September 10, 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 on the Center for Medicare and Medicaid Services’ (CMS) proposed rule on the Medicare Program: Revisions to Payment Policies under Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; etc., which was published in the Federal Register on July 27, 2018.

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 for implementing significant policy modifications related to evaluation and management documentation requirements, recommendations to streamline the roll-out of appropriate-use criteria, and the continuation of efforts to reduce administrative burden for providers participating in MIPS.
Evaluation and Management (E/M) Documentation Requirements
EHRA has consistently supported efforts to reduce clinician burden related to reporting requirements, provided that these program modifications are proposed in a manner that allows both developers and clinicians appropriate time to implement changes. We are concerned that the proposal to implement the consolidation of E/M codes by January 1, 2019, does not give sufficient time for developers to make changes to accommodate these policy updates and will result in confusion in the market and potentially increase, rather than reduce, clinician burden.

Further, EHRA is concerned that these documentation requirement changes may not be adopted by private payers, creating the potential for disparate documentation practices based on varying payer sources.

Appropriate Use Criteria (AUC)
EHRA supports the proposal to allow for voluntary participation in AUCs for 2019, in advance of applying penalties in 2020. Additionally, EHRA supports CMS’ proposed revisions to the hardship criteria; however, we do recommend expansion of these criteria to take into account factors such as low patient volume and suggest CMS undertake efforts to minimize the documentation burden associated with clinicians submitting hardship exceptions for each imaging order.

EHRA continues to request further information on key components of the AUC program, including:

- Clarity on provider-led entities and the AUC method they use
- The interaction between clinical decision support (CDS) mechanism and the ordering system
- Communication of the relevant data from the ordering provider to the furnishing provider
- Communication of the relevant data from the furnishing provider to the claims processor

Merit-Based Incentive Program (MIPS)
EHRA appreciates CMS’ continued efforts to find the appropriate balance between encouraging and expanding provider participation in MIPS with the long-term goal of reducing clinician burden through development of meaningful measures. Specifically, EHRA supports the proposal to expand MIPS participation to a broader set of clinicians and allow providers not meeting all of the low-volume threshold to opt in to MIPS participation.

CMS’ proposal to expand measures related to opioid-use are consistent with EHRA’s efforts to leverage health IT to combat this public health issue. However, we recommend the development of measures that are more preventative in nature and can help address risk of abuse, rather than focusing measures exclusively on treatment.

Further, we recommend that implementation of these new measures occur at least 18 to 24 months after finalization of rulemaking.
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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Chair, EHR Association
NextGen Healthcare

Sasha TerMaat
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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.
Providing Choices in Documentation

**Allow providers to use MDM, or time, or continue to use the current framework (1995 and 1997 documentation guidelines) to document an E/M visit**

While EHRA understands the desire to give providers flexibility in billing their encounters, the current proposal, as described, replaces overly prescriptive documentation requirements with overly ambiguous proposals.

It is important to acknowledge that CMS is not the only payer to use Current Procedural Terminology (CPT), documentation guidelines (DGs) and relative value units (RVUs) to determine payment levels. These concepts are deeply embedded within existing EHRs and changes will require significant effort on the part of developers and payers in conjunction with a massive education effort for providers, coders, and auditors. This initiative is long overdue, but the scope and ramifications should not be underestimated, and all stakeholders should be involved in the process.

While EHRs have been a valuable tool for providers when assessing their documentation compliance, introducing significantly different documentation requirements based on payer status would require additional development that is not feasible given the proposed timeframe for implementation.

It is not clear if providers will be allowed to choose which DG to use on a case-by-case basis or if they must select a method to use consistently. Additionally, there are third-party payers who may or may not choose to follow CMS’ lead and it is unlikely that these payers would be prepared to institute such radical changes on January 1, 2019. The additional burden on providers to determine which payer and which method should not be underestimated.

