HiMSS Electronic Health Record Association

33 W. Monroe, Suite 1700
Chicago, IL 60603
Phone: 312-915-9582
E-mail: agorden@himss.org

AllMeds, Inc.
Allscripts Healthcare Solutions
Amazing Charts
Aprima Medical Software, Inc.
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May 29, 2015

Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Attention: CMS–3310–P
Baltimore, MD 21244–8013

Re: CMS–3310–P

Dear Administrator Slavitt:

The Electronic Health Records Association (EHRA) appreciates this opportunity to comment on the proposed "Electronic Health Record Incentive Program—Stage 3" rules. As developers of electronic health record (EHR) systems, we have extensive experience with developing products for ONC certification and assisting EHR users in participating in the meaningful use (MU) Stage 1 and Stage 2 programs, which informs our attached suggestions.

Established in 2004, EHRA is comprised of almost 40 companies that supply the vast majority of operational EHRs to ambulatory practices and hospitals across the United States, in addition to other forms of health IT designed to support the nation's delivery system reform initiatives. The EHR Association operates on the premise that the rapid, widespread adoption of health IT 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 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 efforts to simplify and focus meaningful use in this Stage 3 proposal will be key to the ongoing success of the program. Complexity and insufficient time for development and implementation of new requirements in past stages of the program have resulted in the unfortunate need to modify program requirements mid-stream. With Stage 3, CMS should focus on advance, consistent guidance on a targeted proposal with adequate time for developer and provider preparation.

In the attached detailed comments and in our corresponding comments to ONC on the 2015 Edition certification proposed rule, we have noted areas where we think appropriate simplicity will aid the program, such as in the single definition of meaningful use and unified reporting periods. We have also noted areas where past experience with meaningful use leads us to believe there will be complexity and

inefficiency, and we offer alternative approaches where feasible. In particular, we have seen that sometimes the effort to measure complicated metrics results in more developer and provider effort than the actual EHR feature and policy goal itself. We call out several examples where we feel this risk is repeated in MU Stage 3, and make corresponding recommendations for how measurement can be simplified and attention appropriately focused on the policy goals.

Finally, EHRA has consistently emphasized that, for successful implementation of new EHR features, sufficient time must be given for software development and rollout. We are concerned that the large scope of the 2015 Edition certification proposed rule will result in few certified EHRs available prior to or early in 2017, potentially jeopardizing the proposed 2018 Stage 3 timeline. We do note, however, that many of the proposed functions in the 2015 Edition are not essential for achievement of corresponding MU Stage 3 objectives. CMS can reduce the timeline necessary for development by minimizing dependency on certification requirements that are not necessary for Stage 3, narrowing the definition of certified electronic health record technology (CEHRT), and considering whether some or all Stage 3 objectives can be met with 2014 Edition CEHRT in which providers have already invested and acquired experience.

Thank you for your consideration of our suggestions. We look forward to working with CMS and EHR users to make Stage 3 a success.

Sincerely,

Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

Leigh Burchell
Allscripts

Pamela Chapman
e-MDs

Richard Loomis, MD
Practice Fusion

Meg Marshall, JD
Cerner Corporation

Ginny Meadows, RN
McKesson Corporation

Sasha TerMaat
Epic

About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational 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.ehrassociation.org.

EHRA Comments
CMS Meaningful Use Spring 2015 Stage 3 Proposed Rule

Federal Register link to CMS Stage 3 Proposed Rule: http://www.gpo.gov/fdsys/pkg/FR-2015-03-30/pdf/2015-06685.pdf

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Definition of Meaningful Use and EHR Reporting Period
CMS reference: page 26/16737 (definition), 35/16739 (reporting period)

Single Definition of Meaningful Use
We agree with CMS's assessment that a single definition of meaningful use (MU) applicable to all program participants, regardless of when they first began to participate, will provide helpful simplicity to the program that will benefit EHR developers and EHR users. We are strong supporters of interoperability, and agree that having all participants on the same standards and timelines will better facilitate meeting interoperability goals. For example, in 2014 we observed that some providers struggled with Stage 2 if other providers in their area were still in Stage 1 and not adopting features required for connecting to other EHRs on the same timeline.

The timeline of transitioning to Stage 3 in 2017 and 2018 is dependent on sufficient time to develop, test, certify, and implement EHRs certified to the new features proposed in the ONC 2015 Edition. We are concerned, therefore, and are also commenting to ONC, that the scope of the proposed 2015 Edition is very large, and the size of that Edition, including its non-MU criteria, might jeopardize CMS's proposed Stage 3 timeline. It is essential that CMS and ONC work together to ensure that the scope of new functionality introduced for certification is achievable in the required timeline.

Aligned EH Reporting Period with Calendar Year
We support overall CMS quality measurement alignment to reduce the burden on providers. In this regard, we agree that it makes sense to align the meaningful use eligible hospital (EH) reporting periods with the calendar year as proposed, to match the hospital IQR quality measurement reporting periods. We do ask that CMS be mindful of potential disruptions for hospitals in 2015 relative to anticipated MU incentive payment timing.

2017 Transition
CMS and ONC will want to carefully evaluate the timeframe and scope of Stage 2 of MU in determining whether Stage 3 and the 2015 Edition proposals are feasible.

For example, because the scope of the 2015 certification Edition is significantly larger than the 2014 Edition, it seems to us that more time should be allowed for development, testing, and implementation, though the timeline forecast for transitioning to Stage 3 (See Table 1) seems very similar to Stage 2 timelines, especially for 2017 but also for 2018 given that both will be full year reporting periods. This analysis does highlight the importance of CMS shifting out the mandatory start of Stage 3 by one year to 2018 as proposed, and also underscores that very few providers are likely to be in a position to attest to Stage 3 in 2017.

Table 1: Comparison of Stage 2 and 3 Timelines		
Milestone	**Stage 2 Timeline**	**Stage 3 Timeline**
Release of NPRMs	February 2012	March 2015
Release of Final Rule	September 2012	Tentatively fall 2015
Final High Quality Certification Test Methods	Early 2013	Tentatively early 2016
Beginning of Stage	October 2013 (EH), January 2014 eligible provider (EP)	January 2017 (optional), January 2018 (required)
Time from Final Rule to beginning date	Sept 2012 to Oct 2013 = 13 months (Note that 2014 had quarter reporting periods)	December 2015 to January 2017 = 13 months (With a full year reporting period in 2017)

The ability for a workable transition from Stages 1 and 2 to Stage 3 will be key, and we are pleased to see that CMS addressed the need for a transition with their proposal. It will be important for CMS to preserve the flexibility proposed for EPs to select a stage in 2017 without needing to justify their selection with a specific reason (as was required in the 2014 flexibility option). Such justification introduces complexity around evidence that is unnecessary for a 2017 transition year.

As EHR developers, we are concerned that the proposed scope of the 2015 Edition will mean that few EHRs are available to support meaningful users with Stage 3 in 2017, and that some vendors and/or their customers may also be challenged by the need to deploy and implement 2015 certified EHRS to support meaningful use for all of 2018. One of the most important factors for the success of Stage 3 will be allowing adequate time for its implementation. There are several options to provide sufficient time, including a 90-day reporting period in 2018 as the first required year of Stage 3 or removing unnecessary dependencies on 2015 Edition certification as described below.

Certification – 2014 Edition and 2015 Edition

As mentioned in the earlier section on the 2017 transition, we are concerned that the proposed scope of 2015 Edition certification jeopardizes the timeline proposed for MU Stage 3 by CMS.

In particular, it seems that 2015 Edition certification introduces dependencies for development, testing, implementation, and training of new software features that are not actually necessary to meet the Stage 3 MU objectives. CMS should consider whether permitting use of 2014 Edition CEHRT to achieve some or all Stage 3 MU objectives would better facilitate the desired timelines.

