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May 3, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0044-P
P.O. Box 8013
Baltimore, MD 21244-8013

Attention File Code CMS-0044-P

[Filed Electronically]

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive
Program—Stage 2

Dear Ms. Tavenner:

On behalf of the members of the EHR Association, we are pleased to submit our comments on the Center for Medicare and Medicaid Services' (CMS) Notice of Proposed Rule-Making (NPRM) for Meaningful Use Stage 2.

The attached responses were developed through the collaborative effort of 138 individuals, representing 25 of the 42 EHR Association member companies, working over the past several weeks to ensure thorough review and consideration of the proposed rule. We appreciate CMS' care and thoughtfulness in developing this proposed rule. We especially appreciate the clear and effective efforts by CMS to listen to and respond to feedback on Stage 1 and suggestions for Stage 2. Key points that we highlight include:

1. We strongly support and appreciate CMS' proposed one-year extension of Stage 1 of meaningful use and ONC's support for this change. The original proposed timeline contained untenable deadlines for EHR development and implementation, as well as training and quality assurance testing on-site within the provider organizations. CMS and the Office of the National Coordinator for Health IT (ONC) signaled their intention to fix the timeline in various announcements over the last six months, and, in the proposed rule, were responsive to industry input by moving start dates for Stage 2 to October 2013 for eligible hospitals (EHs) and January 2014 for eligible providers (EPs).

Along with many others in the industry, we have advocated for many months that ONC and CMS address the challenges that the current timeline and associated meaningful use and certification requirements create for providers and vendors, and the likely impact on the overall success of the HITECH program. As our members have carefully reviewed the development and operational implications of the proposed rules and reflected on our experiences with Stage 1, we have concluded that this challenging situation has been exacerbated in recent months due to the likely timing for release of the Stage 2 final rules, the number and immaturity of the proposed clinical quality measures, the proposed certification criteria, and that all providers will be required to upgrade to the 2014 Edition of their EHR regardless of their stage of meaningful use. Combined with the still tight schedule, this latter requirement would exponentially amplify the number of upgrades required in a very short period of time for those who attested in 2011 and those who will attest in 2012, 2013, and 2014.

We therefore strongly recommend that additional steps, many of which have been discussed at length over the past months, are taken in the CMS and ONC final rules to more completely address the challenges associated with the start of Stage 2.

Given this continued and now elevated concern, we urge CMS to take these considerations into careful account when making decisions on the scope of the Stage 2 final rules, as well as every possible effort to expedite release of those rules. As was generally agreed across the industry and by the HIT Policy Committee, a full 18 months is needed between release of the final rules and when providers need to upgrade. As of now, however, it is expected that this period will be reduced to approximately 12 months for EHRs and 15 months for EPs. We therefore encourage CMS to consider a shorter reporting period for 2014 of 90 or 180 days, given the need for substantial implementation deployment to thousands of providers within a very short timeframe. We have also encouraged ONC to consider allowing providers who are still in Stage 1 in 2014 to continue to use 2011 Edition certified EHR technology at their discretion.

2. The EHR Association recognizes and appreciates better alignment of quality measures and associated reporting requirements across multiple federal and private sector programs. In the proposed rule, CMS has demonstrated the increased priority it is placing on alignment of various quality reporting programs and we support these efforts.
3. At the same time, we are concerned that EHR developers and their clients will be challenged by the large number of proposed clinical quality measures (CQM) and the dearth of available detail on their final specifications. The data elements needed to support the proposed and final measures will add to the large volume of data elements proposed for meaningful use and certification. As a result, there could be increased development and implementation complexity that will make it especially challenging to develop quality data capture workflows that are usable and integrate well into clinicians' workflows. In addition, we have concerns that virtually none of the quality measures were initially designed for EHR-based reporting. The expectation that specifications for the CQM will not be available until summer 2012 creates additional pressure on both vendors and providers.

Given the above considerations, CMS should finalize far fewer measures for Stage 2 and be highly selective on the measures chosen according to the criteria that we outline.

Additionally, rather than requiring providers who are in Stage 1 in 2014 or 2015 to report on the Stage 2 measures and reporting obligations for the CQM, we also recommend retaining the existing Stage 1 measures and reporting requirements for providers in Stage 1 in 2014 or 2015 but implementing these measures using applicable 2014 edition versions of the specifications. The EHR Association is very supportive of CMS' efforts to quickly move toward broad and effective interoperability and appreciates the obvious coordination with ONC. We strongly support an attainable but feasible requirement (and quantitative threshold) for electronic information exchange, as we believe it will be an important driver of health data exchange and interoperability, which is an essential component of the shift to accountable and integrated care models.

4. We are pleased that many elements of both the CMS and ONC proposed rules are aimed at substantially increasing the use and benefit of standards-based interoperability and exchange. We have suggested, however, specific changes to the proposed rule to ensure that healthcare professionals and organizations can effectively share information across health systems and vendors before, during, and after the start of Stage 2, while also ensuring they get full credit for all standards-based electronic exchanges that support coordination of care for patients, whether via Direct, NWHIN Exchange, or health information exchanges (HIEs).
5. We are proponents of the value of increased patient engagement and inclusion of robust patient engagement objectives and measures in Stage 2. We specifically support both the measure associated with ensuring patients have access to their information (view, download, and transmit) and the measure focused on increasing communication between patients and providers (secure messaging). At the same time, our detailed comments propose several refinements to the proposals, including ensuring that providers in fact have the flexibility that CMS proposes with regard to specific data transport methods, that they are not held responsible for the actions of their patients that are out of their control, and that the proposals for online patient image access be revised to reflect technical realities.
6. We support expanding the clinical decision support (CDS) measure from one rule to five "interventions", and we agree that associating CDS with CQMs makes sense in principle. At the same time, we do not believe that these CDS interventions should be required to be linked to five CQMs used by the provider or implemented via new ONC standards.
7. The EHR Association supports CMS's proposed provider-focused imaging objective and measure for Stage 2. Images provide critical information that providers use to diagnose and manage diseases; access to needed images should enhance care and prevent potentially duplicative imaging tests. We agree with CMS to not require images to be stored in the EHR, but to be accessible through the EHR, such as by a link. Based on our members' experiences with EHRs and imaging-focused health IT, we have suggested refinements to CMS' proposal.
8. We are very pleased that CMS and ONC have taken steps to make the EHR Incentive Program more applicable to specialists. These include exclusions for certain measures, new CQMs, imaging and registry reporting menu options, and a proposed exemption for payment adjustments (for not being meaningful users) for eligible professionals (EPs) whose clinical practice is not consistent with meaningful use requirements. We propose some enhancements, but applaud CMS efforts.
9. Our CMS and ONC comments provide detailed suggestions to improve the accuracy and feasibility of reporting on progress against meaningful use measures. Based on Stage 1