The proposed rule implies that there is an expectation that providers will continue to choose different levels for an E/M visit; however, given the proposed blended payment rate, it is unclear why a provider would ever choose to bill anything other than a Level 2. While individual provider groups may currently have internal incentives/performance metrics based on E/M level distribution, this practice would probably cease given the blended payment rate, rendering the need to bill anything above a Level 2 for a Medicare beneficiary a moot point.

“...we propose to allow practitioners to choose, as an alternative to the current framework specified under the 1995 or 1997 guidelines, either MDM or time as a basis to determine the appropriate level of E/M visit.”

Additionally, CMS states that they believe visit level audits will no longer occur, making the basis to determine an appropriate level of E/M visit irrelevant.
“...we believe that eliminating the distinction in payment between visit levels 2 through 5 will eliminate the need to audit against the visit levels, and therefore, will provide immediate relief from the burden of documentation.”

Given the stated intention to halt visit level audits, EHRA requests CMS’ plan for documentation audits under the proposed flexible documentation guidelines.

**Time**
EHRA is generally supportive of the proposal to extend the time-based standard to encounters in which counseling and/or care coordination does not account for more than 50 percent of the face-to-face practitioner/patient encounter. The proposed rule provides little or no guidance as to the documentation requirements to support this proposed time method, other than indicating the total amount of time spent face-to-face with the patient.

We recognize that variations in physician documentation practices, office processes, and nonclinical factors contribute to the amount of time a provider spends with a patient. EHRA requests that CMS provide more explicit direction as to what documentation will be required to support an E/M level based on time spent face-to-face with the patient.

**Medical Decision-Making (MDM) documentation guidelines**
MDM documentation guidelines have long been viewed as ambiguous. Lowering the minimum documentation requirement for MDM to a Level 2 (low complexity) will mitigate confusion as to what is required from a billing perspective to document for medical decision-making.

**Reducing redundant documentation**
EHRA supports the proposal to help reduce redundant documentation and address the problem of ‘note bloat.’ This proposal will likely improve the medical record as a communication instrument for all providers.

We are interested in whether CMS intends to extend this philosophy to other parts of the unified medical record, in which many providers are required to re-document patient data such as medication lists and allergies. There is inconsistency between Medicare Administrative Contractors (MACs) as to the necessity for providers to personally document this information which is easily reviewable in a unified medical record. Explicitly eliminating ambiguity on this point would alleviate provider burden and redundant documentation.

**Unintended consequences**
While reducing clinician burden is a priority for CMS, it is important to recognize the potential for unintended consequences of these proposed changes on other, equally important, goals for CMS. Structured documentation necessary for quality measurement, standards-based interoperability, and clinical decision support is typically generated by an EHR capturing data elements entered by the provider during the course of documentation.
While technology such as Natural Language Processing has improved in recent years, EHRA does not believe it is sophisticated or widely implemented enough to replace the need for structured documentation.

**Shifting complexity with HCPCS add-on codes**

The benefit of reducing complexity, by reducing five levels to two, is counterbalanced by shifting complexity with additional HCPCS codes that are reliant on training coders in proper utilization, in a compressed time frame.

We appreciate CMS consideration of specialty providers and recognition of the inherent complexity of their patient population. We would appreciate CMS clarifying if there are any documentation requirements associated with using these specialty HCPCS codes to account for the situation in which a designated specialist may also see patients in a primary-care capacity.

**Measuring improvement**

EHRA would welcome additional information from CMS on the plan to assess benefits and impacts of proposed changes. While the projected financial effect of the blended payment rate projects minimal impact, it is not unreasonable to expect that CMS would publish comparative numbers at the end of 2019, including the distribution of documentation methods used, in order to determine the effectiveness of the changes. Also, it would be helpful to hear CMS’ plan to monitor the effects of the burden reduction proposal on other CMS programs linked to physician documentation.

**Medicaid Promoting Interoperability (PI) Program**

**Electronic Clinical Quality Measures (eCQMs)**

EHRA is supportive of CMS’ efforts to harmonize current quality measure options across programs as quickly as possible, and we encourage cross-program alignment for future requirements.

