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June 22, 2018

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 34 member companies of the Electronic Health Record Association (EHRA), we are pleased to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (IPPS). We appreciate this opportunity to provide input on CMS' efforts to facilitate interoperability and to reduce clinician burden by focusing on high-value reporting measures.

EHRA members serve the vast majority of hospitals and ambulatory care organizations that use electronic health records (EHRs) and other health information and technology (IT) to deliver high quality, efficient care to their patients. The Association, established in 2004, operates on the premise that the rapid, widespread adoption of health IT has and will continue to help improve the quality of patient care as well as the productivity and sustainability of the healthcare system. Our core objectives focus on collaborative efforts to accelerate health IT adoption, enhance usability of EHRs, advance interoperability, and improve healthcare outcomes through the use of these important technologies.

Our comments focus on the need for appropriate timelines, the importance of aligning reporting requirements and measure calculations across all programs, and suggestions regarding the interoperability request for information (RFI).

Timelines

EHRA has consistently emphasized that any program changes must be communicated with enough lead time to allow for education, testing, implementation, roll out, and certification. Changes made with inadequate lead times are often problematic.

We are pleased to see that CMS is holding firm to the repeatedly delayed implementation date of using ONC 2015 Edition Certified EHR Technology (CEHRT) in 2019. EHR developers have made significant investments in ONC 2015 Edition and the unpredictability of when it is needed by healthcare providers has made those investments difficult. The current timeline plan should be maintained.

In addition, we urge CMS to focus on stability in reporting periods, with sufficient lead time and avoidance of mid-year changes. As an example, we see how adding measures related to the opioid crisis to Promoting Interoperability (PI) could be valuable, but the proposed timeline to introduce new measures is not feasible for 2019. An extended timeline is necessary to update certification requirements and roll out new measures in EHRs. Additionally, while we support the policy intent, we would like to see those measures modified to be more meaningful and measurable in order to maximize their effectiveness. Such revision must happen prior to rollout to avoid waste.

Alignment

We strongly encourage CMS to look for opportunities to align programs and measurements; inconsistent reporting requirements produce additional burden on providers and developers. While we appreciate the alignment of program names, this does not address much more significant challenges, such as the challenge associated with capturing and calculating measures differently for the Medicare and Medicaid programs. To avoid burden in certification and software development, CMS must keep individual measures consistent between their Medicare and Medicaid programs, even if the scoring approach varies.

In addition, CMS must be judicious with measure changes and new measures. Regarding measure changes, we see most of the proposed changes as not preferable to the previous measures in the program and as representing thousands of hours of work across the industry. Retaining the previous measures will avoid this burden. Regarding new measures, we've provided suggestions on areas needing clarity in our attached commentary.

We strongly support CMS' efforts to reduce physician burden, which is why EHRA is concerned about the many changes to each individual measure, as these changes create additional hardship for providers and developers, requiring coding updates and reimplementation.

Interoperability RFI

We question the utility of new Conditions of Participation (CoPs) for Medicare around data sharing, especially in light of 21st Century Cures ongoing regulatory implementation. Further regulatory action on data sharing and interoperability should wait until the rulemaking mandated by 21st Century Cures is complete. For example, a CoP related to information blocking is contingent on ONC's definitions on safe harbors.

It is additionally unclear how interoperability expectations in the CoPs would be evaluated and audited, but it seems likely that evaluation and auditing of these items would generate additional hospital burden.

Our detailed responses related to these issues and others are included with this letter.

Thank you for this opportunity to comment. We look forward to continuing to work with CMS and other stakeholders to advance widespread secure data exchange and to reduce clinician burden.

Sincerely,



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Epic



Cherie Holmes-Henry
Vice Chair, EHR Association
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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.

Electronic Health Record Association Detailed Comments on 2019 IPPS Proposed Rule

Hospital Value Based Purchasing Program

Separating the Value Based Purchasing (VBP) program from the Inpatient Quality Reporting (IQR) program, removing measures from IQR, leaving in VBP

EHRA would like to use this as an opportunity to encourage CMS to consider the pace at which programs are introduced and stabilized. Change itself impacts clinician burden due to updates to workflows, compliance and software changes. We recommend a strategic roadmap for burden reduction efforts that includes appropriate lead-time for changes in current and introduction of new programs.

For example, four of the ten measures CMS is proposing to eliminate from the VBP program have yet to be used in the program. Two were introduced in the 2018 IPPS rule, and two in the 2017 IPPS rule. The final 2018 IPPS rule was published less than a year ago under the current administration. This type of instability creates burden, e.g. program fluctuations, short notice changes, etc. It appears in practice that early adopters are punished while laggards are rewarded by waiting to see if a change actually comes to fruition. The answer to this challenge is not to avoid quick retirement of burdensome measures, but to introduce steps to ensure that such burdens are not introduced in the first place to prompt wasted investment.