For example, eligible providers (EPs) have been successfully e-prescribing using 2014 Edition CEHRT in MU Stage 2, and this same functionality could support the proposed e-prescribing objective and measure. It is, therefore, concerning that the new certification requirements for the 2015 Edition (b)(3) e-prescribing criterion are estimated by EHRA members to require 3,600 hours of development for each

product. This development work is required to incorporate new functionality and interface standards proposed by ONC, many of which will provide minimal benefit to providers due to poor alignment with other improvements necessary to the standards (e.g., adopting "structured sigs" provides minimal utility until NCPDP removes the character limit on the sig). If CMS permits EPs and EHs to use either 2014 Edition or 2015 Edition certified software for e-prescribing, providers could begin work on achieving higher thresholds for e-prescribing immediately in 2015. If CMS requires the use of 2015 Edition certified software for e-prescribing in Stage 3, Stage 3 will be dependent on the success of large and minimally useful software development projects that will divert resources from other MU and non-MU projects.

In the table below, EHRA evaluates each of the proposed MU Stage 3 objectives and the corresponding certification criteria. As discussed above regarding e-prescribing, it seems reasonable to allow accomplishment with 2014 Edition CEHRT for several objectives and measures. We urge CMS to consider this option as a potential way to give EPs flexibility on how they approach upgrading their software. Some other objectives could be partially accomplished with 2014 Edition CEHRT, and providers would have additional options if they upgraded to 2015 Edition CEHRT. CMS could similarly consider whether EPs would benefit from being afforded the opportunity to pursue MU Stage 3 using 2014 Edition CEHRT.

	Measure	**Does this objective depend on 2015 Edition CEHRT?**	**Comments**	**Proposed CEHRT Definition**
1	Protect patient health information	No	Privacy and security criteria are unchanged from the 2014 Edition in the 2015 Edition CEHRT	CEHRT not directly necessary to meet this objective.
2	eRx	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Providers could use either: 2014 Edition (b)(3) or 2015 Edition (b)(3)
3	Clinical decision support	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	CDS either: 2014 Edition (a)(8) or 2015 Edition (a)(10) Drug interactions either: 2014 Edition (a)(2) or 2015 Edition (a)(5)

4	CPOE	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Any one of these three options: ● 2014 Edition (a)(1) ● 2014 Edition (a)(18), (a)(19), and (a)(20) ● 2015 Edition (a)(1), (a)(2), and (a)(3)
5.1	Access to VDT or API	Partial	VDT capabilities are part of 2014 Edition CEHRT; API capabilities would be an option providers have if they upgrade to 2015 Edition CEHRT	Providers could use either: 2014 Edition (e)(1) or 2015 Edition (e)(1)
5.2	Access to patient education	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Providers could use either: 2014 Edition (a)(15) or 2015 Edition (a)(17)
6.1	Usage of VDT or API	Partial	VDT capabilities are part of 2014 Edition CEHRT; API capabilities would be an option providers have if they upgrade to 2015 Edition CEHRT	Providers could use either: 2014 Edition (e)(1) or 2015 Edition (e)(1)
6.2	Sending patients secure messages	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT; the criteria is unchanged	Providers could use either: 2014 Edition (e)(3) or 2015 Edition (e)(2)
6.3	Patient generated data	Yes	Providers could meet objective 6 with 6.1 and 6.2; this measure would be an option if they upgraded to 2015 Edition CEHRT	Could achieve limited document capture with 2014 Edition (a)(17), complete functionality requires 2015 Edition (a)(19)
7.1	Sending a summary of care at transitions in care	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	While the measure could be met with 2014 Edition functionality, we suggest that adoption of 2015 Edition be required to encourage expanded interoperability.
7.2	Incorporating	No	Could be accomplished	While the measure could be met

	a summary of care at transitions in care		with either 2014 Edition CEHRT or 2015 Edition CEHRT	with 2014 Edition functionality, we suggest that adoption of 2015 Edition be required to encourage expanded interoperability.
7.3	Clinical information reconciliation	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Requires either: 2014 Edition (b)(9) or 2015 Edition (b)(2)
8.1	Immunization registries	Partial	Submitting to an immunization registry could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT Bidirectional immunization information exchange could be an option for providers who upgrade to 2015 Edition CEHRT	Requires either: 2014 Edition (f)(1) and (f)(2) or 2015 Edition (f)(1)
8.2	Syndromic surveillance	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Requires either: 2014 Edition (f)(3) or (f)(7) or 2015 Edition (f)(2)
8.3	Case reporting	Yes	Providers could meet objective 8 with other options This measure would be an option if they upgraded to 2015 Edition CEHRT	Requires 2015 Edition (f)(3)
8.4	Public health registry reporting	Partial	The specific standards referenced in 2015 CEHRT do not seem to match the broad applicability of public health reporting described by CMS	CMS should clarify that the flexibility intended to providers to count current methods of submission means that they are not limited to the specific types of submission which have standards adopted in certification, and that

			If reporting that does not use the CEHRT standards is permitted, than this objective could be achieved with any version of CEHRT More options might be available when providers upgraded to 2015 Edition CEHRT	CEHRT is not required for this measure CEHRT options (not required), could include: 2014 Edition (f)5) and (f)(6) 2015 Edition (f)(4) 2015 Edition (f)(6) 2015 Edition (f)(7)
8.5	Clinical data registry reporting	No	There are no certification standards for clinical data registry reporting in either 2014 Edition or 2015 Edition	CEHRT not necessary to meet this objective
8.6	Reportable labs to public health (EH only)	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Requires either: 2014 Edition (f)(4) or 2015 Edition (f)(3)
	Clinical Quality Measures (CQMs)	No	Could be accomplished with either 2014 Edition CEHRT or 2015 Edition CEHRT	Providers could use either: 2014 Edition (c)(1); (c)(2); or (c)(3); or 2015 Edition (c)(1); (c)(2); or (c)(3) Additional features such as (c)(4) might be available with 2015 Edition.

In sum, we suggest that MU Stage 3 allow EPs and EHs to use products certified to 2014 Edition or 2015 Edition where such usage permits them to satisfy the final objectives and measures. This option would enable an "agile" development and deployment approach, minimizing the development and implementation costs of major upgrades, allow additional flexibility for providers struggling with taking upgrades, and also allow for use of modular products to meet gaps where there are no corresponding 2014 certified measures.

To facilitate this flexibility, the ONC definition of Base EHR and the CMS definition of CEHRT need to accommodate the possibility of a combination of 2014 Edition and 2015 Edition certified modules.

Denominators

CMS reference: page 54/16744

We appreciate the consistency and continuity proposed for Stage 3 in carrying forward the definitions of these concepts from Stage 2. This consistency makes it easier for providers and developers to understand MU denominator definitions and avoids introducing unnecessary change to meaningful use reporting.

We do point out that the reference in Stage 2 to "four" denominators has caused some confusion in the past with EHR users and MU auditors, as there are actually more than four permutations. The "four" were described as:

1. Unique patients
2. Office visits
3. Transitions initiated
4. Transitions received

However, Stage 2 included permutations of these measures, such as "2 or more office visits in the 24 months prior to the reporting period," and "unique patients with an office visit."