Also, it is important to consider the potential negative impact of too many options confusing providers when states are making individual decisions. It is difficult for EHR developers to implement or support providers when there are many state-based variances in program requirements.

Because 2021 will require 90 days for all participants, for 2019 and 2020 eligible professionals (EPs) should continue to be allowed to choose between 90 days or a full year in order to facilitate consistency in length of performance period, as desired.

**Program Year 2021 requirements**

We request that CMS provide education materials for clinicians around the 2021 timing for attestation. Additionally, because variations across states are always difficult for EHR developers to support, as much harmonization as is possible will benefit all stakeholders.
**Syndromic surveillance measure**

EHRA is supportive of expanding access to this measure to include more EPs participating in the Medicaid PI program.

It will be important to harmonize the measures/objectives of the Medicaid PI program with the MIPS PI category, in order to reduce development burden on developers and education burdens on clinicians participating in both programs.

**Medicare Shared Savings Program (MSSP)**

EHRA is very supportive of efforts to harmonize reporting measures across programs, and thus reduce reporting burden for clinicians and groups participating in quality payment programs (QPP).

**Physician Self-Referral Law**

EHRA recommends an exception to the Physician Self-Referral Law (also known as the ‘Stark Law’) to allow for the subsidizing of cybersecurity needs such as cybersecurity software, cybersecurity hardware, cybersecurity training, tools for threat information sharing, and hardware. We recognize that having the right tools is not enough and that updates to the Stark Law should make exceptions for operational support such as IT assistance and other skilled services to aid smaller organizations with deployment and maintenance of these cybersecurity solutions.

Additionally, to encourage adoption of interoperable EHR technology for all types of providers that participate in Medicare, EHRA recommends that two key provisions be made as exceptions under the law:

1. Any risk-bearing entity under an alternative payment model (APM) that qualifies as an Advanced APM under the Medicare Quality Payment Program should be eligible to be a donor of EHR items and services under the exceptions to the physician self-referral law and the anti-kickback statute. We believe CMS and the Office of Inspector General (OIG) already have this authority without need for further statutory authorization.

2. Any provider participant in an APM that qualifies as an Advanced APM under the QPP should be eligible to receive donations under the exceptions of either the self-referral law or the anti-kickback statute. We believe CMS has the authority to consider including recipients such as post-acute care providers, skilled nursing facilities, long term care hospitals, intermediate rehabilitation facilities, and home health agencies in the definition of “recipient” under the anti-kickback statute exception.

We believe the definition of eligibility of which EHR items and services can be donated could align with the donation provisions and qualifications that are already established under the physician self-referral law and anti-kickback statute exceptions.
Finally, EHRA recommends the exceptions be updated to include language on information blocking, both by donors and their suppliers of the donated health IT, as defined by Section 4004 of the 21st Century Cures Act (Cures). Donating resources should not include conditions limiting information flow within and beyond APMs, but should remain open as considered in Cures.

**Appropriate Use Criteria (AUC)**

**Timeline**
Ensuring smooth and easy workflow for all parties involved, particularly the ordering provider, is essential; it is actually the furnishing provider that stands to benefit, while being dependent on the ordering provider to communicate the essential data for the claim.

In that context, EHRA seeks the following clarification and offers several suggestions. As we have identified in earlier feedback on the proposed AUC initiative, the program requires many parts to come together, specifically:

- Clarity on provider-led entities (PLEs) and the AUC Method they use (including the mapping of their specific scoring system to the CMS proposed three-part categorization)
- Interaction between the clinical decision support mechanism (CDSM) and the ordering system and ensuring the relevant data is provided by the CDSM to the ordering system, preferably in an industry standard format, considering both data necessary for the claim and data relevant for other purposes
- Communication of the relevant data from the ordering provider to the furnishing provider, including any information about potential exemptions to be supplied in a newly proposed modifier
- Communication of the relevant data from the furnishing provider to the claims/billing system that in turn generates the appropriate claim

We support the general consideration to start with early adoption and pilots in 2019 before the program starts on January 1, 2020, with an initial year for educational and operations testing when claims will not be denied for failure to correctly include AUC consultation.