Measure Removal Factors for Hospital VBP Program

EHRA agrees that Measure Removal Factor 8 provides a valid and beneficial cause for removing measures from the program. However, we would appreciate additional transparency into the factors that go into determining cost as well as the factors that deem the cost to be burdensome.

Hospital Acquired Condition Reduction Program

Separate HAC Reduction program from VBP and IQR

EHRA appreciates the desire to reduce burden, but encourage that the same processes be used across programs (e.g. HAC reduction program should be the same as IQR) to reduce duplication.

Suggestions for whether electronic clinical quality measures (eCQMs) would benefit the HAC Reduction Program at some point in the future

EHRA feels that adding options for electronically submitted measures would be beneficial. However, we would urge that any additions be done thoughtfully and with regard to alignment, timeliness of implementation, and the amount of burden that will be incurred. The addition of measures simply for the sake of electronic submission would not be helpful. Future eQMs should be selected based on using data elements that are already commonly captured within electronic health records.

Revision of Hospital Inpatient Admission Orders Documentation Requirements under Part A

Removing requirement that written inpatient admission orders are a specific requirement for Medicare Part A payment

EHRA appreciates the desire to reduce documentation burden on clinicians where possible. Given that hospitals may have adopted admission documentation policies consistent with the current requirements, we suggest CMS state that hospitals can continue to use the written admission order process to document the necessary requirements. We recommend CMS highlight which requirements are still in place and what specifically is changing or being eliminated. This would circumvent questions and misunderstandings, especially as hospitals have built a reliance on admission orders for specific processes or marking critical milestones indicating the start of inpatient services.

To that same comment, CMS should consider unintended consequences of this type of change, which may directly impact initiation of patient status' that are integral to the billing process. Static process requirements, such as these, are commonly used as an anchor for many other process triggers based on timing requirements or other calculations. When these actions are no longer required, these processes and workflow may need to be reconfigured.

While we agree with this proposal, EHRA encourages CMS to look for feedback to understand downstream and potentially unintended consequences of these types of changes. CMS could consider this change as a removal of prescriptive behavior as used by auditors for payment recoupment but encourage the continued use of an admission order process.

Inpatient Quality Reporting Program

Proposal to adopt an additional measure removal factor, "the costs associated with a measure outweigh the benefit of its continued use in the program"

EHRA supports the removal of 39 measures from the IQR program, as they have been in place for many years and are regarded as topped out or not providing value to the IQR program. In this case, we would even encourage CMS to consider removal of measures more quickly in instances where they have been long adopted, topped out, or no longer of value.

This proposal removes seven eQMs for the 2020 measurement year; however, it leaves them in place for 2019 even though CMS has noted their ineffectiveness. We recommend CMS remove these

measures for the 2019 measurement year to alleviate burden from hospitals to report and developers to certify measures that are no longer of use. For example, an inpatient EHR must all rewrite measures in CQL which would have very limited utility before being phased out, which is wasteful.

Also, we recommend CMS allow hospitals to use the eCQM specific Extraordinary Circumstances Exception to apply for an exclusion from the eCQM portion of the 2019 program year if the hospital cannot use four of the remaining eight eCQMs.

Proposal to remove a total of 39 measures from the Hospital IQR Program

The hybrid hospital-wide readmission measure was introduced in 2018 as voluntary and then required in future years, however this measure was not listed in the table that shows all measures for 2019 and beyond (see tables for different program years are on p.1217, 1220, 1222). We assume this means it is being retired.

Page 1848 shows the potential reduction of burden of not including the hybrid hospital wide readmission measure in calendar year 2019. These types of start/stop decisions create additional burden and loss of interest to participate in future development or pilots.

Possible future inclusion of the Hospital Harm - Opioid-related Adverse Events eCQM in the Hospital IQR Program

1. If inclusion of the Hospital Harm - Opioid-related Adverse Events measure is finalized, we feel that an initial inclusion on a voluntary basis would be most beneficial in obtaining valid and reliable data. Also, we would like clarification on whether or not health IT developers will be required to support/certify the measure if it is introduced on a voluntary basis.
2. EHRA feels that whether the measure is adopted on a voluntary or mandatory basis, measure submission should count toward one of the four required measures.
3. EHRA feels that initial voluntary participation will provide a better testing ground for whether this measure would be appropriate for mandatory inclusion.

EHRA appreciates the recent efforts toward alignment in the various quality programs, particularly between IQR and Promoting Interoperability (PI). We encourage maintaining this alignment in future rulemaking for these programs.