In the Stage 3 proposal, we count 12 denominators and exclusions, and will provide specific feedback on each objective as they are discussed:

1. "Prescriptions written for drugs requiring a prescription in order to be dispensed other than controlled substances" (Objective 2 - EP)
2. "Prescriptions written for drugs requiring a prescription in order to be dispensed" (Objective 2 - EP)
3. "Permissible prescriptions" (Objective 2 - EP exclusion)
4. "New or changed prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances for patients discharged" (Objective 2 - EH)
5. "Medication orders created" (Objective 3 - EP exclusion, Objective 4.1)
6. "Laboratory orders created" (Objective 4.2)
7. "Diagnostic imaging orders created" (Objective 4.3)
8. "Unique patients seen or discharged" (Objective 5.1, 5.2, 6.1, 6.2, 6.3
9. "Office visits" (Objective 5.1 exclusion, 5.2 exclusion, 6.1 exclusion, 6.2 exclusion, 6.3 exclusion
10. "Transitions of care and referrals" (transferring or referring provider) (Objective 7.1)
11. "Number of patient encounters where…was the receiving party" (Objective 7.2, 7.3)
12. "Patient encounters where the provider has never before encountered the patient" (Objective 7.2, 7.3)

We also note that the 2015 Edition certification proposed rule calls for EHRs to support all CMS-acceptable measurement approaches. Because some CMS measurement concepts, such as "seen by the EP," are deliberately left to the discretion of the provider, and could theoretically be defined differently by thousands of providers across the country, we do not think it is possible that EHRs could support all CMS-acceptable approaches. We ask that CMS and ONC refine this ONC proposed approach, and enumerate and define which measurement options specifically should be supported by all EHRs and where they are leaving flexibility for EHR developers and EHR users to adjust measurement concepts to

meet their needs, with the understanding that some EHRs might offer different options. ONC FAQ 11-12-032-2 would be a reasonable starting place.

For example, some EHRs might include support for managing and measuring telemedicine encounters and count those toward MU requirements. Other EHRs might not include support for telemedicine encounters. So, while it is helpful for CMS to offer guidance on how telemedicine encounters ought to be counted, it would not be practical for ONC to attempt to certify that all EHRs support all CMS measurement options since not all EHRs might even have such features to begin with.

Objective 1: Protect Patient Health Information
CMS reference: page 60/16745

We appreciate the consistency proposed for Stage 3 with past definition of these concepts in Stage 2, and suggest this objective remain as proposed in the final rule.

Objective 2: eRx
CMS reference: page 67/16747

Thresholds
CMS cites the median performance rate of EPs at e-prescribing as 89% for Stage 1 and 92% for Stage 2 as justification for the proposal to raise the threshold to 80% in Stage 3.

We have examined CMS's published data set and our own experience with e-prescribing, which suggest that the proposed 80% threshold is too high. We offer the following comments:

- According to CMS's January 2015 data set, 2,348 EPs who successfully attested for Stage 2 and 13,088 EPs who successfully attested to Stage 1 would not hit the 80% proposed threshold.
- In some cases, providers might have qualified for an exclusion from the measure based on lower volumes of medication orders in their first year of MU and in the shortened reporting periods of 2014, and might also struggle with the new thresholds when they report for a full year.
- CMS's data set only includes providers who have successfully attested for MU, and does not include EPs who have not been able to meet past thresholds.
- The data set does not indicate EP specialty, and our experience shows that success with e-prescribing can be specialty-specific, as some specialties (for example, rheumatology) have increased frequencies of ordering types of medications that are not yet supported by Surescripts (such as tapers or compounds).

We know that provider specialty is captured during attestation, so we suggest that CMS analyze e-prescribing performance stratified by specialty and determine if the proposed threshold is attainable for all specialists.

Similarly, our experience with e-prescribing indicates that when providers adopt e-prescribing functionality they generally do so comprehensively for all patients seen where all of the patient's prescriptions are eligible for e-prescribing. "Partial" adoption of e-prescribing tends to be in specialties where medications are not eligible or patient preference is for paper prescriptions. Therefore, we are uncertain that raising thresholds will have a substantial impact on increased e-prescribing, and might have the unintended effect of excluding specialists from successful participation.

Alignment of Meaningful Use with Certification

CMS's goals for MU e-prescribing as proposed could be met with 2014 Edition CEHRT. We suggest that CMS continue to permit 2014 Edition CEHRT to be used for e-prescribing for Stage 3. If 2015 Edition CEHRT is required for e-prescribing in Stage 3, there will be several unintended consequences:

1. Progress toward Stage 3 will be slowed because ONC has proposed 2015 Edition features that are not required for achieving MU but that would require significant time to develop and implement in healthcare settings.
2. Providers will express frustration that EHR development resources continue to be focused on certification requirements rather than features they have requested.
3. Providers will express confusion over the relationship of certified EHRs and MU, and will question whether it is necessary for them to implement all of the features required to be demonstrated in certification.

Measurement Clarifications

There has been some confusion in Stage 2 as to the expectation for performing a formulary query for medication refills. We suggest that CMS formalize its unofficial guidance that formulary queries for refill e-prescriptions are optional to be counted in the numerator of this measure. We appreciate the clarification that over-the-counter medications continue to not be included.

Objective 3: Clinical Decision Support
CMS reference: page 75/16749

Clarifications

We appreciate CMS's clarification regarding the broad range of clinical decision support (CDS) types that can count for meaningful use. We highlight the need for clear guidance on provider measurement and documentation, and also emphasize that when only one narrowly defined CDS item is certified, broader interpretations might not match all certification requirements.

Alignment of Meaningful Use with Certification

CMS's proposed goals for MU CDS could be met with 2014 Edition CEHRT. We suggest that CMS continue to permit 2014 Edition CEHRT to be used for CDS for Stage 3.

If 2015 Edition CEHRT is required for CDS in Stage 3, there will be several unintended consequences:

1. Progress toward Stage 3 will be slowed because ONC has proposed 2015 Edition features that are not required for achieving MU, but that would require significant time to develop and implement in healthcare settings.
2. Providers will express frustration that EHR development resources continue to be focused on certification requirements rather than features they have requested.
3. Providers will express confusion over the relationship of certified EHRs and MU, and will question whether it is necessary for them to implement all of the features required to be demonstrated in certification.

Selecting CDS in Alignment with CQMs

EHRA supports the recommendation that providers set internal goals regarding CQMs and related CDS interventions. We also note that the work to develop EHR functionality around a quality data model that shares standards to work with both CDS and quality measurement, as discussed in the proposed rule, must take into careful consideration the perspectives of all parties involved. EHR developers,

providers, content owners, and others will all need to work closely together to create a standard that is feasible for all. The EHRA encourages CMS to include as many participants as possible from different backgrounds to help in the creation of this shared standard.

Objective 4: CPOE
CMS reference: page 81/16750

Alignment of Meaningful Use with Certification
CMS's proposed goals for MU CPOE could be met with 2014 Edition CEHRT. We suggest that CMS continue to permit 2014 Edition CEHRT to be used for computerized physician order entry (CPOE) for Stage 3.

If 2015 Edition CEHRT is required for CPOE in Stage 3, there will be several unintended consequences:

1. Progress toward Stage 3 will be slowed because ONC has proposed 2015 Edition features that are not required for achieving MU, and that would require significant time to develop and implement in healthcare settings.
2. Providers will express frustration that EHR development resources continue to be focused on certification requirements rather than features they have requested.
3. Providers will express confusion over the relationship of certified EHRs and MU, and will question whether it is necessary for them to implement all of the features required to be demonstrated in certification.

In particular, we are concerned that a reference to updated certification criteria proposed in the 2015 Edition might require EHR users who have already successfully implemented lab order interfaces to have to re-implement those interfaces using the proposed new standards. While the standards might present efficiencies for new implementations, providers who have already installed lab interfaces will not see benefit commensurate with the effort of re-implementing.

Measurement Clarification
We appreciate the clarifications to existing policies such as who is eligible to enter orders. Our understanding is that the discussion of these concepts clarifies existing policy and does not change or introduce new policies.

Change in Imaging Categorization
Generally, EHRA members anticipate that EHR users likely already use CPOE for a broad range of imaging orders, and that the expanded definition is not likely to present challenges for achieving a threshold. We would appreciate clarification that any sort of imaging study should be counted, including optical coherence tomography (OCT), so that denominators will be equivalent across vendors and that no complex setup will be necessary to ensure that some imaging studies are included and others are excluded.

