help access patients who might otherwise be hard to reach; we recommend CMS issue more training materials and guidance. Allowing healthcare workers to provide care to patients across a large region from a single location is efficient and time-saving.

Proposing to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by FDA under section 505.

The EHR Association supports this proposal. Based upon input from our EHR developer clients, this change would allow for further support of patients' recovery in opioid treatment programs. Payment for naloxone treatment can help assist patients in their recovery process.

Welcoming comments if the definition of OUD treatment services should be further revised to include overdose education. Additionally, should this education be built into the current weekly bundled payments for episodes of care or should it be listed as add-on payment.

The EHR Association supports this proposal. Based upon input from EHR developer clients, this change would prompt providers to include this type of patient education/resources as a part of the overall bundle being used to treat patients.

Proposing to create two add-on codes for naloxone. GOTP1 (nasal naloxone) and GOTP2 (auto-injector naloxone).

The EHR Association is supportive of creating these new codes which would allow for easier delineation of data for research and clinical decision support (CDS). Our clients have found that additional payment for naloxone is also a critical aspect to OUD treatment and is necessary to help those with addiction issues as they work through the OUD program.

Seeking comment on the addition of another add-on payment specific to injectable naloxone.

Our clients have found that payment for naloxone treatment can help assist patients in their recovery process.

Periodic assessments required with these bundles have been allowed to be done via two-way telecommunications and audio only interactions. Once the PHE is lifted it is proposed to still allow periodic assessments to occur via two-way communications but not audio only.

We support continuation of audio-only as well as two-way communications. Many patients still experience difficulties in obtaining audio/video capabilities, but still need this beneficial assistance.

Comprehensive Screenings for Seniors: Section 2002 of the SUPPORT Act.

We request further clarity on what is meant by enforcement and importance on physician vigilance, as well as further definition of what is meant by screening for potential substance use disorder, and context of what screening would include (e.g., patient history, PDMP).

Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs).

Although not addressed in the 2021 ruling, we seek additional guidance from CMS regarding the changes made in the 2020 rule related to Security Risk Analysis (SRA). When a provider plans to perform their SRA beyond the deadline (October 31, 2021) CMS stated they would be working with states to provide audit documentation needed when submitting beyond October 31. We have not seen such documentation and would like to know if that information was provided.

Proposal to align eCQM specifications available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for CY 2021.

We agree with the alignment of Medicaid PI and QPP eCQMs again in 2021, however the abbreviated reporting period can cause concern. We would appreciate more guidance from CMS related to eCQM measures that require an entire year reporting period such as the influenza measure. When calculating certain measures such as this example an abbreviated reporting period creates timing logic issues which could result in limited or no patients qualifying for the measure.

Updates to Certified Electronic Health Record Technology due to the 21st Century Cures Act Final Rule (Promoting Interoperability and IQR).

CMS's 2021 Physician Fee Schedule proposed rule would require provider adoption of 2015 Edition Cures Updates for the purposes of Certified EHR Technology (CEHRT) compliance by August 2, 2022 for Promoting Interoperability and IQR participants. The EHR Association has concerns with the proposal's interpretation of the timing of the expected readiness for both health IT developers and providers.

The Cures Act final rule communicated that a deadline of August 2, 2022 would be established for developers to make health IT certified to the Cures Updates available to their customers. ONC also specifically reiterated this in a July***** response to a question submitted by the EHR Association, where we requested clarification if this date correlated in any way to when healthcare providers would need to have Cures Updates in place for their own CEHRT compliance.

> ****** *Question to ONC: Does the 24-month deadline mean healthcare organizations have to implement the new certified technology and be using it, OR does it mean it needs to be available from their health IT vendor (but not necessarily in use) within 24 months?*
>
> *ONC Response: The "provide its customer…by May 2, 2022" provisions require health IT developers to solely make the updated health IT available to its customers by the specified date. In the Cures Act final rule we state, "In general, health IT developers have 24 months from the publication date of the final rule to make technology certified to these updated criteria available to their customers, and during this time developers may continue supporting technology certified to the prior version of certification criteria for use by their customers." (85 FR 25666) These provisions do not require that the updated health IT must be in production use by customers as of May 2, 2022.*

We recognize the separation of CMS and ONC respective authorities, where CMS is tasked with establishing the timeline of requirement for adoption and use that would be associated with any applicable provider focused program. However, we want to make it specifically clear that the work to be taken into account for this adoption must be fully inclusive of the efforts of both health IT developers and their customers for development, certification, distribution, and upgrade activities. The initial timeline for health IT developers to make available certified updates to all of their customers must be considered, ***followed second*** by the activities necessary for adoption and implementation by their clients. The CMS deadline also falls in the middle of a program year, and does not provide a clear line for

when providers would need to have these capabilities adopted relative to other annual implementation and reporting requirements.