Addressing challenges related to eCQM use

Q1. Some aspects of eCQMs that are most costly to EHRA members include:

- Each time requirements change, health IT developers need to follow up on those changes within tight time frames, causing heightened resource use that could be allocated toward providing new functionality that is more important to customers.
- When individual measures include errors or are not appropriate to clinician need, time and resources still must be allocated to providing tools for data capture and reporting, even though the measures are fundamentally unusable. Measure development needs to be done in collaboration with providers and IT developers so that time and resources are not invested in invaluable measures.
- Changes to measures that have been identified for removal from programs in the near future create a great burden on developers; for example, re-writing measures in CQL code that will only be captured for a single reporting year.

Q2. EHRA appreciates CMS' efforts at alignment between programs and encourages further alignment in future rulemaking.

Q3. A significant barrier is in the often-vague interpretation of measures. The wording of some measures can be ambiguous and cause confusion between developers and providers regarding what exactly is the intent of the measure.

Q5. EHRA members appreciate each instance when we are contacted by CMS, CMS subcontractors, and Measure Stewards for feedback. However, EHRA members want to ensure that we are providing appropriate feedback, and often need more time to accommodate evaluation of the questions posed and to consult with additional organizational resources to provide the best possible information.

Additionally, individual Association members have reported that they are often asked the same questions from different measure developers/subcontractors. A separate feedback loop to foster communication amongst subcontractors/measure developers may be beneficial to avoid duplication of efforts.

Q9. EHRA feels that it would be beneficial to have more information on which tools should be used for each purpose. For example, Cypress QRDA Validation Utility, PSVA, and QualityNet are three independent tools; what are the use cases for each? Could there be one tool that is kept current and matches both certification and CMS expectations?

Promoting Interoperability (Meaningful Use)

Renaming the program

EHRA's main concern with the change from Meaningful Use to Promoting Interoperability is the alignment of measures and calculations across programs, which CMS has worsened in this proposal.

Medicaid implementation of the program

EHRA requests CMS do more to align the Medicare and Medicaid PI programs. Many health systems have both hospitals and EP/ECs that participate in both programs and stretch across state lines. There will be increased burden for these health systems, as they are required to maintain disparate program compliance with different objectives, measures, and scoring methodologies. This is not in alignment with CMS' objective to reduce provider burden.

We believe these programs should be aligned and look forward to CMS' proposals in the Physician Fee Schedule with the hopes that CMS will continue to take steps to align Medicare and Medicaid programs across multiple venues of care. To reduce state burden, we offer a suggestion that CMS provide attestation information to the states, proving compliance with the program measures.

EHRA commends CMS on its goal to reduce burden, with the understanding that one way to achieve this is to streamline the requirements across programs. EHRA strongly feels that measure alignment across the programs is a critical factor, especially when a single EHR is utilized across multiple care settings. So long as the individual measure logic definitions are identical, even if the scoring algorithms are different, this will reduce hospital, developer, and state burden.

For example, keeping the logic definitions the same across programs allows developers to maintain a single path for development, coding, testing, certification, training, and updating documentation/education materials. Additionally, it simplifies the process of evaluating changes in new Final Rules and in configuration of in-production systems in an integrated care setting. EHRA asks CMS to consider the complexities in a single EHR trying to effectively and accurately track similar actions using different logic definitions.

To do this, it is imperative that any changes to measures (for example, combining 2 measures into 1 measure) are made for both Medicare and Medicaid. Branching the programs to contain different sets of measures creates significant waste across the industry.

Certification requirements

EHRA is supportive of CMS requiring 2015 Edition CEHRT.

So long as new/additional certification requirements are not mandated for CEHRT or measure contributions, the EHRA would be supportive of the January 1, 2019 timeline. However, if CMS creates measures/objectives that mandate changes to an EHR in order to be supported, or ONC changes the existing certification program in any way, i.e. adding new criteria or modifying existing criteria, the EHRA would not support a January 1, 2019 adoption timeline given the intensive resource burden inherent in doing so.

Regarding certification more broadly, we are unclear how new measures will be treated. We seek guidance on whether the new measures will be made a part of the certification pathway; and, if so,

whether there is sufficient time to fold those new requirements into an update to the 2015 Certification Edition.

If ONC 2015 Edition certification is updated, the timeline for adoption will need corresponding updates.

Measures

The timing of proposing new requirements makes it impossible for any program requirement to use these capabilities in 2019 reporting periods.

We suggest delayed implementation of any such measures beyond 2019. While we support the policy intent, the timeline is not feasible in 2019.

As one example of timing considerations, there are competing regulatory initiatives. For example, refer to the January 1, 2020, adoption for 2017071 NCPDP standard and the requirement in the proposed PI update that mandates electronic prescribing for controlled substances (EPCS) for Schedule II drugs, making compliance with an additional opioid CEHRT capability adoption in 2019 extremely unlikely. This creates an unrealistically short development cycle to allow time for certification and then provider adoption and use. This timeline makes it unlikely any hospital could take advantage of this option until very late in 2019.