Objective 5: Patient Electronic Access to Health Information
CMS reference: page 89/16752

Measure 5.1: Provided Access to VDT or an API

24 Hours of Its Availability

CMS proposes that EPs and EHs provide access for patients within 24 hours of the availability of the information. In general, we have concerns with the proposed very short availability time period. With the proposed shorter timeframe for access to information, EHRA members discussed the definition of ''availability" and ambiguity about what that means.

For example, if a lab test that a provider ordered returns a result from the lab on a Friday, and that provider only practices in that clinic Monday through Thursday, what is expected?

- Is the result considered available to the provider when it comes over the lab interface to the EHR on Friday, even though the provider does not work at that clinic on Fridays or over the weekend?
- If yes, does this requirement set an expectation that automatic release of information will be used or that providers will review labs every day to hit a 24 hour timeframe?
- If no, what marks the "availability" of the result? When the provider is back in the clinic Monday morning? The next time the provider logs in to the EHR? When the provider first looks at the result in the EHR? The provider's work schedule might not be known in the EHR and seems to unnecessarily complicate reporting.

We note that measuring the time ranges in this objective presents a great deal of complexity. We suggest that this threshold be clarified to state within 24 hours of the provider signing off on the results or within 96 hours of the result being populated in the EHR. Such an alternate approach would allow adequate time for review by the physician but has a fail-safe period after which the patient can see the result if the physician has not reviewed it.

Alternate Proposals

Provision of an application programming interface (API) to patient-selected applications will have ramifications for which providers will need to plan, including:

1. Contracting and business agreements with application developers;
2. Education around how patients can take advantage of new opportunities;
3. Technical preparations including upgrading CEHRT to the 2015 Edition;
4. Hardware considerations regarding providing highly available external access to their data through the API; and
5. Expansion of the security risk analysis to account for the greatly increased risks of unauthorized disclosures that are possible when opening up their database to outside applications.

Given the necessary work to prepare to offer an API, CMS's proposal to permit providers to offer either the ability to view, download, and transmit (VDT), *OR* access to an API and application built on that API is more appropriate than alternative options considered.

Timing of Access

CMS has not specified in the proposed rule a timeframe for when patients could be provided access to these features in order for such access to count for MU. In the past, EHRA members were directed by CMS staff that, when no timeframes are specified for a particular measure, actions (such as providing

access) that took place before, during, and after a reporting period should be evaluated in the numerator of that MU measure.

This policy was correspondingly adopted in ONC 2014 Edition certification, which differentiated in the test procedure for (g)(2) automated measure calculation which measures (such as patient access) were expected to include actions that take place before, during, and after reporting periods, and evaluated the EHR's capability to differentiate during the certification process. Since the prior Final Rules were issued, EHRA has had to escalate concerns that, through unanticipated FAQs, this policy was arbitrarily changed midway through Stage 2. Our concerns were documented in a July 2, 2014 letter to CMS.

In short, EHRA was concerned that:

- CMS provided guidance in an updated FAQ that could not have been foreseen by EHR developers or EHR users, and that was not previously part of CMS or ONC regulation or guidance.
- The FAQ was not widely publicized and EHRA members only became aware of its update by accident.
- EHR developers had already made investments in 2014 Edition certification, including MU reports, and had not budgeted time to revise their work based on unanticipated CMS FAQs.
- Some providers had already attested using CEHRT prior to the issuance of this guidance, and some were planning to attest in the near term future without plans to take changes to their CEHRT based on this CMS FAQ.
- EHRA assessed the industry impact of the proposed change by surveying membership and determined that 92% of EHRs would require development to support the change, and that making the change would take an average of 100 development hours per product and 33 certification hours per product, or 39,500 hours across all the products currently certified to that criterion.

We are pleased that CMS has indicated that it does not expect EHR changes as a result of this FAQ, but the EHRA continues to be concerned that making changes to measurement expectations after developers have made investments in software development results in waste and challenges for EHR users. Instead, the Final Rule for Stage 3 should provide adequate specificity for development and certification, and areas left ambiguous or open in the Final Rule should deliberately remain so and not be modified in disruptive FAQs.

EHRA would prefer unambiguous and consistent policy on measurement timing rather than any particular measurement scheme. We defer to providers on what they would consider the most appropriate time period in which to measure provision of access, with the consideration that if a patient is already provided "access" at some point in the past (e.g., a username and password, activation code to set up an account, instructions on how to set up an account if they decide they would like to have one), this work does not necessarily have to be repeated (i.e., patients who have accounts and use them don't need to be offered access every year, patients who have declined accounts and acknowledge they have sufficient information to get one if they change their mind similarly don't always want to be asked about this yearly either).

Measure 5.2: Access to Education

Measure Appears Topped Out

A review of the performance of EHs and EPs in MU Stages 1 and 2 shows high performance on this objective, consistent with performance on other objectives that CMS has considered "topped out" and removed from Stage 3. We suggest that this broadly adopted, successful objective also be considered topped out and measurement removed from Stage 3 so development, compliance, and measurement focus can shift to other patient engagement goals.

We are also concerned that this objective is an example of overly-prescriptive requirements for providers. From a patient's perspective, it does not make a difference whether they are provided education based on a CEHRT suggestion or because of other processes their provider has in place.

Unfortunately, the measure only counts the EHR-suggested education, and now only education that is provided electronically, restrictions that are not in alignment with the desired outcome of educating patients. Requirements to count only "suggested" patient education have had an extremely deleterious effect on patient care and efficiency, as well as provider satisfaction with EHRs. Many practices routinely give out patient education based on the condition (e.g., trimester of pregnancy) or situation (e.g., age of the pediatric patient or pre-op orders), and practices have configured order sets to include these options. Because the order set cannot count unless it is specific to the patient, vendors may have had to support separate order displays based on these criteria rather than allowing use of a global order sheet that takes advantage of end-user familiarity with the workflow.

In some situations such as providing vaccine information statements, it is much more efficient to pre-print educational materials and to hand them out during high volume vaccination programs, such as flu shot clinics, rather than requiring a printer in every room. Removing this objective will address the overly prescriptive nature of how it is expected to be measured.

Alignment with CEHRT

ONC's 2015 Edition proposed certification criteria narrows focus on use of Infobutton as a standard for context-sensitive linking. Generally, we have understood the ONC and CMS policy to allow provider options to the specific functions demonstrated in certification, as described in ONC FAQ 3-11-024-1.

If this measure is not removed in Stage 3, we suggest explicit clarification of that policy in relation to this proposed measurement. Are providers expected to only measure education provided using the Infobutton standard, or is the variety of other electronic means included in CEHRT reasonable to also be counted toward this threshold?

As mentioned above, this approach is overly prescriptive and impairs productivity, and also places an undue burden on EPs who may serve a population without high levels of internet access or computer skills (e.g., the elderly or poor), or those who need to provide education in a language not commonly available from third party providers. Cost for educational content is also a consideration. Although MedlinePlus is free and does support the current Infobutton standard, most other such products have associated costs. As with other measures that require partners in the exchange, there is no guarantee that they will update to the newly identified Infobutton requirements.

Measuring Access
Our understanding is that measurement of "access" in the context of patient education is similar to the measurement of "access" provided in measure 5.1 to VDT features. For example, if a patient were provided access to context sensitive-links in a patient portal that also provided VDT features, the measurement of 5.1 and 5.2 would be identical. We ask CMS to confirm this understanding.

Timing for Access
CMS has not specified in the proposed rule a timeframe for when patients could be provided access to education. If this objective is retained, CMS should be specific in the Final Rule as to the measurement expectations to avoid the kind of Stage 2 confusion and waste described above in our extended discussion of timing on measure 5.1. As we noted in comments to 5.1, we defer to providers on what they would consider the most applicable time period in which to measure provision of access to education, with the consideration that if a patient is already provided "access" at some point in the past, this work does not necessarily have to be repeated.