experience across vendors and providers, we urge CMS to focus on ensuring that (1) measure definitions are clear and enable accurate and efficient reporting, (2) definitions of key terms and concepts are explicit in measure specifications and the final rule preamble, and (3) CMS and ONC reconsider their intention to require providers and their EHRs to track when functions are enabled or disabled or actions triggered. The need to measure and report on such events could impede clinical flexibility and exceed EHR capabilities.

On behalf of the EHR Association, we appreciate the tremendous effort that went into the development of this important NPRM, and we look forward to working with CMS staff to clarify Stage 2 requirements that will impact our customers and all of our member companies. We also congratulate the Secretary and the entire Department of Health and Human Services on the success of this important program in clearly accelerating the adoption of health IT, part of the broader effort to transform and improve healthcare delivery for all Americans.

Sincerely,



Carl Dvorak
Chair, EHR Association
Epic



Charles Jarvis
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee



Leigh C. Burchell
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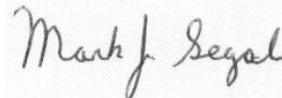
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About HIMSS EHR Association

HIMSS EHR Association is a trade association of Electronic Health Record (EHR) companies that join together to lead the health information technology industry in the accelerated adoption of EHRs in hospital and ambulatory care settings in the US. Representing a substantial portion of the installed EHR systems in the US, the association provides a forum for the EHR community to speak with a unified voice relative to standards development, the EHR certification process, interoperability, performance and quality measures, and other EHR issues as they become subject to increasing government, insurance and provider driven initiatives and requests. Membership is open to HIMSS corporate members with legally formed companies designing, developing and marketing their own commercially available EHRs with installations in the US. The association, comprised of more than 40 member companies, is a partner of the Healthcare Information and Management Systems Society (HIMSS) and operates as an organizational unit within HIMSS. For more information, visit <http://www.himssehra.org>.



**EHR Association Response to
Center for Medicare & Medicaid Services
Notice of Proposed Rule-Making
Meaningful Use MU2**

Topic/Section: MU2 Implementation Timing (FR 77 p.13703)

Issue:

CMS proposes a one-year extension of Meaningful Use MU1 (MU1) for providers who attested successfully in 2011 because Meaningful Use MU2 (MU2) requires changes to both technology and workflow that cannot reasonably be expected to be completed in the time between the publication of the final rule and the start of the EHR reporting periods.

Comment:

We strongly support this essential proposal. Many industry stakeholders, including the EHR Association, have emphasized the need to adjust the originally proposed timeline, as it did not allow sufficient time for safe development and implementation. Coordinated with the ONC proposed rule on standards and certification, this extension will positively affect all providers who will be pursuing meaningful use in FY/CY 2013, as they would have been responsible for implementing or upgrading to "MU2 certified" EHRs. The combined changes proposed by CMS and ONC with respect to meaningful use timing and certification will substantially reduce the problems that would have been created by the current timeline.

We remain concerned, nonetheless, that the timing of the MU2 final rule and the start of the MU2 reporting periods will still be challenging for development, testing, certification and implementation, as there will likely be only a 12-14 month time period between the two. In particular, we are concerned that vendors and providers will need to partner on an unprecedented number of implementations and upgrades in a very narrow period of time due to the proposed requirement that all providers participating in the program must be on the 2014 editions of their software.

For the industry to have a successful transition to MU2 under the current timeframe, we think it will be important for CMS to:

- Set public expectations as to key milestones (i.e., publication of a final rule, availability of certification test scripts, the availability of final quality measures specifications), and expedite these steps as much as possible.
- Align the scope of measures and certification criteria for MU2 with the time available for development and implementation.

Because the flexibility provided by a 90-day reporting period in an EP's or EH's initial year of meaningful use has delivered great value by allowing staggered implementation and upgrade timelines, as well as additional implementation flexibility, we therefore request that CMS strongly consider a 90- or 180-day reporting period for all providers for 2014. In fact, we ask that CMS consider such an approach for any future first year of a stage of the program during which all providers are expected to be on the same edition of their EHR. We are confident that this approach would be beneficial to a successful transition to 2014 certified EHRs and the new, more advanced measures.

Topic/Section: Changes to Stage One Criteria for Meaningful Use (FR 77 p.13704)

While we generally support the changes made in Table 3, which would apply certain changes to the MU1 criteria, there is one proposed change to MU1 requirements that would explicitly require an EP or EH to be using the 2014 edition of their EHR – the View, Download and Transmit measure.

For the reasons outlined above related to the unrealistic number of providers who would need to go through implementation, training and testing of the 2014 software editions at the same time if even those in MU1 of the program had to be on that same version, we encourage CMS not to require that those providers satisfy the proposed View, Download and Transmit measure during their MU1 participation. Instead, they should adopt the other changes to MU1 from Table 3 but wait until MU2 to satisfy the View, Download and Transmit requirement.