However, EHRA is concerned that nationwide deployment, where the claims systems can communicate the data but where necessary interoperability among the other components is not yet widely adopted, will risk further inefficiencies in provider organizations and distract from their main mission to care for patients. We suggest CMS monitor this carefully in 2020 to assess appropriate steps to ease associated burdens and risk.

**Reporting AUC consulting information**
EHRA commends CMS for clarifying that it does not require the physician to report consultation, but would like to have more education around the requirements in regulatory documents.
We note that a number of CDSMs communicate a score (e.g., 0-9), but not the determination of whether (1) the imaging service would adhere to the applicable AUC; (2) the imaging service would not adhere to such criteria; or (3) such criteria were not applicable to the imaging service ordered.

EHRA strongly urges that CMS include in the PLE’s AUC Method authorization mapping of the AUC Method’s scoring system to CMS’ adherence indication whether the ordered service did or did not adhere to the applicable AUC(s), or no criteria were available. Such mapping can then be consistently used by varying CDSM supporting that PLE’s AUC Method to communicate to the ordering system, or in the absence of (standard) integration be consistently applied by a downstream system prior to generating a claim.

We seek clarification on what data is used to relate the AUC data on the claim with what the CDSM actually provided to establish best practice to retain such data for potential audit, as the AUC Consultation Identifier number (as issued by the CDSM to identify the specific AUC consultation) is not proposed to be communicated on the claim. In this context, it would help to clarify who bears responsibility in cases where such data is not available during an audit, considering that the furnishing provider submits the claim while the ordering provider interacted with the CDSM. In particular, understanding the obligations of the ordering provider would benefit from this clarification.

**Claims-based reporting**

In order to minimize provider burden, appropriate education resources for physicians must be made available well before 2020; there is little available currently.

There are instances where radiologists can and do determine, based on the patient presentation and best practice, that a higher level/different exam type is warranted. The radiologist has the ability to amend the original order based on Medicare Claims & Benefit Rules. In these scenarios, it is not clear whether the furnishing provider is to perform the AUC consultation for the updated imaging study while the original imaging study request is cancelled, without further information required from the original ordering provider for CMS. We ask CMS to clarify such data correction mechanisms.

We suggest that CMS clarify that AUCs only need to be obtained for the following Medicare Patients based on source of payment (SOP) codes:

1    MEDICARE
11   Medicare (Managed Care)
111  Medicare HMO
112  Medicare PPO
113  Medicare POS
119  Medicare Managed Care Other
12   Medicare (Non-managed Care)
121  Medicare FFS
122  Medicare Drug Benefit
123  Medicare Medical Savings Account (MSA)
EHRA suggests that CMS clarify the definitive source on the Medicare Learning Network where the most current advanced imaging studies requiring AUC consultation will be formally listed as well as clarify that updates would be made no more frequently than annually.

We are concerned that the diagnoses/clinical area/indications used by CDSMs is not mapped back to ICD-10 diagnosis codes, thus requiring separate maintenance. We seek clarification of the expected update timeline for CDSM for diagnoses/clinical/indications, and ask CMS to encourage alignment with ICD-10 to minimize or eliminate mapping between EHRs and CDSMs.

**Hardship exclusions**

These hardships, as proposed, can exist over longer periods of time and could result in clinician burden if it must be reported for every single order during that time frame. Due to potential confusion over hardships being on a case-by-case basis versus one-time, as it has been for other programs, sufficient provider education will be needed to ensure requirements are met for every order eligible for the exclusion.

Additionally, the absence of a patient volume exclusion creates additional burden for providers who have a small number of Medicare patients but need to contract for CDSM content and EHR enhancements to accommodate those patients.