90-day reporting period for 2019 and 2020

EHRA suggests the need for a consistent reporting period without last minute changes for functional measures moving forward. This would bring stability and validity to the timelines and less speculation about impending delay notices from CMS year over year. Knowing in advance would help reduce burden on clinicians and organizations implementing CEHRT and new workflows to support these programs.

Overall, EHRA is agnostic on the length of the reporting period; we simply encourage CMS to create a uniform reporting period across all programs and suggest deferring this important question to providers/hospitals on the length of the reporting period.

Promoting Interoperability - Proposed Measures

Query for Prescription Drug Monitoring Program (PDMP)

CMS should address states that do not have a statewide PDMP, Missouri for example, potentially adding an exclusion for those without.

Harmonize e-Prescribing Standards

EHRA notes that the 2015 Certification Edition calls for SCRIPT 10.6 while the Medicare Advantage final rule called for using SCRIPT 2017071 starting January 1, 2020. We suggest that CMS work with ONC to harmonize the requirements to ensure there is a consistent set of interoperability requirements

supporting the various regulatory initiatives.

Include EPCS

EHRA supports the inclusion and encouragement for e-prescribing of controlled substances, recognizing the low adoption rate to date. Considering the challenges with two-factor authentication and the investments associated with that as major contributors to slow adoption, we suggest CMS work with the DEA to further look at standards and capabilities in that space, including the use of mobile devices (compare the use of cell phones and authorizing payments) to improve upon the ease of use and reduction in cost.

Open PDMPs through Medication History Access

EHRA supports the need to enable access to medication histories from PDMPs. We recognize the variations in access requirements/restrictions across states and lack of state adherence to industry standards to share data, not only view data. To achieve the full potential of interoperability with PDMPs that can improve on the current opioid crisis, and substance abuse in general, view-only access is not sufficient. Data exchange that can enable clinical decision support (CDS) to assist the clinician as well as patients is essential to achieve that potential. We urge CMS to work with ONC, the states, and PDMP suppliers to collaborate with EHR developers to establish common standards to open up PDMPs in a secure environment.

We note that, particularly in the mobile space and in consumer-focused capabilities (an area that CMS should consider as an important patient engagement component, albeit outside the scope of the IPPS), the use of open, free standards is important. Thus, anything beyond the scope of e-prescribing would require careful consideration of the appropriate standards that provide a better match for stakeholders involved. Therefore, in the short term, that may still necessitate the use of NCPDP SCRIPT standards for medication history queries from EHRs; while, long-term, we suggest convergence on the use of HL7 FHIR[®], such as CDS Hooks or other consumer facing Apps. This shift will more extensively connect EHRs and consumer facing Apps with PDMPs.

The proposed rule does not address variations in PDMPs as a result of state and local requirements, use of variant formulary schedules, and other variations that challenge the open, transparent exchange of data. EHRA urges CMS to work with state and local jurisdictions, ONC, PDMP suppliers, and other health IT developers (e.g., EHR and consumer App developers) to arrive at a common set of formulary schedules, a common data set, and consequently a common set of interoperability standards that can easily work within and across state and other jurisdictional boundaries. The severity and impact of the opioid crisis should enable us to remove any obstacles resulting from these boundaries so caregivers and patients have the necessary data readily available.

Measure Logic Feedback

This measure should be prescription-based for simplicity, not evaluating medications administered within a hospital stay. Similarly, the measure logic should respect historical measure constructs (such as the denominator options of, e.g. all ED visits in the denominator vs Observation Services denominator).

EHRA seeks clarification on whether hospitals are under any duty to query multiple registries if the hospital location is near a state border. Clarification on this would be helpful for hospitals, but from a reporting logic perspective, querying at least one PDMP would have to be sufficient.

We do wish to emphasize the need for workflow integration of PDMP-related requirements, and the challenges of a lack of a consolidated response that presents a patient-centric view of all opioid prescribing activity.

The proposed numerator definition ignores typical workflow for PDMP queries. For example, some states require logging into an external portal, which would be difficult for a developer's system to track.

EHRA believes the proposed denominator should reference patients discharged during the reporting period instead of opioids prescribed during the reporting period; and, as such, we recommend that the denominator be "Discharges where Schedule II medications were prescribed."

For the proposed exclusion, EHRA recommends that if a state does not permit direct integration with an API then those hospitals be excluded from this measure. Requiring a workflow that is not interoperable will increase clinician burden.

Proposed modifications to "Send Summary of Care" measure

EHRA is supportive of the name change for this measure to "Support Electronic Referral Loops by Sending Health Information" and the removal of the previously defined Stage 3 threshold.

Verify Opioid Treatment Agreement

EHRA suggests that the exclusions to the Opioid Treatment Agreement measure should include consideration for patients with certain diagnoses (e.g., various cancers) or settings (e.g., hospice).