Topic/Section: State Flexibility (FR 77 p.13706)

Issue:

On p. 13706, comments are requested on MU2 flexibility for states to impose separate Medicaid requirements.

EHR Association Comment:

We therefore strongly support the CMS proposal that state-specific requirements not be permitted to exceed the capabilities of certified EHR technology. As EHR vendors, we strongly believe that programmatic consistency across states will greatly reduce overall program complexity, costs, and confusion.

We also suggest that it would be helpful to EPs and EHs if states follow a common timeline for establishing state-specific requirements so that providers can plan around common deadlines by which they could determine if their state would have specific requirements or not. This can be especially important for EPs and EHs that see patients in multiple states.

Topic/Section: Estimated Time Burdens for Meeting Reporting Requirements of This Program (FR 77 p. 13790)

Issue:

It is estimated on p. 13790 that the total time for an EP to report on the core set of objectives and measures would be eight hours 12 minutes, and that the EH time for reporting is seven hours 54 minutes. It is estimated that to prepare and report 12 quality measures, an EP would spend two hours and an EH would spend 20 minutes.

EHR Association Comment:

Our experiences with customers during MU1 indicate that these estimates are dramatically underestimated. For example, it might take many EPs eight hours to even read and understand the entire contents of the Final Rule.

The estimates do not seem to be based on the fact that attestation does not simply happen after a reporting period, but it is in fact an ongoing process that is set up prior to a reporting period, monitored throughout, and then closely analyzed.

Topic/Section: CPOE (FR 77, p. 13708, 13818)

Changed Measurement Method

We agree that the MU1 method of counting CPOE by the number of patients with at least one medication order has been confusing, and the proposed method of counting by CPOE-generated orders compared to total orders appears that it will be more straightforward. EPs and EHs manage CPOE adoption at an order level, not at a patient level, so the new measurement method will be better matched with actual practice.

Threshold

With the change to the way the measure is calculated (new numerator), as well as the addition of two new CPOE areas of focus, however, we have heard from our clients that they are concerned that the proposed 60% threshold will be challenging, and that establishing a new higher threshold based on previous meaningful user experiences is not valid if the metric changes.

Measurement

We do note that it will be challenging to include non-EHR orders in the denominator and that EPs or EHs who have written paper orders will have a substantial, manual measurement burden. Although electronic medication orders have been encouraged by MU1 and e-prescribing incentives, EPs not connected to lab or imaging systems electronically will be particularly challenged. We have tried to identify a method that would avoid having to consider paper orders while preserving the simplicity proposed, but we do not have any suggestions. So despite the added complexity of counting paper orders, we support the new proposed method as less complex and preferable to the MU1 method.

Clarifications

The members of the EHR Association appreciate and support the clarification that the NCPDP standard must only be used if an electronic prescription is transmitted between organizations and that electronically transmitted prescriptions within one organization should be counted as e-prescribing even if alternate formats not included in certification and associated standards are used.

Exclusions

Controlled Substances

We support the continued exclusion of prescriptions for controlled substances based on the lack of readiness across the country and the fact that some state regulations interfere with such prescriptions. For example, we are only aware of three states piloting controlled substance e-prescribing. Some states will also require legislative changes prior to permitting controlled substance e-prescribing, and it seems unlikely the required changes and pharmacy certifications will all be in place by 2014. For these reasons, we suggest this exclusion be maintained in the final rule.

Distance from Pharmacy

We appreciate the intent of the exclusion for EPs who are not within 25 miles of a pharmacy that accepts e-prescriptions, but have several concerns.

1. Timing: The exclusion is phrased “[a]ny EP who...does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 miles of the EP’s practice location at the start of his/her EHR reporting period.” If an EP does not have a local pharmacy that accepts e-prescriptions the day before the reporting period, but one starts accepting e-prescriptions the first day of his reporting period, that EP will be challenged to immediately implement e-prescribing and achieve MU2 thresholds. We suggest that the exclusion include a grace period to account for the time associated with e-prescribing implementations (even contracting with an e-prescribing hub can take several months), and that providers who do not have pharmacies that accept e-prescriptions as of six months prior to their reporting periods are excluded from this measure.
2. Patient preference: The exclusion is phrased “[a]ny EP who...does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 miles of the EP’s practice location at the start of his/her EHR reporting period.” We anticipate that patients of an EP who only have one pharmacy accepting e-prescriptions 25 miles away might prefer to take their prescriptions to closer pharmacies that do not support e-prescribing, causing a provider to miss the threshold. This is an important consideration because the proposed exclusion doesn’t take into account where patients live – while an EP might be 25 miles away from a

pharmacy that accepts electronic prescriptions (a long distance, surely), the patients could live even further away. For example, if an EP practices 25 miles south of a city where an e-prescribing pharmacy is located but the majority of his patients live further south than his clinic, they are unlikely to drive the even greater than 25 miles north to the one pharmacy that permits e-prescribing. Ultimately, too, we are not certain that a different distance radius will solve this challenge.

An alternate approach would be to base the exclusion on the patient's pharmacy preference, with the idea being that if a patient preferred a pharmacy that accepts e-prescriptions, any medications ordered should be e-prescribed; but that if the patient preferred a pharmacy that does not accept e-prescriptions, that any medication orders would be excluded.

Perhaps an alternate form of measurement or optional exclusion could be introduced so that providers who will exceed the proposed threshold would not be burdened with any additional documentation, whereas providers who are located in areas where e-prescribing is less prevalent could choose the alternate form of measurement.

3. Reporting: The exclusion is phrased "[a]ny EP who...does not have a pharmacy within their organization and there are no pharmacies that accept electronic prescriptions within 25 miles of the EP's practice location at the start of his/her EHR reporting period." We are uncertain how this exclusion will be determined, particularly for EPs who move practices. We would like to clarify that determining this exclusion, like the others for the objective and measure, will not be the responsibility of certified EHR technology, and that EPs will use other resources to make this determination.