Transitive Effect
If multiple providers share an EHR, EHRA does not believe that it is necessary that each provider individually provide a patient with access to educational materials. For example, a patient sees Provider X in January and is provided access to a patient portal with Infobutton context-sensitive linking. In February, the same patient sees Provider Y, who shares CEHRT with Provider X, and Provider Y realizes that the patient has already been provided access to educational materials and further action is not necessary.

This approach does not preclude Provider Y from offering other types of education, or reminding the patient of what is available to him in the portal. However, those other actions are not what CMS seems to be measuring. Therefore, we request that CMS clarify that duplicative provision of access to education is not expected.

Objective 6: Coordination of Care through Patient Engagement
CMS reference: page 103/16755

Measure 6.1: Patients Engage with VDT or an API

APIs
As discussed earlier regarding measure 5.1, provision of an API to patient-selected applications will have ramifications providers will need to plan for, including:

1. Contracting and business agreements with application developers.
2. Education around how patients can take advantage of new opportunities.
3. Technical preparations including upgrading CEHRT to the 2015 Edition.
4. Hardware considerations regarding providing highly available external access to their data through the API.
5. Expansion of the security risk analysis to account for the greatly increased risks of unauthorized disclosures that are possible when opening up their database to outside applications.

Providers will want to carefully plan how they undertake and approach this work.

Measurement and Attestation

EHRA agrees with CMS's assessment that there are technical limitations to measurement of API usage given the variety of different systems that could be involved in that ecosystem. There is no proposed requirement that an application using data from an API be capable of supporting MU measurement (via certification to (g)(1) automated numerator calculation, for example); and even if a particular application did perform that calculation, it is not clear that the provider who is attempting to measure her patient's API usage would have a relationship with the holder of the data regarding the usage of that application, and had access to that usage information.

Given the above concern and our broader concern that (1) complex measurements have caused EHR developers to have to spend more time measuring things than developing the features and (2) measurement needs can inadvertently limit patient and provider options in achieving these goals, we suggest that a simpler approach to measurement across both VDT and API provision be considered, such as attestation. We note that, on page 16756-7 CMS seems to propose an attestation option:

> "For the API option, we propose that providers must attest that they have enabled an API and that at least one application which leverages the API is available to patients (or the patient-authorized representatives) to retrieve health information from the provider's certified EHR."

It is not clear if attestation replaces the threshold-based measurement proposed on other pages, or if it is a supplement to it (though that would seem duplicative). On balance, we suggest that attestation might be the best way to evaluate this measure for patient engagement with either the VDT capabilities or application use with an API.

Measures

As indicated above, we suggest that attestation will be the best approach for measurement. If a threshold is retained, we note that the measures for this objective seem to be written as though the threshold would have to be exclusively achieved with one option. For example, it seems that if 20% of a provider's patients used the VDT capability and 20% of a provider's patients used an application with a certified API, the provider would fail, as neither option exceeded the 25% threshold.

We suggest that use of a combination of options would offer providers clinically valuable flexibility, particularly as they are upgrading or changing their CEHRT. CMS should clarify that providers could use a combination of the two options to hit the 25% threshold.

Timing for Action

If the measure is not changed as we suggest, CMS has not specified in the proposed rule a timeframe for when patients would need to view, download, or transmit their health information. If this objective is retained, CMS should be specific in the Final Rule as to the measurement expectations to avoid the confusion we experienced in Stage 2 as described above in our extended discussion of timing on measure 5.1. As we noted in comments to 5.1, we defer to providers on what they would consider the most appropriate time period in which to measure patient engagement.

Transitive Effect

If multiple providers share an EHR, information documented by the entire care team will be made available to patients to view, download and transmit, or access via an application and API. We assume

CMS will continue the past policy that all providers contributing documentation to the patient's chart will have that patient in the numerator.

Measure 6.2: Secure Messaging

Clinical Relevance

CMS proposes that messages would need to be clinical in nature to count toward this objective. We have identified several concerns about measurement complexity.

First, there is a general concern that CMS should not force users to provide extra documentation for this objective simply to support measurement. For example, requiring providers to document the nature of their message to a patient would have a negative workflow impact. Introducing a checkbox for determining if information is clinically relevant degrades EHR usability and policies requiring such non-value-added documentation should be avoided.

We considered whether in general it might be reasonable to presume whether a message is clinical based on the role of the user who sends the message. For example, if a biller sends a message to a patient, it is presumably not clinical. Alternately, if a clinician sends a message, it is probably clinical in nature. However, clinicians could send messages that are not clinical, and it is certainly possible that some users could send both types of messages (e.g., a clinic clerk has responsibility for sending appointment reminders as well as flu shot reminders).

On balance, given these concerns and the goal of measurement simplicity, we suggest that all messages to patients be counted regardless of content.

Timing for Action

In Stage 2, the secure messaging measure required patients to send messages during the reporting period. In Stage 3 proposed rule, CMS has not specified a timeframe for when providers would need to send secure messages to the patient. CMS should be specific in the Final Rule as to the measurement expectations to avoid the kind of Stage 2 confusion described above in our extended discussion of timing on measure 5.1. As we noted in comments to 5.1, we defer to providers on what they would consider the most appropriate time period in which to measure patient engagement.

Transitive Effect

CMS should clarify that the Stage 2 expectation for this measure to have a transitive effect will be continued in Stage 3. For example, consider a patient who sees her primary care provider and two specialists from the same clinic who use the same EHR. A care manager at that clinic is responsible for reviewing upcoming preventive care needs and messaging the patient. This scenario would seem to satisfy the need to message the patient for all three of the EPs. Our understanding is that sending patients duplicative messages for different measures from each provider is not required, nor is associating messages sent by non-EP members of the care team (e.g., nurses or care managers) with a particular EP required.

Measure 6.3: Patient Generated Data

Alignment with CEHRT

EHRA is concerned that the CMS description of this measure seems inconsistent with the matching ONC proposed 2015 Edition certification criterion (a)(19).

The proposed measure from CMS seems to focus on:

- Data provided by non-EPs who do not share access to the provider's CEHRT;
- Patient generated data of several types:
    - Device data such as from personal fitness monitors;
    - Patient-entered data such as health questionnaires.

The proposed certification criterion (a)(19) from ONC seems to focus on:

- Documents that are uploaded (such as advance directives or birth plans);
- Generic patient information electronically and directly shared, such as from a device (with no standards).

The variety of items that might be included make this proposal likely to require more time spent in measurement than in achieving the objective. We suggest that alternate methods to report this measure be considered, such as attestation.

Given the scope of the certification criterion and what is described by CMS, we remain puzzled by what is intended to be counted. It appears that any of the following would be considered:

- Patient documents such as advance directives or birth plans;
- Questionnaires a patient fills out;
- Patients updating their own health information (patient generated history, current medications, or vitals);
- Patients connecting devices to an EHR (e.g., personal fitness devices or home monitoring equipment such as scales or blood pressure cuffs).

Non-Clinical, Non-EP, Sharing Access

The objective proposes to measure "non-clinical" information provided by caregivers who are "not EPs" and do not share access to the provider's CEHRT.

Several of the examples given seem to be clinical in nature, so CMS should consider alternate categorization for this proposal.

It is also not clear how an EHR would distinguish whether information came from "an EP" or "not an EP" for straightforward measurement. This distinction would make measurement prohibitively complicated and should be avoided.

Finally, it is not clear why information from therapists or nutritionists who do not share access to CEHRT is measured, but information from therapists or nutritionists who do share access to CEHRT is not measured. Wouldn't both methods achieve the goal of improved coordination of care for the patient?