We understand CMS' intention to allow for a "flex" period for the use of 2015 edition CEHRT as well as Cures Updates until August 2, 2022 to allow providers attesting to Promoting Interoperability the option to attest early in 2022, followed by later upgrades in 2022 or into 2023 to then attest to Promoting Interoperability later in 2023. However, this does not provide the same flexibility to those attesting to IQR or the A-APM track within the Quality Payment Program, or those opting to use eCQMs for quality within MIPS. We do not believe that CMS' proposal gives appropriate due consideration to the full weight and timeline of effort required for health IT developers to certify, and for providers to adopt, the Cures Updates whereby ability to meet program requirements is on par with previous use of prior versions of CEHRT.

While the Cures Updates are not a full criteria set update, they are still considerable. From past experience working with our provider customers, we have seen firsthand how much time is needed to install, implement, train, and adapt to new workflows and capabilities and to be at a level of use of the new certified capabilities to successfully attest to the various CMS programs. In the past, CMS has had to either postpone required adoption dates or engage in declining to enforce them with every prior adoption requirement for a new version of certification criterion, and we believe it informative to the adoption of the Cures Updates to build in a flex period for their initial use.

Considering all of this, we highly recommend CMS consider extending the flex period, currently proposed to end on August 2, 2022, through the end of calendar year 2023. By adopting this within CMS programs, it would establish a more straightforward deadline for Cures Updates to be implement by providers and allow for sufficient time

We are proposing to revise the Shared Savings Program quality performance standard effective for performance year 2021 and subsequent performance years. This proposed revision would align the Shared Savings Program quality performance standard with the proposed APP under the Quality Payment Program as participants in the Shared Savings Program would be required to report quality for purposes of the Shared Savings Program via the APP.

Overall, this timeline and the lack of requirements are concerning for making this change in 2021. We would like to see more details. Using an already existing methodology for submitting would make it simpler. However, requiring a different submission mechanism would complicate participation.

The EHR Association has previously requested a minimum 18 months for development.

At a high level, the APP would replace the current Shared Savings Program quality measure set to streamline reporting requirements for Shared Savings Program ACOs and would be a complementary path to the MIPS Value Pathways. The APP is designed to reduce reporting burden, create new scoring opportunities for participants in MIPS APMs, and encourage participation in APMs.

We agree with the proposal to create a similar MVP pathway specific to APMs. However, we believe that this proposal contradicts the rationale for delaying the MVP pathway due to provider burden associated with COVID-19 and also having to learn new reporting requirements. We understand that this proposal for the participation in an APP will be optional; however, this is a brand new pathway to providers and may be confusing with other changes of sunsetting the APM scoring standard and adding the MIPS APM type to the participation statuses. We support sunsetting the APM scoring standard and adding MIPS APM type to the participation statuses under MIPS to achieve consistency in the 2021 reporting period and reducing provider burden. However, we recommend introducing both the MVP and APP models at the same time to allow providers to understand their options and have more time to prepare for this change.

Although we understand the proposal based on the potential historical data discrepancies due to COVID-19, we believe that solely basing MIPS scoring on performance benchmarks potentially penalizes the providers by not allowing them to forecast and estimate their performance throughout the performance year. Therefore, we recommend that the better of performance benchmarks and historical benchmarks are used for scoring.

We are proposing for the performance period in CY 2021 to maintain the Electronic Prescribing objective's Query of PDMP measure as optional.

The EHR Association agrees with the proposal to allow this to be maintained as a bonus due to the lack of national standards and due to EHR integration complexities. We also agree with the increase of 5-10 points bonus.

We are proposing to replace the word "incorporating" with the word "reconciling" in the name of the measure. The new name would read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.

The EHR Association is in support of this name change, as it aligns the measure name with the EH/CAH PI change finalized earlier this year in the IPPS.

We would, however, like to draw attention to the fact that multiple name changes can be confusing for healthcare organizations and health IT developers supporting those organizations, since a new measure name has frequently been used (historically) to imply that the measure's requirements have changed, which is not the case in this instance. Name changes also result in software developers and other stakeholders needing to make tedious and burdensome updates to tools, processes, and materials, including report name changes, changes to documentation preserved for audits, updates to training materials, and updates to end-user facing documentation. Time spent on name changes diverts resources from more impactful projects requested from users, such as usability enhancements.

We are proposing to add the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: the Support Electronic

Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure.

CMS is proposing that participants would attest to the three following statements to get the 40 points.

- **I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.**
- **The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.**
- **I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).**

CMS should add clarity as to how to deal with situations related to HIPAA when patients request their data not be shared as a part of opt out/in state requirements, because not *every* patient's data will be shared to HIEs.