The use of the Medication History transaction seems a poor fit for supporting a measure denominator for the Opioid Treatment measure, as the transaction does not really support the concept of prescription days but uses a duration which has no start or stop date needed to reconcile overlap given the denominator definition.

The proposed measure may be difficult if not impossible for developers to calculate. The proposed denominator is based on patients receiving an e-prescription for a Schedule II opioid who also have a total of 30 or more cumulative prescription days on the Schedule II opioid being prescribed. The NCPDP 10.6 Medication History query, as CMS refers to it, does not contain a field for prescription days. We suggest CMS consider another measurement that is based on structured data to be used for measurement calculations. Moreover, the proposed denominator is extremely complicated, relying on third party data that may not even be able to be returned in a discrete fashion. If non-discrete data is provided, an EHR would be unable to generate calculations based on that data.

Upon considerable review and discussion, EHRA finds that this measure would contain unreliable data, which would create suspect calculations. The measure, as proposed, means that it would be possible for an EHR to receive duplicative data (e.g. receive the same medication history from Surescripts, PDMP, and/or health system), which raises the question on how an EHR would handle not only the duplicative data but in how cumulative days would be calculated with this data. There are simply too many variables currently to be able to ensure clean data is used for calculations.

The EHR cannot determine if someone “sought an agreement” as listed in the proposed numerator. The measure must be rewritten to be measurable. From a workflow perspective, it is not expected that if no agreement were present that a hospitalist would write up the treatment agreement at discharge; they would refer the patient for treatment; and, during that session, a treatment agreement would be created. Overall, the proposed numerator definition does not match the typical workflow for these types of situations.

Providers may not know of an opioid treatment agreement facilitated by another provider. There are no standards for the exchange of such agreements. Moreover, an opioid treatment agreement is not based on clinical information, it is provider-requested. We suggest consideration that the opioid treatment agreement be available not only within a provider but across providers through PDMPs. We recognize this requires further definition of exchange standards, but believe this to be an important next step.

Data shows that there is no significant patient improvement by having an agreement in place. We provide the following articles as evidence:

- <https://www.ncbi.nlm.nih.gov/pubmed/20513829>
“**CONCLUSION:** Relatively weak evidence supports the effectiveness of opioid treatment agreements and urine drug testing in reducing opioid misuse by patients with chronic pain. Further research on effective ways to monitor and reduce opioid misuse is needed, especially in primary care settings.”
- <https://www.ncbi.nlm.nih.gov/pubmed/22786449>
“**EVIDENCE:** fair to limited) 6. A robust agreement which is followed by all parties is essential in initiating and maintaining opioid therapy as such agreements reduce overuse, misuse, abuse, and diversion”
- [https://www.jpain.org/article/S1526-5900\(08\)00832-8/fulltext - sec4](https://www.jpain.org/article/S1526-5900(08)00832-8/fulltext - sec4)
“...found that institution of adherence monitoring (signed controlled substance agreement, periodic monitoring, periodic drug testing, pill counts, and education when necessary) was associated with a rate of controlled substance abuse of 9% (defined as receiving controlled substances from any place or source other than the prescribing physician), compared with 18% in an earlier cohort.”

The measure merits reconsideration.

Modifications to TOC measure

EHRA appreciates the statement, “We also wish to encourage eligible hospitals and CAHs to use the document template available within the CCDA which contains the most clinically relevant information that may be required by the recipient of the transition or referral.”

We strongly believe that to support users to get the right data at the right time for the right patient, it is appropriate to determine when to send all or some of the data. This becomes increasingly more appropriate with the emergence of HL7 FHIR based APIs that enable interactive, data element level access that can complement document level access. For example, the scenario where a referring/transitioning provider forwards a targeted document with essential information that can be followed up by the receiver with targeted queries for more as needed, can help all parties to right-size the data exchange, while still having the opportunity to access ALL when needed.

In this context, we want to ensure CMS is aware of key initiatives to further improve on making appropriate documents available. A joint initiative between CommonWell, Carequality, Argonaut, and HL7 is establishing further guidance on an appropriate document template for either the inpatient stay and outpatient visit to summarize the clinically significant data, tied together with a provider’s key clinical notes.

As these initiatives yield additional capabilities to right size and focus information exchange (without disabling accessing ALL data either), CMS should ensure that it does not introduce incentives that have an unintended consequence of discouraging using such new/alternate approaches. We recognize that, while we have made great strides in sharing clinical information across providers and other stakeholders, there is still much to learn on how to right-size information sharing. Therefore, CMS must enable innovations that can help us find that right balance.

While we encourage flexibility, we recognize that at this stage not all EHRs support all document types available within the HL7 C-CDA framework nor are all applicable in every setting/use case.