Drug/Formulary Checks

We are pleased that CMS acknowledges that not all drug formularies are linked to all certified EHR technologies. The availability of external formulary information is dependent on (1) making an insurance eligibility match with the patient and (2) the insurance company publishing their formulary through Surescripts and a PBM. There is wide variance in the match rates for both of these criteria, based on geographic location and insurance plan inclusion. If such an electronic link is not available, importing and maintaining formulary information is time-consuming (especially since formulary format information is not always conveniently provided).

However, for a formulary check to be meaningful, it must be patient-specific. We are confused by the requirement to check a medication order against an irrelevant drug formulary. This proposed requirement seems to require computer processing power to perform a function that is not valuable to the clinician and could in actual fact be distracting (if frequent messages of "no relevant formulary available" are displayed).

We suggest revision of the measure requirement as follows:

1. When e-prescribing a medication order, first determine if there is a relevant formulary for the patient:
 - If there is no formulary, continue with message transmission and place the patient in the numerator.
 - If there is a relevant formulary for the patient, compare the order against the formulary. If the comparison generates relevant information, present that information to the provider. If the provider continues with message transmission, place the patient in the numerator.

This proposed refinement is focused on avoiding irrelevant detailed comparisons of orders against irrelevant formularies, and also on steering clear of the unnecessary display of irrelevant information to the provider.

Given that the measurement does not account for whether relevant comparisons are being made, we suggest that this MU2 proposal is not worth the new complexity introduced. For that reason, we propose that attestation that the drug/formulary checks are enabled would be far simpler and still achieve key CMS goals of balancing costs and benefits.

We note that ONC has proposed a certification criterion suggesting that CEHRT “would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed.” Our comments to ONC will include details on why we think the complexity of this measurement proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here as well:

2. Auditing of “enabling” or “disabling” something as complex as drug-formulary checks is not just one yes/no setting. Enabling checks likely involves multiple steps, which likely vary among different CEHRT. The steps might include loading formulary content from a third party and ensuring that patients’ insurance information is captured for comparison. It might not be possible for CEHRT to programmatically determine whether this feature is enabled without intervention from a person (whether the EP or a member of the organization’s staff).

In reality, the CEHRT will not be able to account for all possible ways that enabling this functionality could happen, especially if some of these might be non-intended uses. CEHRT can provide valuable auditing tools, but ultimately users will need to attest about their compliance with these tools.

3. In addition, drug-formulary checks might be temporarily disabled while performing system maintenance (for example, if loading updated formulary content). We are concerned that such normal software-related events are not considered in the requirement that this functionality remain enabled throughout the entire reporting

period. Periodic planned (or unplanned) downtime to update checks should not bar achievement of meaningful use.

In addition, although we agree that CEHRT can provide helpful information about how frequently certain interactions are being executed, frequency of execution is irrelevant to the proposed measurement of this objective.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that appropriate interaction checking was enabled throughout the reporting period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Measurement

Measurement challenges with this objective include establishing exclusions described above, the revision that we request regarding measurement of drug-formulary checks, and, as cited in our CPOE feedback, the challenge for any EPs who additionally use paper orders to total those into their denominator. We therefore suggest changing drug-formulary measurement to attestation and revising the exclusions as suggested above.

Topic/Section: e-Prescribing Discharge Medications (for EHs) (FR 77 p. 13729, 13821)

Menu

We agree that it is appropriate to introduce this new objective as menu rather than core.

Clarifications

We appreciate the ongoing clarification in the discussions of EP e-prescribing (p. 13710) that the NCPDP standard must only be used if an electronic prescription is transmitted between organizations, and we support counting prescriptions that are electronically transmitted within one organization even if alternate formats that are not included in certification are used. We suggest that this proposal be unchanged in the final rule and ask that CMS clarify that it applies to e-prescribing discharge medications.

Exclusions

Controlled Substances

We support the continued exclusion of prescriptions for controlled substances based on the lack of readiness across the country and some state regulations interfering with such prescriptions. For example, we are only aware of three states piloting controlled substance e-prescribing. Some states will require legislative changes prior to permitting controlled substances e-prescribing and it seems unlikely the required changes and pharmacy certifications will all be in place by 2014. For these reasons, we suggest that this exclusion be maintained in the final rule.

Distance from Pharmacy

We appreciate the intent of the exclusion for EHs who are not within 25 miles of a pharmacy that accepts e-prescriptions, but have several concerns.

1. **Timing:** The exclusion is phrased that “[a]ny EH who...does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 25 miles at the start of the EHR reporting period.” If an EH does not have a local pharmacy that accepts e-prescriptions the day before the reporting period, but one starts accepting e-prescriptions the first day of the reporting period, that EH will be challenged to immediately implement e-prescribing and achieve MU2 thresholds. We suggest that the exclusion include a grace period to account for the time associated with e-prescribing implementations (even contracting with an e-prescribing hub can take several months), and that providers who do not have pharmacies that accept e-prescriptions as of six months prior to their reporting periods are excluded.
2. **Patient preference:** The exclusion is phrased that “[a]ny EH who...does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 25 miles at the start of the EHR reporting period.” We anticipate that patients of an EH that only has one pharmacy accepting e-prescriptions 25 miles away might prefer to take their prescriptions to closer pharmacies that do not support e-prescribing, causing an EH to miss the threshold for this measure.

This is an important consideration because the proposed exclusion does not take into account where patients live – while an EH might be 25 miles away from a pharmacy that accepts electronic prescriptions (a long distance, surely), patients could live even further away. For example, if an EH is located 25 miles south of a city where an e-prescribing pharmacy is located but the majority of patients live further south than the hospital, they are unlikely to drive the even greater than 25 miles north to the one pharmacy that permits e-prescribing.