Timing for Action
EHRA points to several measurement challenges above and suggests that attestation is a more appropriate method. If a threshold is retained, CMS will need to specify a timeframe for when patient generated information would need to be incorporated. CMS should be specific in the Final Rule as to the measurement expectations to avoid the kind of Stage 2 confusion described above in our extended discussion of timing on measure 5.1. As we noted in comments to 5.1, we defer to providers on what they would consider the most appropriate time period in which to measure patient engagement. We suggest that CMS consider that some of the proposed types of information are valid for varying timeframes. For example, a patient might not need to update his advance directive during each reporting period, while a patient who is uploading his vitals to his patient portal but has not done so this reporting period might indicate a different level of engagement.

Transitive Effect
It is not possible to associate the type of information described for this measure with particular EPs when they share an EHR. CMS should clarify that there is no expectation that items such as advance directives or patient-entered questionnaires would be associated with particular EPs, and that the information would count for all EPs who see the patient.

Objective 7: Health Information Exchange
CMS reference: page 116/16758

Interoperability is a key priority of the EHRA and its members, and we are pleased to see focus on it with Objective 7: Health Information Exchange.

Measure 7.1: Send a Summary of Care at Transitions in Care

Transport
CMS asks for comment on whether the Stage 2 policy of requiring transport using the specific standards identified by ONC should be continued in Stage 3, or if any electronic transport method should be considered sufficient. ONC's certification proposal will ensure that all CEHRT supports a minimum set of standards-based requirements for transport of summaries of care. If some EPs and EHs find it more convenient to use other electronic transport methods, EHRA agrees that this approach would be appropriate flexibility from CMS. Moreover, such a policy would encourage some EPs and EHs to pilot new standards as they become available.

MDN
ONC has proposed message delivery notifications (MDN) as part of an optional certification criterion in the 2015 Edition. Given that adoption of this standard will likely phase in over time, and that the flexibility discussed above regarding transport methods means that not all exchanges will use Direct (and MDNs), we do not see MDN as a feasible method for reporting on transitions of care in Stage 3. Measurement methods similar to those in Stage 2 will continue, with optional use of MDN as one possible method of measurement.

Measurement
There are no specific timeframes identified by CMS for the sending of a summary of care document. If the time period is intended to be flexible, permitting providers flexibility to send at any point, this should be explicitly clarified to avoid later confusion.

Measure 7.2: Incorporate a Summary of Care at Transitions in Care

Incorporate Definition

We are uncertain what "incorporate" is intended to mean. There seems to be variance between CMS's discussion and the referenced ONC definition. Is "incorporate" intended to refer to when a summary of care is received and matched with a patient, or when a summary of care is reconciled into the local chart (which seems to duplicate measure 7.3)?

Shared EHRs

It is unclear whether Measure 7.2 is intended to measure only referrals between systems, or if referrals between providers who share access to the same EHR would also be counted. We do not see value in incorporating a CCDA when providers already share EHR access, so we assume that this is intended for providers who do not share access to the same EHR.

New Patients

CMS uses the terms "new patients" and "never before encountered patients". Are these intended to be the same? Or does this refer to the CPT definition of a new patient as "one who has not received any professional services from the physician, or another physician of the same specialty who belongs to the same group practice, within the past three years"? EHRA suggests a single definition to be used with consistent wording across measure 7.2 and 7.3.

Measurement

There are no specific timeframes identified by CMS for the request of a summary of care document. If the time period is intended to be flexible, permitting EPs flexibility to request at any point, this should be explicitly clarified to avoid later confusion.

Threshold

Success with this objective will depend on the cooperation of other providers in the community and on adoption of new workflows; thresholds for the measure should be set appropriately.

Measure 7.3: Clinical Information Reconciliation

Shared EHRs

It was unclear whether 7.3 is intended to measure only referrals between systems (which seemed to be the intention of 7.2), or if referrals between providers who share access to the same EHR would also be counted.

New Patients

CMS uses the terms "new patients" and "never before encountered patients". Are these intended to be the same? Or does this a "new patient" refer to the CPT definition of a new patient as "one who has not received any professional services from the physician, or another physician of the same specialty who belongs to the same group practice, within the past three years"? EHRA suggests a single definition to be used with consistent wording across measure 7.2 and 7.3.

Measurement

There are no specific timeframes identified by CMS for performing clinical information reconciliation. If the time period is intended to be flexible, permitting EPs flexibility to reconcile at any point, this should be explicitly clarified to avoid later confusion.

Threshold
The measure has both expanded in scope and in the performance threshold. We suggest that it would be more effective to either focus attention on the broader scope of reconciliation or to raise the threshold for the previous measure (medication reconciliation).

Objective 8: Public Health and Clinical Data Registry Reporting
CMS reference: page 135/16762

Proposed Panel of Options
EHRA requests clarification so that we understand the proposal correctly, and that the following are examples of how EPs and EHs could successfully meet objective 8:

1. An EP submits to an immunization registry, submits case reports of reportable conditions, and submits to a public health registry.
2. An EH submits to an immunization registry, submits to a syndromic surveillance registry, submits reportable labs to public health, and submits to a clinical data registry.
3. An EH submits to an immunization registry and to three clinical data registries.
4. An EP submits to an immunization registry and proves that she is excluded from syndromic surveillance reporting, case reporting, public health registry reporting, and clinical data registry reporting.

Active Engagement
We agree that "active engagement" is a more appropriate category name than "ongoing submission", given that not all engagement involves ongoing submission.

Previous Submission
In Stage 2, CMS adopted a policy that, if an EP or EH was submitting to a public health registry using the previous standard identified in certification, and their public health agency was not ready to accept using the latest standard identified in certification, the submission using the previous standard would continue to be considered acceptable. EHRA suggests CMS continue this policy.

List of Registries
EHR developers and providers will find significant value in a list of registries that are able to accept data using the standards identified for certification. We strongly encourage the creation and central maintenance of such a list.

Exclusions
We anticipate that many registries and public health agencies will not be able to receive data using the standards specified in this timeframe. Therefore, we anticipate many EPs and EHs will be attempting to prove that they are excluded from the measures, and that proving an exclusion could generate a great deal of bureaucratic work without benefit to patients. We considered the following challenges:

- Certain exclusions are jurisdictionally-based, when specialty-based seems more applicable (e.g., clinical data registry reporting).
- It is not clear what a sufficient level of due diligence is to prove that there were not applicable recipients for submissions, causing concern for EPs that their documentation will be considered insufficient during an audit.

- Some registries impose their own requirements, which can include additional data capture requirements beyond what is in CEHRT, proprietary certification, licensing of their submission methods and content, membership in their organization, fees/dues, or transport mechanisms that are beyond what are standardized in certification.

Finally, it is unclear what is expected if a provider submits in the manner that is expected by their public health agency or registry, but that method does match certification (e.g., if a provider sends immunization data to a registry and the registry is using older standards or does not do bidirectional data exchange). CMS should clarify that this is sufficient to meet the measure.

Measures

8.1 Immunizations

EHRA observes that immunization registry reporting is the most widely adopted public health submission today, and that submission would be more efficient if public health agencies standardize to the same requirements that EHRs must meet in certification as well as a common transport mechanism. We urge HHS to work on standardization for registries to further the overall goal of national interoperability. In particular, we are concerned that CDC seems to be working on additional and conflicting EHR certification, which we do not believe will add value.

When providers submit to an immunization registry in the method expected by their agency, but not using the standards used for certification, this approach should meet measure requirements for the purposes of MU. For example, if a state registry still expects HL7 2.3.1 or is not ready in 2018 for bidirectional exchange, providers should still be considered to have met this objective.

8.2 Syndromic Surveillance

Urgent Care

It is unclear why CMS has removed urgent care contexts from EP MU and included them in EH MU. Urgent care is not a place of service that would otherwise fit CMS's definition of EH, and urgent care providers successfully participate in the MU program as EPs. We suggest that CMS correct these references on syndromic surveillance to match the broader context of the EP/EH definitions.