We also suggest receiving CMS guidance as to audit documentation that participants should gather when attesting to this measure.

We ask for clarification as to the CEHRT reference to g10, because this certification will not be required by the effective date of this rule/measurement period.

For the 2021 performance period, we are proposing to remove 14 MIPS quality measures: 2 MIPS quality measures that are extremely topped out; 1 MIPS quality measure that is duplicative to another current quality measure; 1 MIPS quality measure that is duplicative to one of the new proposed MIPS quality measures; 2 MIPS quality measures that do not align with the Meaningful Measures Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; 1 MIPS quality measure that does not meet current clinical guidelines; and 2 MIPS quality measures that are under the topped out lifecycle. - All-Cause Hospital Readmission administrative claim removed and replaced with A-1 Hospital Wide 30-day all cause unplanned readmission.

We are supportive of this proposal to remove measurements that do not add value to the quality of care, and instead add more meaningful measurements.

As discussed in section IV.A.3.c.(1)(b) of this proposed rule, we are proposing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period.

The EHR Association supports this proposal, which focuses on electronically reported measures rather than abstraction, in alignment with CMS' interoperability initiatives.

Switching submission mechanisms and quality measure specifications is a large change for practices that have historically reported via the CMS Web Interface, and we encourage CMS to consider feedback from clinicians, who voice concerns about this proposal and recommend a transition period of at least one year.

We are proposing to add 2 new administrative claims outcome measures, remove 14 quality measures, and make substantive updates to 92 quality measures where the changes will require the removal of an existing benchmark.

The EHR Association supports this proposal to remove measurements that do not add value to the quality of care, and instead add more meaningful measurements.

Third party intermediaries may be selected during the performance period to be audited for a given requirement. As a part of our outreach to a selected third party intermediary, we intend on providing additional direction with regards to the timeline and information needed for the audit. The results of the audit will be reviewed to inform future approval of a third party intermediary, and if remedial action is warranted, we will utilize our existing authority as described in § 414.1400(f). We believe use of this information in approval determinations will help reduce the risk of third party intermediaries that are unreliable, thereby avoiding a possible increase in burden to clinicians who may inadvertently select an unreliable third party intermediary for purposes of reporting for the MIPS program. We request comments on our proposals; specifically, we request comments on whether there are other factors that should inform our considerations when approving third party intermediaries.

We understand the reasoning for performing audits on third party intermediaries. However, we encourage CMS to remove the auditing of Improvement Activities for third party intermediaries. Improvement Activities have been and will continue to be a source of validation difficulty during auditing, because improvement activities aren't necessarily tracked within the EHR. These items are often narrative information tracked elsewhere by the provider, and thus should not be considered an auditable item for the third party intermediary.

Although we are not proposing to add data validation requirements for health IT vendors at this time, we are considering ways to impose such requirements in the future. We are soliciting comment on whether we should impose data validation requirements on health IT vendors as part of the third party intermediary approval process and if so, how the data validation requirements for health IT vendors should differ, if at all, from those proposed for QCDRs and Qualified Registries. We believe that potentially requiring health IT vendors to validate the data they submit to us for purposes of the MIPS program will lead to the submission of data that can be considered more reliable and accurate. Therefore, we seek comment on the future application of such requirements on health IT vendors and if there are factors unique to health IT vendors that should be considered when developing such a policy. For instance, we are seeking to further understand where data quality issues may arise in data submitted by health IT vendors on behalf of MIPS eligible clinicians.

Health IT vendors, through certification, do validate and generate and perform real world testing. If CMS undertakes additional validation of quality measures, it should replace work already required by ONC through the ONC certification program and real world testing, to avoid duplicative efforts.

We are also seeking comment on whether health IT vendors currently submitting data on behalf of MIPS eligible clinicians possess the capabilities to engage in the data validation processes we are proposing for QCDRs and Qualified Registries. We are also seeking comment regarding the burden on health IT vendors of adopting the data validation requirements as proposed for QCDRs and qualified registries and whether the imposition of these requirements on health IT vendors would discourage health IT vendors from serving as third party intermediaries.

The EHR Association opposes this proposal for several reasons. We do not believe that CMS has provided enough detail regarding the proposed data validation for QCDRs and Registries for us to offer an affirmative response to the question. Additionally we feel that the request is likely duplicative of the certification, validation, and real world testing we are already performing. Finally, regardless of the proposed changes, requiring additional, superfluous work of CEHRT and health IT vendors is costly and unnecessarily burdensome.

We propose beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we would assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we would suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted.

Depending on the measure, changing a measure to a truncated period can create reporting data issues; this policy may not always be easy or even able to be implemented. We suggest CMS consider a review period with stakeholders.

We also have concerns about making these changes right up to the beginning of the data submission period.