Ultimately, too, we are not certain that a different distance radius will solve this challenge. An alternate approach would be to base the exclusion on the patient’s pharmacy preference, with the idea being that if a patient preferred a pharmacy that accepts e-prescriptions, any medications ordered should be e-prescribed, but that if the patient preferred a pharmacy that does not accept e-prescriptions, including a mail order pharmacy, that any medication orders would be excluded.

Perhaps an alternate form of measurement or optional exclusion could be introduced, so that EHs who will exceed the proposed threshold would not be burdened with any additional documentation, whereas EHs that are located in areas where e-prescribing is less prevalent could choose the alternate form of measurement.

3. Reporting: The proposed exclusion is phrased that “[a]ny EH who...does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 25 miles at the start of the EHR reporting period.” We are uncertain how situation this will be determined based on the current proposed rule. We thus request clarification that the Certified HER Technology is not required to provide the determination of this exclusion and that EHs will use other resources to make this determination.

Refills v. New Prescriptions

CMS requests comment on whether it would be unnecessarily burdensome to distinguish refills of prescriptions that were being taken prior to the patient’s arrival at the hospital from new prescriptions given after discharge. Indeed, needing to make this distinction would be unnecessarily burdensome. We recommend that all prescriptions be counted, regardless of whether they are refills or new.

Drug-Formulary Checks

We are pleased that CMS recognizes that not all drug formularies are linked to all certified EHR technologies. The availability of formulary information is dependent on (1) making an insurance eligibility match with the patient and (2) the insurance company publishing their formulary through Surescripts and a PBM. There is wide variance in the match rates for both of these criteria, based on geographic location and insurance plan inclusion. If such an electronic link is not available, importing and maintaining formulary information is time-consuming (especially since formulary format information is not always conveniently provided).

For a formulary check to be meaningful, however, it must be patient-specific. We are confused by the requirement to check a medication order against an irrelevant drug formulary. This proposed requirement seems to require automating a function that is not valuable to the clinician and, in actual fact, could be distracting (if frequent messages of “no relevant formulary available” are displayed).

We suggest clarification as following:

1. When e-prescribing a medication order, first determine if there is a relevant formulary for the patient.
 - If there is no formulary, continue with message transmission, and place the patient in the numerator.
 - If there is a relevant formulary for the patient, compare the order against the formulary. If the comparison generates relevant information, present the information to the provider. If the provider continues with message transmission, place the patient in the numerator.

Our suggested clarification is focused on avoiding irrelevant detailed comparisons of orders against irrelevant formularies, and also on steering clear of the unnecessary display of irrelevant information to the provider.

Given that the measurement does not account for whether relevant comparisons are being made, we suggest that this MU2 proposal is not worth the new complexity introduced. For that reason, we propose that attestation that the drug/formulary checks are enabled would be far simpler and still achieve key CMS goals of balancing costs and benefits.

We note that ONC has proposed a certification criterion suggesting that CEHRT “would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed.” Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

2. Auditing of “enabling” or “disabling” something as complex as drug-formulary checks is not just one yes/no setting. Enabling checks likely involves multiple steps, which likely vary among different CEHRT. The steps might include loading formulary content from a third party and ensuring that patients’ insurance information is captured for comparison. It might not be possible for CEHRT to programmatically determine whether this feature is enabled without intervention from a person.

In reality, the CEHRT will not be able to account for all possible ways this could happen, especially if some of them might be unintended uses. CEHRT can provide valuable auditing tools, but ultimately users will need to attest about their compliance with these tools.

3. Drug-formulary checks might be temporarily disabled while performing system maintenance (for example, if loading updated formulary content). We are concerned that this is not accounted for in the requirement that they remain on throughout the entire reporting period. Periodic short downtime to update checks should not prohibit meaningful use.

We agree that CEHRT can provide helpful information about how frequently certain interactions are being executed. However, frequency of execution is irrelevant to the proposed measurement of this objective.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that appropriate interaction checking was enabled throughout the reporting period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Measurement

Measurement challenges with this objective include the challenges of establishing exclusions described above, the clarification we requested regarding measurement of drug formulary checks, and, as cited in our CPOE feedback, the challenge for any EHRs who additionally use paper orders to total those into their denominator.

Specific Notations

The numerator counts “patients...who have all the elements of demographics (or a specific notation if the patient declined to provide one or more elements or if recording an element is contrary to state law) recorded as structured data.” We support accounting for patients who decline to provide information or EPs or EHS who practice in states that prohibit such collection. However, where a state prohibits the collection of a certain data element, we suggest that a single system notation of this state prohibition should be deemed sufficient. Otherwise, we suggest that the objective and measure remain unchanged in the final rule.

We appreciate clarification that the preliminary cause of death is not required to be entered in any particular time window. We are uncertain, however, how this clarification should be addressed for meaningful use reporting for this measure, especially for patients who die close to the end of the reporting period. We suggest that the measurement simply be whether the patient had a cause of death recorded, regardless of when that was entered. It would be possible that a patient dies shortly before the close of the reporting period but that the cause of death is entered *after* the end of the reporting period. We do not think the volume of this occurrence will significantly affect reporting, nor is it appropriate to introduce any additional reporting complexity to account for it.

Disability Status

Public comment is requested on including patient disability status in demographics. We suggest that it is premature to include disability status without pre-existing consensus on a definition and an applicable reasonable standard, and as a result, the EHR Association does not support this as a new demographic or stand-alone data element for MU2. If disability status is included for a future stage, we note that some providers might include disability status information in the problem list; please provide clarification as to why some disabilities would be stored in the problem list and some stored elsewhere.

Gender Identity and/or Sexual Orientation

Public comment has been requested on including gender identity and/or sexual orientation in demographic data collection. We believe it is appropriate to defer to clinicians and interested community members as to the suitability and priority of capturing gender identity and/or sexual orientation. As software developers, however, we note that consensus on appropriate standards for capturing such data would be necessary with sufficient notice to add relevant fields to our EHRs.

Measurement

Measurement challenges with this objective include the clarification suggested earlier about “specific notations” of state prohibitions and the time window of the preliminary cause of death.