We note that ONC does not require these other document types/templates for 2015 Edition CEHRT. Therefore, delivery of these optional templates within the suggested timeframe may be unlikely. We therefore suggest that with the flexibility and encouragement provided by CMS, users not be limited to the three document types enumerated in the 2015 Edition certification, nor should an expectation be set that providers will have those other document types/templates immediately available. Providers and EHR developers should and can work together to identify and prioritize the most relevant document types/templates, which can provide input into future rulemaking as to which one(s) are ready to be subjected to certification.

EHRA supports the renaming of this measure and supports this measure not having a reporting threshold per the proposed scoring methodology, so long as these changes are consistent across all Incentive Programs.

Removal of Request/Accept SoC

EHRA appreciates CMS' responsiveness to previous feedback on the burden associated with data collection, workflow, and calculation of this measure. However, EHRA finds that the removal of this measure does not reduce burden.

See comments on the proposed Support Electronic Referral Loops measure.

Removal of Clinical Reconciliation

EHRA appreciates CMS' responsiveness to previous feedback on this measure and are supportive of its removal from this program given that the workflows for implementation do not require health IT engagement. However, EHRA finds that the removal of this measure does not reduce burden.

See comments on the proposed Support Electronic Referral Loops measure.

New HIE Measure; Support electronic referral loops by receiving and incorporating health information

EHRA strongly disagrees with this proposed measure. This new measure is inherently more complex in its requirements as well as being more difficult to calculate because it blends several measures that were previously calculated independently. EHRA recommends that a single measure be utilized for every requirement that CMS wishes reported.

We have additional concerns about the timeline to implement these changes for the 2019 reporting period, especially given the effort required to calculate a new measure (which requires over 1,000 development hours) as well as additional testing/certification efforts. For these reasons, EHRA recommends keeping the original measures rather than creating a newer, more convoluted measure.

Modification of Patient Exchange

EHRA supports the renaming of this measure and supports this measure not having a reporting threshold per the proposed scoring methodology, so long as these changes are consistent across all Incentive Programs.

Modification to Patient Access

EHRA supports the renaming of this measure and supports this measure not having a reporting threshold per the proposed scoring methodology, so long as these changes are consistent across all Incentive Programs.

Additionally, we support the proposal to retain this measure and move to a lower threshold of one patient so that CMS can utilize the new performance-based scoring method.

CMS can assist marketplace acceleration of relevant patient-facing applications by working with ONC to specify specific standards that must be used in the provision of API access as a minimum. Currently, health IT developers can have their own API technical requirements for application developers to meet to connect to their application. Convergence on a common standard can accelerate access to and adoption of client facing applications, whether deployed independently and directly with EHRs or through national networks.

We appreciate that non-electronic data exchange (paper as well as faxing) should not contribute to any measures related to promoting interoperability.

Modification to Registries

EHRA supports most of the proposed modifications; however, we would like to point out that some states, such as Oklahoma, Iowa, Minnesota, and some counties in Colorado, do not accept syndromic surveillance files. Thus, the proposal does not apply to all states uniformly. While we appreciate that this is covered by an exclusion, we felt it prudent to share the information we have gathered.

We request CMS clearly define the requirements in selecting a second measure beyond syndromic surveillance. For example, would a hospital/critical access hospital (CAH) have to be excluded from all the remaining measures in order to claim an exclusion? If a hospital/CAH is excluded from syndromic surveillance, do they need to select another measure to reach two or are they only required to select one other measure and attest to the exclusion?

EHRA supports the interest to improve electronic exchange across the continuum of care and to be able to perform clinical information reconciliation, agreeing that 2015 Certification Edition generally supports the necessary capabilities. However, where this involves receipt from 42 CFR Part II or behavioral health settings, both the ability to appropriately convey computable consent and having the necessary capabilities in the sending systems (considering current EHR technology adoption levels in those settings), initial adoption may be slower than desired. That should not necessarily preclude inclusion of such measures to contribute toward the performance score.

Also, we note that existing measure exchanges between the inpatient setting and post-acute settings are already captured, thus we urge caution against the recreation of duplicate measures that would specifically focus on exchanges with those settings.

RFC Health Information Exchange across the Care Continuum

EHRA supports interoperability but worries that the proposed new measure is duplicative and increases burden without value.

The proposed measure removes transitions to other hospitals or CAHs, but counts all other transitions and referrals. We believe CMS intended to base this measure on transitions and referrals to/from

providers that are not eligible for the PI and MIPS programs. This would focus the measure to encourage growth in electronic exchange outside locations where it has already been incentivized.

However, EHRA finds it counterproductive to measure these items separately from other measures, as most facilities are already functioning in the way CMS has expressed that they want them to function. EHRA members have never interpreted the current measure to look only at hospital-to-hospital exchange; as a result, our EHRs are already including in their metrics those documents sent to alternative care facilities rather than those simply sent to another hospital.