EP Objective

There is no implementation guide for this standard, reflecting a lack of priority interest among receiving agencies across the country. Given this lack of interest and lack of standards, EHRA does not believe that this is an appropriate MU objective for EPs. We suggest that it be removed as an EP option, and that the number of required measures for public health for EPs be decreased by one. If an EP is able to submit to his or her jurisdiction, then this could be considered sufficient to meet measure 8.4.

8.3 Case Reporting

EHRA is not aware of any public health agencies accepting reportable condition case reports using the standards identified for certification. We question whether this measure is really practical for widespread adoption.

8.4 Public Health Registry

CMS seems to anticipate a broader range of public health registry submissions than are included in ONC certification, which generates several concerns among EHRA reviewers.

First, is its CMS's intention that the types of submission included in 2015 Edition ONC certification would be acceptable exclusively? That would seem to significantly limit provider flexibility to the NHSN reporting, healthcare surveys, and cancer registry reporting. We suggest that CMS clarify that other types of public health registry submission might also be considered sufficient. Exclusions should still be based on the readiness of public health agencies to accept submissions using certified standards.

Second, we anticipate that different types of health IT modules will likely certify to different types of public health registry standards identified by ONC. The same type of module is unlikely to be designed for both hospital antimicrobial resistance reporting as well as outpatient cancer case reporting, for example. The modular approach of certification supports this, but if an EP or EH is in a jurisdiction where they expect to be excluded, and then suddenly the public health agency is ready to accept, an EP or EH might need to do more work before they can submit, including purchasing and installing a new module pertinent to that type of submission.

8.5 CDR

CMS indicates on page 16767 that EPs and EHs will used CEHRT to submit to clinical data registries, but there are no standards identified by ONC in 2015 Edition CEHRT for submission to clinical data registries. We understand the mapping of the proposed ONC 2015 Edition public health criteria to objective 8 as follows:

f1 - immunization reg → 8.1
f2 - syndromic surveillance → 8.2
f3 - reportable labs → 8.6
f4 - cancer registries → 8.4
f5 - case reporting → 8.3
f6 - antimicrobial use and resistance → 8.4
f7 - healthcare surveys → 8.4

Even if a standard were to be added, there is not an applicable standard to suggest and we are uncertain how a standard would be identified. There are currently many clinical data registries, but they do not use a single standard. Each registry has widely varying:

- Expectations for what data is submitted;
- Submission formats;
- Submission transport mechanisms.

Submission to clinical data registries would be far more efficient if a single standard could be identified for the data submitted, how it ought to be formatted, and how it is transported. However, EHRA is under the impression that registries have such varying use cases for what they do with the data that they are not close to standardizing in that fashion.

CMS should clarify that clinical data registry submission does not need to use CEHRT to be considered sufficient for measure 8.5, or this will not actually be an option for MU Stage 3. Given that change, the exclusions will also need to be adjusted to account for submission not being feasible given the current data capture and registry requirements.

8.6 Reportable Labs

We do not have any specific comments on submission of reportable lab results beyond our general comments on all of the objective 8 measures.

Definition of CEHRT

page 16768:

The CEHRT definition would include, for the reasons discussed previously, meeting the 2015 Edition Base EHR definition and having other important capabilities that include the capabilities to:

- *Record or create and incorporate family health history;*
- *Capture patient health information such as advance directives;*
- *Record numerators and denominators for meaningful use objectives with percentage-based measures and calculate the percentages;*
- *Calculate and report clinical quality measures; and*
- *Any other capabilities needed to be a meaningful EHR user.*

First, we are concerned that the "any other capabilities needed to be a Meaningful EHR User" is vague. We suggest that this term be clarified with a specific list.

Second, EHRA is concerned that including software not needed for meaningful use in the definition of CEHRT and the incorporated 2015 Edition ONC Base EHR definition will have the effect of requiring EPs and EHs to possess and potentially implement software that is not necessary for their achievement of MU.

In Stage 1 of MU, similar policies created this issue of the need to possess software functionality that was not desired by providers, part of the statutory definition of a Qualified EHR, or required for MU, and ONC attempted to clarify with an extremely complex definition of what it meant to possess software. The modular structure introduced in Stage 2, where EPs and EHs were explicitly not required to possess components they did not need, was much simpler and gave appropriate flexibility to providers to select their EHR modules.

In Stage 3, the base EHR and CEHRT definitions should include only software necessary to achieve meaningful use. Where MU Stage 3 gives providers options, such as the public health objective 8, providers should not be required (by virtue of including it in other definitions) to possess software that they individually might not need. Providers can then choose whether software certified to other criteria is important to them or not.

Clinical Quality Measures (CQMs)

Alignment of Multiple CMS Quality Reporting Programs, Including Electronic Reporting

The EHRA strongly supports efforts by both CMS and ONC to align the clinical quality requirements across CMS quality measurement and reporting programs in order to further the ability to measure the quality of care across settings and time for a patient. This alignment is essential to support patient-centered outcomes measurement, quality improvement and the move to value-based care.

Specifically, we generally support the efforts underway in the ONC Standards and Interoperability Framework (Clinical Quality Framework) to align the development of shared quality improvement standards for both clinical decision support (CDS) and electronic clinical quality measure (eCQM) development and implementation. We agree that these efforts will lead to improvements in the implementation and use of both the eCQMs and related CDS. However, we are concerned that these new standards are still in a very early development stage, and require extensive testing, pilot implementation, and revisions before they should be required for broad-based implementation in a federal program.

Requiring the use of a QUICK, FHIR-based standard for eCQMs is premature, as there have been no pilots to date using the developing standards with eCQMs, and these standards continue to evolve rapidly. We are concerned that premature inclusion could disrupt the critical improvements and progress already made, and recommend that these new standards are not required until they are fully tested, piloted and refined, and deemed ready for broad implementation.

Alignment efforts should also include alignment of required data elements across ONC and CMS programs. The ONC 2015 edition certification NPRM proposes an updated Common Clinical Data Set as well as a different set of data elements to be used to filter eCQM results. The Inpatient Prospective Payment System (IPPS) NPRM also proposes the use of a set of core clinical data elements for use with quality measures. These data sets lack alignment of definition and vocabulary standards across similar data elements such as age (birth date, age at admission), gender (sex), and vital signs, as examples. Alignment of data elements is essential both to furthering interoperability and to streamlining the implementation of new measures and their specifications.

Electronic Reporting Proposed for CY2018

The EHRA supports the proposal to require electronic submission of quality measures in 2018, as compared to previous rules that proposed requiring such submission as early as CY 2015.

To make mandatory electronic reporting feasible, we urge CMS to include providers, the EHR vendor community, certification tool developers, and other relevant stakeholders in the discussion of new measures, measure specification updates, reporting period considerations, reporting method options, and the alignment of programs among other quality measure related topics to ensure this requirement is achievable by all participants by CY 2018.

Each group of stakeholders has a unique perspective (workflows, technical feasibility, EHR data capture capabilities, etc.) that is important to consider. We also encourage creation of a more nimble eCQM specification update process to avoid burdening our clients with clinically inaccurate specifications for the entire next reporting period. At the same time, each eCQM specification update requires

development, testing, and potential workflow changes. Therefore, gathering more feedback upfront from all stakeholders on the proposed specification updates rather than issuing updates more frequently would be favorably received.

CQM Reporting Requirements for EPs

Although we support the goal of continued alignment across programs, it is impractical to provide all ambulatory quality measurement updates in the PFS rule. EHRA is very concerned that the release date of the PFS rule does not leave enough time for development and implementation of changes to CQM reporting, beyond very minor modifications. If the PFS Final Rule is released in October, there are at most three months to analyze the document, develop the necessary software changes, test those changes, and make them available to customers to implement by January 1. This is simply not sufficient time for EHR developers and providers to consume and deploy modifications.

EHRA has consistently stated that 18 months is needed from the release of new requirements to the expected implementation date.