Topic/Section: Vital Signs (FR 77 p. 13712, 13818, 13820)

We appreciate the additional flexibility added to the exclusions for this objective. We suggest that this objective and measure remain unchanged in the final rule.

Measurement

We have not observed measurement issues in MU1 and suggest the measure remain unchanged.

Topic/Section: Smoking Status (FR 77 p. 13818, 13820)

We suggest this objective and measure remain unchanged in the final rule.

We note, however, that it can be confusing and challenging for clinicians when there are very similar but not identical data capture requirements between MU objectives and clinical quality measures. In this case, NQF 0028 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received cessation counseling intervention if identified as a tobacco user) is also an MU1 and proposed MU2 measure, but each approach measures a different age range and takes a different approach to smoking and/or smokeless tobacco use. These discrepancies can lead to confusion among clinicians.

We therefore suggest harmonization between the two measures associated with Tobacco Use before the release of the final rule for MU2 to allow vendors the appropriate time to make the necessary adjustments.

Measurement

We have not observed measurement issues in MU1.

Topic/Section: Clinical Decision Support (FR 77 p. 13714, 13818, 13820)

Increased Number of Interventions

We support CMS' proposed expansion of the clinical decision support objective from one rule to five interventions.

Relation of Interventions to Quality Measures

We agree that a focus on interventions related to clinical quality measures (CQM) is appropriate and agree that generally EPs and EHs should be encouraged to use CDS interventions to improve quality on priority conditions, as established by a linkage to a nationally established CQM.

We are concerned, however, with and oppose the specific proposal that “[p]roviders would implement [five] clinical decision support interventions that they believe will result in improvement in performance for [five] or more of the clinical quality measures on which

they report.” We believe this proposed change introduces unnecessary rigidity related to two elements of the meaningful use program that present the greatest challenge to providers (clinical decision support and clinical quality measurement).

1. The selection of high priority clinical quality measures proposed in the regulation is not sufficient for all eligible providers or hospitals according to their scope of practice. For example, there are few opportunities for clinical decision support interventions relevant to children's hospitals in the proposed measures, and the same is also true for specialty providers in ambulatory practice.

Consequently, rather than require providers to implement clinical decision support interventions according to the CQMs on which they report or more generally, a fixed list of CQMs, we recommend that providers be allowed to use their clinical judgment regarding which clinical decision support interventions would best benefit patients within the scope of their practice. We would expect that many providers will implement clinical decision support interventions around quality measures on which they expect to report, where applicable, but we also foresee instances where such linkages would not be desirable and thus would not make such an association between CDS interventions and CQMs a requirement of the rule.

2. Providers might not know exactly which clinical quality measures they intend to report until the conclusion of the reporting period when they can determine conclusively that measures have non-zero denominators. Yet, they will be asked to implement clinical decision support interventions prior to the start of the reporting period. If they implement clinical decision support related to a selection of five of the quality measures to work on improving performance and decide later to report to CMS on a different selection of quality measures, we believe they should still receive credit for this objective and measure. Again, we propose that, while selected interventions should be associated with one or more of the final set of CMS CQMs (assuming that this final set has sufficient breadth and depth), CMS should not require that the interventions be linked to CQMs reported by the EP.
3. As stated above, providers might wish to change their interventions mid-reporting period, based on how they are doing with an intervention or changes in clinical priorities. We suggest that CMS clarify that providers could modify or replace interventions during the reporting period and still meet this objective and measure so long as they use at least five interventions throughout the entirety of the reporting period.

If CMS continues to wish to link CDS interventions to CQMs, we suggest that they do so based on the entire list of CQMs in the final set but not only those CQMs reported on by that specific provider.

Relation to CEHRT

On p. 13708, CMS proposes that, “[a]s with MU1, EPs, EHs, and CAHs must use the capabilities and standards that are certified to meet the objectives and measures for MU2. In meeting any objective of meaningful use, an EP, EH, or CAH must use the capabilities and standards that are included in certification.” We see several problems with this broad requirement as it would apply to the CDS objective and measure.

The first is that the only standard identified by ONC for CDS functionality is §170.204(b)(1), HL7 Context-Aware Knowledge Retrieval (“Infobutton”) Standard, International Normative Edition 2010 (see p. 13847). We do not think that either CMS or ONC intends that providers would be required to use the Infobutton standard as their sole method of clinical decision support interventions to meet meaningful use. Although the Infobutton standard might be helpful in some cases, it is not sufficient or appropriate for use with all CDS interventions, given that it is a standard that permits carrying of context when doing referential searching.

Moreover, given the broad definition of CDS interventions proposed by ONC on p. 13847 as “. . . not simply an alert, notification, or explicit care suggestion. Rather, it should be more broadly interpreted as the user facing representation of evidence-based clinical guidance.” we are not certain how CDS would be measured if five interventions took place enabled by an Infobutton search or if they were related to relevant clinical quality measures.

CMS should clarify in the preamble of the Final Rule and any associated measure specifications that the Infobutton standard need not be used for any or all of a provider’s CDS interventions.

We do suggest that, when an EP or EH chooses to enable Infobutton for referential searching, such enablement be considered one of their five clinical decision support interventions, and it should be stated that additional interventions that utilize the information for interventions associated with specific QMs could count as additional interventions.

Intervention Attributes

We would like to clarify that, since drug-drug and drug-allergy interaction checks are separate from the CDS interventions, the attributes of a CDS intervention do not need to be included with each drug-drug or drug-allergy interaction. Not all of the attributes of an intervention are relevant for drug-drug and drug-allergy interactions, and we think including such superfluous information would require onerous implementation in terms of build-out and ongoing maintenance, as well as potentially reduce the usability of such checks.