We would like to additionally point out that Direct Address standards do not specify the location of the physician when sending a message, so there is no way to distinguish when, for example, Dr. Smith is sending a document as the attending physician at the hospital versus Dr. Smith at his clinic. The healthcare industries would assume an enormous burden to granularly differentiate by document recipient/sender, and the proposed measure does not accommodate that. We debated the use of discharge disposition as a reasonable method for tracking but that does not enable tracking per document.

Given the challenges in calculating this measure and the fact that the industry is already taking action, EHRA finds no justification to create this measure and strongly recommends its removal.

In general, EHRA finds that retiring a measure completely is better than simply rolling several measures together into a single measure. That said, we would prefer not to continue to have requirements added to certification efforts that are then removed prior to them becoming effective, especially given the large number of development hours required to add or modify requirements.

EHRA is supportive of all recommended removals of measures, as this aligns with CMS's goal of reducing burden and complexity. However, any measure removals or modifications must be aligned across programs to truly meet the goal of less complexity and burden reduction.

What health IT activities should CMS consider recognizing in lieu of reporting on objectives that would most effectively advance priorities for nationwide interoperability and spur innovation? What principles should CMS employ to identify health IT activities?

EHRA recommends that CMS set principles and explain why an activity met the principle. Technology changes quickly and rules would never be able to keep up; providers can justify their activities to the principle.

This is not a Yes/No query, so organizations should be allowed to provide information on how they meet the principles, similarly to how public health provides various levels to attain the goal.

EHRA does not suggest any new statistical reporting, and we recommend CMS provide a way in attestation instead of requiring a reported objective.

Promote Piloting Emerging Technology Standards

EHRA believes that exploration and innovation are essential to progress interoperability and achieve the value of sharing data. Participation in pilot programs, whether FHIR-based bulk data exchange or other use cases, is essential to ensure the proposed standards and implementation guides are clear, practical, implementable, and scalable. Provider organizations participating in such pilots should be recognized and as necessary qualify for exclusions and/or credit points.

We submit that it is not clear what the scope of “health IT activities” could be. On one hand, these could be very specific interoperability activities, such as exchanging notifications to providers/payers on patient appointments; or, on the other hand, participation in research that furthers the state of interoperability. On the first, we could provide a number of interoperability use cases that could be considered for future use. We will focus our feedback on the second type in this response as being different from volume measurements to measure adoption.

We suggest that understanding participation in health information networks would provide valuable insight into the ability to exchange and access data across stakeholders, particularly when this involves geographic and national networks such as HIEs, Carequality, eHealth Exchange, and CommonWell.

Also, EHRA believes that reporting on progress that contributes to a performance score rather than meeting thresholds is more practical and realistic. However, measuring volumes alone is not indicative of the value realized. Doing more does not necessarily translate into doing better.

At the same time, we recognize that measuring the impact of interoperability is very challenging, as it is but one factor in improving health and coordination of care. We suggest that targeted surveys/research, rather than nationwide measurements, may be more suitable to understand the impact, while also sharing/adopting best practices. The topics this may focus on could include patient matching, data quality in data access/exchange, impact/use of notifications to patients/providers, etc. Utilize measures that focus on improving data sharing for specific outcome measure improvement. We suggest that provider participation in those activities should be recognized.

As these health IT activities are being recognized, we suggest that CMS could facilitate funding/grants to enable providers to participate in such health IT activities.

Do stakeholders believe that introducing health IT activities in lieu of reporting on measures would decrease burden associated with the Promoting Interoperability Programs?

This proposed change would result in developer and provider burden reduction. We do not need to measure every item, but how would they be introduced without introducing additional burden? Evidence should be able to be produced by the EHR, without requiring extra steps by the user.

EHRA believes that participating in activities that may not yield direct contributions to measurement, yet create value, would change the perception from “burden” to “valuable to the participant.” They would have the opportunity to focus on the best use of health IT supporting clinical care rather than just using

and reporting on use of health IT. All the while, they are participating in the program, creating opportunities for best practice sharing, and laying a foundation for continued interoperability improvement.

If additional measures were added to the program, what measures would be beneficial to add to promote our goals of care coordination and interoperability?

EHRA recommends that aligning requirements with provider workflows would be beneficial to both providers and developers.

Program changes should be done with intention and to move the program in the right direction. We do not feel changes are intentional or evidence-based. For example, advancing care information measures were completely cut prior to the completion of one year.

Rapid changes do not align with the organizational work effort to employ the previously identified requirements. Adoption timeline effort, development time, and money expended are wasted. An alternative could be providing organic evidence of use during audit instead of system generated reporting. For example, PDMP has no certification criteria and was not presented on a timeline tied to program needs.

Given these challenges, EHRA suggests CMS provide a probationary period for a new requirement before incorporation and use.

EHRA cautions against adding measures that only indicate volumes and focus, instead, on outcome measures that have a high correlation with the presence/absence of interoperability. For example, 30-day readmission rates are impacted by sufficient data sharing. Such a measure, in combination with targeted survey/research, could provide better insight into what data is critical to share, and how and when it is shared, rather than adding volume metrics for everyone to collect.