EHRA is in support of the proposal to continue active communication and the maintenance of the eCQM library page. This page is a valuable resource for EHR vendors and providers.

We also encourage CMS to allow only minimal changes for state Medicaid programs because it is not feasible to maintain separate form and method requirements for individual states for electronic submission of CQMs.

CQM Reporting Requirements for Eligible Hospitals and Critical Access Hospitals

EHRA supports opportunities for public comment on CQM selection and reporting, and the continuation of posting the electronic specifications on the CMS website. This website content is an extremely valuable resource for vendors and providers.

EHRA appreciates CMS's clarification that manual abstraction is not considered use of CEHRT, but that electronic information interfaced or electronically transmitted into the system is a reasonable capture method.

CQM Reporting Period

EHRA considers the proposal to require an EHR reporting period of one full calendar year for both MU and CQM EP and EH reporting beginning in 2017 reasonable.

EHRA asks that CMS not expect changes to the form and manner of quarterly submission to be implemented for the very next submission after a final rule is published. EHRA has consistently stated that 18 months is needed from the release of new requirements to the expected implementation date.

Reporting Flexibility EPs, Eligible Hospitals, CAHs 2017

The EHRA supports the proposal to require the most recent version of measure specifications for submission (even if manually attesting), as long as certification policies are appropriate, clearly defined and widely communicated, starting with 2018.

In the past, CMS has stated that once a specific quality measure is certified, there is no need to recertify that measure when it is updated to the latest specifications. Some EHR vendors have heard otherwise from their certifiers or when they were surveyed. For example, one vendor when certifying a handful of new quality measures was asked to recertify all of their previously certified quality measures that had been updated to the latest annual specifications, contrary to CMS's stated policy. Other vendors have been told that they must recertify all measures to the same version of Cypress. The EHRA supports continuation of the CMS guidance that there is no need to recertify a measure when it is updated to the latest annual update specifications.

To eliminate this issue, certifiers should have access to all acceptable versions of Cypress (or Cypress should add versioning support) so that each measure can be certified against all acceptable versions of specifications at any time.

The success of the proposal to require the most recent version of measure specifications for submission depends upon certification policies being clearly defined, and the EHRA is in support of both.

Reporting Methods for CQMs

A proposed list of optional standards that can be used in varied ways by states and private payment organizations will likely lead to all of those standards being required by an EHR developer (as each state/payer chooses their unique combination of requirements). This approach greatly increases the development, certification, training, and workflow modification effort required by the parties involved. For example, although the rule states that CMS has no intention of accepting EH QRDA-III files, states can still decide to require this format. Does this approach mean that QRDA-III would still be a part of certification? If so, CMS not requiring/allowing EH QRDA-III submission while still allowing states to require it results in the same outcome as if CMS had required EH QRDA-III submission. Limiting the list of reporting methods (QRDA-III vs. QRDA-I), reporting periods (quarterly vs. annually), and other variables from which states and private payers can choose will minimize the large impact quality measure development, certification, and implementation already has while standardizing practices across the country.

Certifying EH QRDA-III when it cannot be used for submission has led to unnecessary development and certification efforts. The EHRA is in full support of removing this standard as an acceptable submission option if CMS has no plans to accept it. We request that CMS also remove it as a submission option that states and private payers can choose from, and instead focus on better tools to generate measure statuses from EH QRDA-I documents. States and private payers could use the QRDA-I documents to generate measure statuses from CMS's accepted method of submission.

CQM Specification and Changes to the Annual Update

CMS seeks comments on the annual update timeline and suggestions for how to improve the CQM update process. CMS introduced annual eCQM updates for both EHs and EPs to the EHR Incentive Program in 2013 to reflect non-substantive changes related to evidence-based updates that vendors routinely send to customers (e.g., medication updates). In both 2013 and 2014, the EH April updates and the EP June updates contained very substantial revisions to measure specifications primarily to correct widespread errors in both measure logic and value sets, as well as major revisions to the value sets in an effort to correct, harmonize and consolidate these value sets. These changes required

software development, testing and rollout to customers, as well as requiring extensive implementation work and clinical workflow changes by customers, with a significant impact to providers.

The EHRA appreciates CMS's efforts to work with all stakeholders to improve the annual eCQM updates through the work of the Kaizens as well as the introduction this year of a Change Review Pilot (CRP) process to obtain feedback on measure changes that are being considered. We recommend that the CRP efforts be continued and broadened to include a review process of all measures updates and involvement of additional stakeholders, as well as the release of preliminary measure specifications a few months ahead of the annual update to allow providers and vendors time to review the changes and provide feedback. Posts to JIRA are a good way to gather comments on measures from a variety of stakeholders.

The EHRA continues to recommend that the CMS annual updates should be limited to changes that do not have a significant impact on clinician workflow or provider implementation time, or require extensive software code changes or recertification of the EHR software due to the very short timeline between publication of the changes and required collection of the measure data. If an eCQM requires more extensive modification, and for any *new* eCQMs introduced, additional time must be considered with a minimum of 18 months timeline. In the 2016 IPPS NPRM, CMS acknowledged the need to determine a predictable cycle for the introduction and certification of new measures, as well as the testing of updated measures and submission capabilities. EHRA looks forward to responding to the RFI announced in that NPRM to provide more detailed information and recommendations on this topic.

EHR Technology Certification Requirements for Reporting of CQMs

CMS is considering requiring EHRs to be certified to more than the minimum number of CQMs required, and possibly requiring certification of all eCQM. EHRA strongly opposes this requirement.

Currently, some measures require an infeasible workflow (e.g., a measure requiring access to pharmacy dispensing data), and other measure specifications are flawed. Developers avoid these measures because they are problematic. Including these measures in EHRs will result in provider dissatisfaction with EHRs because of awkward workflows designed to collect data that is not a natural part of the patient care encounter.

The delivery of accurate, error-free specifications and test data would enable EHR vendors to certify to more measures. With MU2, many errors were encountered with the measure specifications as well as the certification test tool and test data. EHRA would like to stress that the accuracy of all data as well as certification tools and requirements will increase the number of CQMs vendors initially certify.

In addition, EHRA strongly supports the principle that EHR developers should be able to decide which measures to support in their products, and in consultation with their users. Developers of a specialty module for dermatology will have different requests from their users than developers of a specialty module for orthopedics. CMS's potential proposal to require vendors to certify for all EP or EH/CAH CQMs does not sufficiently allow for that type of differentiation.

CQM Flexibility in 2017

EHRA supports this proposal for provider flexibility to split the use of CEHRT for CQM reporting from the use of CEHRT for the MU objectives and measures, and allow EHR technology certified to either the 2014 Edition or the 2015 Edition for their CQM reporting in 2017. We refer CMS to the section at the beginning of our comments titled "Certification - 2014 Edition and 2015 Edition" where we propose that many of the Stage 3 objectives and measures as well as the CQM reporting could be accomplished using 2014 Edition CEHRT. We recommend that this flexibility also be considered beyond 2017, given the short timeline between the potential publication of new requirements for CQM reporting and the start of subsequent reporting periods. As we commented on previously, we remain concerned that premature inclusion of new standards and reporting requirements for CQMs could disrupt the critical improvements and progress already made, and recommend that any new standards are not required until they are fully tested, piloted and refined, and deemed ready for broad implementation.

We also support the ability for EPs, EHs and CAHs to use the most recent version of the CQMs and either report using electronic submission or attestation in 2017. We also recommend that CMS require state Medicaid programs to have the same flexibility in 2017 to better align programs. If the Medicare program allows this flexibility but a Medicaid program does not, flexibility in 2017 reporting will not be meaningful or helpful to providers in a group practice using the same EHR but attesting to different programs. Some providers may simply not be able to participate if the program flexibility does not align because their group may not be on the CEHRT that is required for reporting to their specific program.