There are multiple models for clinical decision support, especially given ONC’s definition of a CDS intervention as “the user-facing representation of evidence-based clinical guidance” as indicated above, and we suggest that the requirements should be inclusive of a

provider's choice to use any of these models. There sometimes appears to be a misconception that all CEHRT includes pre-built CDS interventions where both the CDS capabilities and the CDS content are supplied by the EHR vendor. In practice, it is quite common that the EHR vendor provides the CDS capabilities and the CDS content is supplied by the provider, the provider's organization, by a third-party vendor or some combination therein. Moreover, the ONC definition of an intervention could include a wide variety of CDS "interventions" that are not typically thought of as CDS.

Certification will establish that CEHRT has the capability to display required intervention attributes but it will not establish that all interventions built in the system have this information populated, nor would such a requirement be appropriate. In fact, such a requirement could inhibit use of CDS interventions. The EP or EH would need to assure that any content they build or acquire includes such information. However, we do not think information on all attributes is relevant in all interventions, particularly if a provider is creating their own interventions as reminders to themselves. For example, it would be irrelevant to require the provider to enter information about their own funding source.

Moreover, if an intervention takes the EP or EH user out of the EHR – for example, by use of the Infobutton standard to a reference website – then neither the EHR nor the EP has control or the ability to report on whether CDS attributes are available.

Measurement

We believe that attestation is appropriate as a measurement for this objective. We note that ONC has proposed a certification criterion suggesting that CEHRT "would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed." Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

1. Auditing the "enabling" or "disabling" of a CDS intervention is complex and essentially impossible to do on a consistent basis given the ONC definition of an intervention. Enabling an intervention likely involves multiple steps which could easily vary among varying CEHRT and different interventions.

For example, to enhance usability and workflow integration, CDS interventions might be location-specific for a provider practicing in both a family practice clinic and an urgent care clinic. A CDS intervention about preventive care might appear to the provider when they see patients in the family practice clinic but not in the urgent care setting. It might not be possible for CEHRT to programmatically determine whether this feature is enabled without intervention from a person (whether the EP or a member of the organization's staff) to make a determination.

Although slightly less complex, enabling of drug-drug and drug-allergy interaction checking is also not a simple "yes/no" to track. Enabling drug-drug and drug-allergy checks also involves multiple steps that likely vary among different CEHRT. For

example, this enablement might involve loading third party drug content and assigning levels of interaction checks to different categories of users. Again, it might not be possible for CEHRT to programmatically determine whether this feature is enabled without intervention from a person (whether the EP or a member of the organization's staff) to make a determination.

2. Similarly, disabling a CDS intervention might be possible in multiple ways, including ways not intended by designers of CEHRT. As one example, administrative staff might be able to change an intervention so that it is still turned on but simply no longer going to appear (e.g., it is triggered only for patients over 200 years of age). As a second example, a CDS intervention might be enabled that cautions against the use of a particular drug. If the capability to order that drug is subsequently removed from the system, the CDS intervention is effectively disabled (since it will no longer be activated) even though it technically still exists as an active check within the system.

Our point is that CEHRT will not be able to account for all possible ways that disabling could occur, especially if some of these would be unintended uses. CEHRT can provide valuable auditing tools, but ultimately users will need to attest about their compliance with these tools. Thus, disabling of drug-drug and drug-allergy interaction checking is also not necessarily possible to track via CEHRT.

3. CEHRT will not be able to establish if CDS interventions relate to chosen quality measures for that EP unless a user indicates this linkage in the system which is no different than a user attesting this. Likewise, CEHRT cannot assess the validity of this linkage. As noted earlier, it might not be known during the reporting period which quality measures are to be reported. Therefore, we do not suggest this added complexity.
4. CDS interventions or drug-drug and drug-allergy checks might be temporarily disabled while performing system maintenance (e.g., if loading new CDS interventions or updating drug content). We are concerned that this planned (and sometimes unplanned) downtime is not accounted for in the requirement that these interventions remain turned on throughout the entire reporting period. Periodic short downtime to update CDS interventions or drug-drug and drug-allergy checks should not preclude meeting the CDS objectives and measures.

We agree that CEHRT can provide helpful information about how frequently certain interventions and checks are being executed. However, frequency of execution is irrelevant to the proposed measurement of this objective.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that appropriate interventions were enabled throughout the reporting period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Challenge of Counting Interventions

We have some concerns over how clinical decision support interventions will be counted. We suggest that a clear and consistent mechanism to determine what counts as an intervention will be necessary for to allow EHR developers to create consistent reporting capabilities across systems. For example, a clinical decision support implementation that ensures that patients with diabetes get annual A1C and cholesterol measures could be counted as either a single intervention or as two separate interventions, depending upon how it was implemented in an EHR. Clarification on how to count or clarifying that CMS is leaving the explicit discretion regarding tabulation methods to providers is appreciated.

Topic/Section: Incorporate Lab Tests (FR 77 p. 13717, 13818, 13820)

Measurement

We believe that MU1 has revealed challenges with accurate reporting of this measure, challenges that will be exacerbated if the measure becomes core and the threshold is raised, as proposed.

Several of the measurement challenges include:

1. To generate an accurate denominator, the EHR must know not only which lab tests are expected to return a numeric or positive/negative result but which results were returned in this way, even if they were not returned electronically. How does the EHR know which lab orders are in this category? Attempting to have the EHR determine if the result is numeric is actually very complex, technically. For example, some allergy tests will return a numeric result if sent to a particular lab and a text result if sent to a different lab. We suggest that the reporting could be simplified if CMS provides a list of non-numeric or positive/negative test types that should be excluded, along with the associated standards/codes for those tests.
2. CMS requested feedback on the feasibility of reporting by panel components rather than orders. This reporting approach is not feasible, however, because the number of components is variable depending on the lab that processes a particular specimen. Below is an example of a CBC panel and the different components returned by two different labs.