EHRA is supportive of CMS' proposal to allow providers to claim significant hardship exceptions related to their ability to consult AUC using a qualified CDSM. However, we have concerns that the criteria as proposed may cause potential confusion and increase provider burden for those to whom it applies. For example, the proposed criterion of insufficient internet access is one that could potentially persist for a long period of time and could result in increased clinician burden if the exception needs to be reported for every single order during that time frame.

While we understand that a hardship exception applies to specific orders, we are concerned with the documentation burden this may yield if the ordering provider is required to specifically document it on each order. When using electronic ordering capabilities, we suggest that it should be permissible to document a hardship exception to be effective for a period of time, while each order to which that hardship exception applies can communicate it for inclusion on the claim. For manually managed orders, a similar approach should be permissible so it can be on a claim based on the necessary overall documentation, but need not be marked on each order.

Additionally, we seek clarification on how de-certification of an EHR would qualify as a significant hardship since there are no certification requirements related to the AUC program.
Moreover, EHRA is concerned over the applicability of these program requirements and the lack of a patient volume hardship for small practices and other providers who order low volumes of applicable imaging orders. For providers who have a small number of Medicare patients or who order small numbers of applicable imaging orders, requiring them to purchase/contract for access to CDSM content and/or EHR enhancements to accommodate the program will certainly increase their financial and operational burdens.

**Merit-based Incentive Payment System (MIPS)**

**Definition of MIPS eligible clinician**
EHRA is supportive of the proposal to expand MIPS participation to other types of clinicians, including physical therapists, occupational therapists, clinical social workers, and clinical psychologists. The purpose of Promoting Interoperability is to support providers participating in interoperability, and these clinicians are oftentimes the recipients of data or active participants in patient care teams and should have the opportunity to benefit from this performance category.

Also, we understand why there may be clinicians in this expanded group who, for various reasons, feel they cannot meet the measures and objectives included in the Promoting Interoperability performance category. However, given CMS' proposed changes to the Promoting Interoperability performance category, we believe that there are some clinicians in this expanded clinician type who may want to report data for this performance category and may feel that being able to report data for this category is necessary to meet the minimum performance threshold and/or to meet the threshold to earn the exceptional performance bonus.

EHRA recommends allowing these expanded clinician types to opt-in to this performance category, using the mechanism where if data is reported to CMS for the category then the eligible clinician (EC) has opted in. If the EC does not report any data for this category, then the category would be weighted at zero percent and the other categories would be re-weighted appropriately. These clinicians would have the option to claim relevant exclusions related to e-prescriptions or transitions of care, as appropriate. This would allow flexibility for participation and for clinicians to receive credit for activities related to Promoting Interoperability.

**MIPS low-volume threshold**
EHRA believes that continuing to keep the thresholds high in the "easier,” transition years of a program (more than $90,000 in allowed charges, more than 200 beneficiaries and more than 200 covered professional services) will have a negative impact on providers who will be required to meet high reporting standards when they are eventually required to participate in the program. Because developers help with educating providers, this will have negative impacts on both stakeholders.

Continued high participation thresholds creates a negative impact on providers who are between $30,000 and $90,000 (or 100 and 200 beneficiaries) who were required to participate in MIPS during the 2017 performance year but no longer have the option to participate, even if they wanted to and proved their ability to successfully participate in 2017. By not creating an avenue for those providers
who are "between thresholds," the workflow changes that those providers implemented and the technology investments that they may have made to participate in 2017 cannot continue to grow their practices or reinvest positive payment adjustments into additional quality improvement activities. In future rulemaking, EHRA urges CMS to think about ways to allow this group of providers to participate. EHRA is supportive of allowing providers, who meet one but not all of the low-volume threshold, the opportunity to opt-in to MIPS participation. However, we encourage CMS to provide information regarding eligibility for opt-in to clinicians as soon as possible so that those eligible can prepare for a full year of participation. If providers do not find out until after the performance year has started, it may be too late for them to take advantage of this option due to the time required to learn workflows or adopt technology, especially for the Quality performance category which requires a full year of participation.