How can the Promoting Interoperability Program for EEs and CAHs further align with the QPP (for example, requirements for ECs under MIPS and Advanced APMs) to reduce burden for health care providers, especially hospital-based MIPS eligible clinicians?

EHRA suggests participation in activities that would apply across all programs could reduce the burden across all venues, and not require meeting specific objectives.

What other steps can HHS take to further reduce the administrative burden associated with the Promoting Interoperability Program?

EHRA urges CMS to take advantage of opportunities to align programs and measurements. Inconsistent reporting requirements for Medicare and Medicaid have created additional burdens on providers and developers; capturing and calculating measures differently for each program is challenging. This is clearly an opportunity for CMS to demonstrate its commitment to burden reduction.

Another step toward burden reduction would be to ensure that any new measures build upon existing electronic data, rather than requiring additional documentation.

Reducing the number of eCQMs in the Medicare and Medicaid Promoting Interoperability Programs eCQM measure set from which eligible hospitals and CAHs report, by proposing to remove eight eCQMs (from the 16 eCQMs currently in the measure set) beginning with the reporting period in CY 2020.

EHRA supports the removal of these measures from the program. However, due to the timing of the introduction of clinical quality language (CQL), we suggest removal of these measures for the 2019 Reporting Year rather than waiting for 2020. Because the change to CQL is so significant, removing the measures for reporting year 2020 will result in development of these measures to the new standard for only one year of reporting, creating a vast burden on developers.

EHRA appreciates CMS' consideration of past comments on the amount of time needed for development related to measure changes and additions. However, when measures are removed, advance time for development work is not needed. Rather, in this situation, developers would be required to engage in measure analysis, development, testing, customer education, and delivery of new code for seven measures that will only capture a single year's worth of data. By removing the measures for reporting year 2019, developers will be able to eliminate the time and effort needed to update those temporary measures and give attention to areas that are of greater concern to customers.

Clinical quality measurement for EH/CAH participation in PI programs

Reporting Periods

EHRA appreciates the continuity between reporting years.

RFI - Promoting Interoperability and Electronic Healthcare Information Exchange through CoP revisions

If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

Considering the focus that the 21st Century Cures Act has put on information blocking, the need to exchange data to enable value based care, and the advances made in technology and standards to further improve data access/exchange, we do not believe extra CoP/CfC/RfPs are essential.

21st Century Cures rulemaking is underway and will further define information blocking, safe harbors, the USCDI, and TEF. Without these provisions in place, EHRA questions the efficacy of Medicare CoPs related to interoperability. It may increase the administrative burden for hospitals and providers who accept

Medicare and subject them to vague or undefined requirements, particularly without a fully defined regulatory framework.

Moreover, we think other regulatory vehicles for Medicare CoPs would be more appropriate than the IPPS. Currently, interrelated CoP modifications would have to occur in the IPPS, Skilled Nursing Facility, and Physician Fee Schedule, which increases the associated regulatory complexity and compliance burden.

Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

EHRA believes it is reasonable to require enabling patient focused portals and/or APIs to provide patients and their caregivers with access to their data. We submit that it is not clear what a reasonable standard for “undue burden” would be, particularly as it is important to be able to assert that the person requesting/providing the data is who they claim to be. This should be easy and transparent, but may require minimum steps to achieve.

Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?

EHRA does not believe that additional CoP/CfC/RfP requirements on hospitals are essential to drive patients to access their information or further the interaction with other providers, particularly given the requirements on information blocking under the 21st Century Cures Act and its focus on value based care and tools being deployed. This will highlight gaps that health IT suppliers and their clients/consumers will identify, prioritize, and fill.

What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

Without a clear understanding of what the new/revised CoPs/CfCs/RfPs are, it is challenging for EHRA to answer this question. Once requirements are clearly defined, we suggest that a minimum of 18 months will be required to develop, test, deploy, and begin using the new capabilities between health IT suppliers and their user communities.

Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

EHRA believes that drivers -- such as the 21st Century Cures Act focus on information blocking, value based care, and improved data exchange -- will help improve interoperability, and in turn improve overall care coordination and patient safety as a result of improved access to the necessary data. We do not believe further CoPs/CfCs/RfPs are required to drive those improvements through interoperability.

Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

While EHRA believes that the benefits of electronic transmission of data far outweigh the use of paper, we recognize that we are still transitioning from a paper-based system to a fully electronic one. Until such time when the necessary infrastructure and capabilities are in place, we expect continued need for supporting printed output.

Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

Without a clear understanding of what the new/revised CoPs/CfCs/RfPs are, it is challenging for EHRA to answer this question.

What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

Without a clear understanding of what the new/revised CoPs/CfCs/RfPs are, it is challenging for EHRA to answer this question.