**MIPS definitions**
EHRA members have not found that customers are confused by the terms currently used and recommend that this change not be made.

EHRA is not supportive of proposals to formalize definitions for the terms "Collection Type," "Submitter Type," or "Submission Type" as the proposed definitions may result in more confusion for eligible clinicians, developers, and other organizations that support participating eligible clinicians.

The terms "Submitter Type" and "Submission Type" suggest activities that may easily overlap and may cause more confusion to participating eligible clinicians. For example, an EC can choose to report data to CMS through the QPP web portal by logging in and both "attesting" to the Promoting Interoperability category AND "uploading" data for the Quality category. The user would not need to login twice nor would the user be able to say definitively that the submission type they used for MIPS was one or the other, since both are possible. The same is true for direct data submission, where it can be used in tandem with other submission types.

Another example is the proposal to modify the name of measures used in the QPP/MIPS program, which may result in more confusion than clarity because the term "CQM" is often used interchangeably with the term "eCQM" to refer to electronic clinical quality measures. In addition, Medicare Part B claims measures and eCQMs are considered MIPS Clinical Quality Measures so defining those terms as if they are independent concepts would be inaccurate.

**Quality – Claims**
EHRA is not supportive of this change, which would allow only small practice providers to use Medicare Part B claims as a collection type beginning with the 2021 payment year. We feel that this change will result in a negative impact on providers who are part of specialties that do not have eCQMs applicable to them and who have workflows in place to support reporting data using claims already. Requiring them to change these workflows simply due to practice size would cause unnecessary burden, since the goal of reporting data and participating in the program would still be met.
Submission deadlines
EHRA is supportive of changes to reporting deadlines when in the best interest of participating providers (e.g. extending if there are technical issues with the submission website). In general, predictable and achievable deadlines are preferred for planning and education purposes.

Quality – Table 31
EHRA is not supportive of the proposal to allow eligible clinicians to use different reporting periods for different measure types. This proposal would add unnecessary complexity to the program and would require major development changes and operational efforts to support providers leveraging this option.

Quality – eCQM versions
EHRA is supportive of this proposal.

Quality – opioid measures
A new measure such as this should not only be for opioid overuse; we recommend that measures be developed to help identify risk of overuse in addition.

EHRA notes that any measure based upon querying prescription drug monitoring programs (PDMP) has limitations due to inconsistent access to data across states, the data available, and the inability to save the data. Given this state-to-state variety, opioid measures should include only data elements that are consistently collected.

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.

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, allowing for integration of data into a provider’s workflow and CDS beyond the current, customary view-only access to PDMPs.

Once measure requirements are clearly defined, we suggest that a minimum of 18 to 24 months be allowed to develop, test, deploy, and begin using the new capabilities between health IT suppliers and their user communities.

Quality – topped out measures
EHRA supports the removal of topped out measures, and we encourage that it apply to all submission methods.
**Quality – removing measures**

The timing of the rulemaking process, as it relates to product development to support measures that need to be available at the beginning of each calendar year, may result in unintended consequences on clinicians who are preparing for future program years. Where possible, measure updates for eCQMs could include notices about measures being removed so that developers can avoid updating measures only to learn later that the measures are being removed.

We note that removal of the process measures will negatively affect specialty measurement sets, impacting the majority of specific specialties. If the proposal is enacted, measures that will be removed should be identified prior to the removal year.

**Quality – value of the measures**

EHRA believes that adding this additional layer of complexity would make understanding and implementation of measures more difficult.

**2015 Edition Certified EHR Technology (CEHRT)**

EHRA is supportive of CMS requiring 2015 Edition CEHRT. As long as additional certification requirements are not mandated for CEHRT or measure contributions, EHRA supports the January 1, 2019, timeline.

However, if CMS creates measures or objectives that mandate changes to an EHR in order to be supported or if ONC changes the existing certification program in any way, (e.g., adding new criteria or modifying existing criteria) EHRA would not support a January 1, 2019, adoption timeline, given the intensive resource burden inherent in programming updates.

**Promoting Interoperability (PI) – scoring and objectives**

EHRA is supportive of CMS’ desire to modify the PI category scoring methodology in a way that will reduce EC confusion while still promoting the goals of the MIPS program related to interoperability and patient engagement.

However, we have concerns about the potential negative impacts of making large changes to the scoring methodology for the 2019 performance year, given the short timeline that will remain once a final rule is published. MIPS participants often rely on their EHR systems to help them with participation in the program and this requires development of systems that reflect current program rules. If major changes are made to the scoring methodology of PI for the 2019 performance year and those changes are not final until November 2018, it would be unlikely that EHR systems could accommodate those changes until well into 2019. This would hurt 2019 MIPS participants and counteract the desire to improve the clarity of the category scoring.

We are supportive of ways to reduce confusion but encourage CMS to consider giving at least one full calendar year’s notice prior to making major changes to the program, in order to facilitate the necessary time to develop systems that support the program and to educate participating clinicians on the changes.
**PI – New eRx objective measures**
We encourage that timing for the pay-for-performance measure be coordinated with the query mandate.

**PI – New support electronic referral loops measures**
The timeline to implement these new measures before 2019 is too short, for both providers and developers. In addition, this proposal conflicts with 2015 Edition certification requirements, as they currently stand. It would be preferable to retain the current interoperability measures.

**Query of Prescription Drug Monitoring Program (PDMP)**
EHRA agrees with the proposal that cancer, hospice, and end of life patients should be exempt. We are aware, however, that “cancer patient” could include both cancer survivors and those with an active cancer diagnosis and recommend that CMS consult with clinical experts to identify language specific to the patients it is considering excluding from this measure.

Also, we note that the current proposal only addresses the query for the complete PDMP report for a patient. While this will provide all the information potentially of use to a clinician as they are assessing any medication plans, it is overly burdensome to presume that a provider will be able to view and assimilate all the information within a detailed PDMP report for every patient. Accordingly, it is imperative that some type of summary information be provided as part of the PDMP query to enable a provider to make a quick assessment of whether a patient’s PDMP information warrants further detailed review or not. This could be enabled by either CDS within the EHR or summary reports/analytics provided within the PDMP, but should be made available as computable data that can be consumed by the receiving system beyond view-only to enable better support and insight to the provider. Given the current state regulatory environment, where many states do not allow for EHRs to retain information provided by the PDMP, EHR-based CDS is impossible in those states; and, therefore, inconsistent in the utility, while disallowing valuable support to identifying and addressing opioid abuse risk and treatment options.

We would add that it is important to recognize that a “complete” query may not offer a complete patient picture due to the fact that many states do not share PDMP information with other state PDMPs.

**Future approaches to scoring quality**
EHRA is supportive of CMS’ desire to encourage the use of electronic clinical quality measures and would be interested in participating in future dialogues related to identifying ways to encourage more efficient technology-enabled measurement approaches.

**Quality – facility-based**
EHRA supports this change.
**Proposed urology set**
This measure is listed as an eCQM Specification; however, we would like to make CMS aware that the eCQI Resource Center did not have an eMeasure specification for this measure. We request clarification.

**Quality measures proposed for removal**
EHRA asks that CMS indicate earlier in the year that a measure will be proposed for removal. We suggest an indicator on the e-specification or on the website when published on the eCQI in the spring when these updates are published. This could save developers from investing time and effort into evaluating or coding updates that are later removed.

**Alternative Payment Models (APMs)**

**Use of CEHRT**
EHRA is supportive of this proposal; we agree it will continue to encourage the adoption of CEHRT without placing a negative burden on APM participants. We continue to encourage alignment.

**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 further 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 that 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.