LabCorp Panel	Quest Panel
CBC With Differential/Platelet	CBC W/ DIFF & PLT
WBC	WBC
RBC	RBC
Hemoglobin	HEMOGLOBIN
Hematocrit	HEMATOCRIT
MCV	MCV
MCH	MCH
MCHC	MCHC

RDW	RDW
Platelets	PLATELET COUNT
	MPV
Neutrophils (Absolute)	NEUTROPHILS,ABSOLUTE
Lymphs (Absolute)	LYMPHOCYTES,ABSOLUTE
Monocytes	MONOCYTES,ABSOLUTE
Eos (Absolute)	EOSINOPHILS,ABSOLUTE
Baso (Absolute)	BASOPHILS,ABSOLUTE
Neutrophils	SEGMENTED NEUTROPHILS,%
Lymphs	MATURE LYMPHOCYTES,%
	MONOCYTES,%
Eos	EOSINOPHILS,%
Basos	BASOPHILS,%
Hematology Comments:	COMMENT

In summary, we urge that reporting continue to be based on orders, and that CMS provide more explicit guidance as to which orders are expected to be positive/negative or numeric, and which are not, for more accurate and simplified counting.

Topic/Section: Patient Lists (FR 77 p. 13718, 13818, 13820)

We suggest that this objective and measure remain unchanged in the final rule.

Measurement

We think that attestation is appropriate as a measurement for this objective. We note that ONC has proposed a certification criterion suggesting that CEHRT “would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed.”

Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

1. CEHRT might include many capabilities for a provider to generate a report listing his patients with a particular condition. Many of these tools are not limited to just that purpose – for example, the same tool an EP might use to list his patients with specific conditions might be used to find his patients who have missed recent appointments. Auditing the use of this tool to a point where CEHRT can automatically determine if an EP has generated the correct type of list is likely to require extensive additional programming. This functionality could make the CEHRT less usable by slowing it due to the need to log additional information when running such a report; and it could lead to under-reporting due to not anticipating all of the possible workflows a provider might choose.

2. Similarly, a provider might generate such a report in a variety of ways, some potentially not imagined by the CEHRT programmers designing such auditing capabilities. Limiting a provider's flexibility and ingenuity should not be CMS' intention or effect. For example, a provider might search for patients with a particular condition by searching for patients that he has had appointments with, or patients he has consulted on, or patients seen in his department, or patients of his practice, or appointments he had on a particular day. Similarly, he might identify patients with a particular condition based on problems, medications the patients are on, lab results for particular patients, or other creative means provided by his CEHRT. Auditing the use of this tool to a point where CEHRT can determine if an EP has generated the correct type of list is likely to require extensive additional programming; to make CEHRT less usable by slowing it due to the need to log additional information when running such a report; and to underreport due to not anticipating all of the possible workflows a provider might choose.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that an appropriate list was generated during the reporting period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Topic/Section: Send Reminders (FR 77 p. 13718, 13818)

Patient Preference

We are concerned that patients' communication preferences might not always be documented, or that they might be documented but refer to other communication preferences (such as the receipt of lab results) rather than clinical reminders. Is the measure intended to require that at least 10% of patients who have had an office visit in the last 24 months have communication preferences documented? That requirement would be challenging because it requires providers to begin documenting patient communication preferences prior to the onset of MU2.

If it is not intended to require the documentation of patient communication preferences but simply to honor patient preferences when they are known, then we request clarification of how to count reminders sent when the patient's preference is uncertain. We suggest that these reminders should still be counted in the numerator.

Need for Reminders

We appreciate limiting this objective to providers who have office visits with patients. However, we are concerned that in a number of places less than 10% of all of an EP's patients will not need reminders, yet there is no exclusion. For example, if a specialist provides episodic consults but generally sees a patient once and then returns them with advice to the care of their PCP or another specialist, there might not be relevant reminders to send these patients. We suggest that this objective be in the Menu category or that an exclusion be provided.

Challenges of Documentation and Clinically-Relevant Information

We agree with the statement that the EP is best positioned to decide which information is clinically relevant for the purpose of sending reminders, and we agree that EPs should be encouraged to use the capabilities of their EHR in this way. However, we emphasize that CEHRT cannot distinguish between reminders sent based on the EP using clinically relevant information to identify the patients versus reminders sent based on the EP identifying the patients through other means. Because the EP's use of discretion cannot be reported out of the EHR, we do not think this language is appropriate as part of the measure.

Secondly, we request clear guidance on what constitutes an acceptable reminder. Although the objective indicates that the goal of using CEHRT is to determine patients who should receive a reminder for clinical reasons, the measure does not indicate anything about the content of the reminder. We strongly suggest that the measure be clarified to incorporate all requirements of what is to be measured so that clarifications subsequent to the Final Rule are minimized.

We also note that reporting would be simplified by the ability to count all reminders (regardless of their content and how they were determined to be sent), and we support this revised and clarified method of measurement.

Measurement

Measurement challenges with this objective include the documentation and definitional challenges mentioned cited earlier.

Topic/Section: eMAR (FR 77 p. 13821)

We are pleased that this objective was introduced and believe it will be beneficial for patient safety. We suggest this objective and measure remain unchanged in the Final Rule from the proposed rule.

Measurement

We note that ONC has proposed a certification criterion suggesting that CEHRT "would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed." Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments.

Auditing of "enabling" or "disabling" something as complex as eMAR is not just one yes/no setting. Enabling likely involves multiple steps including system configuration and hardware setup. It might not be possible for CEHRT to programmatically determine whether this feature is enabled without intervention from a person (whether the EP or a member of the organization's staff) to make a determination in all cases or for all products.

Consistency with Content in Clinical Summary

We appreciate that there is consistency between the content intended to be included in the summary to be downloaded in the portal and the summary to be transmitted at a transition in care. However, we note that in the case of providing information on a portal, the element “[a]ny additional known care team members beyond the referring or transitioning provider and the receiving provider” does not make sense, because there is not necessarily a referring or receiving provider. This requirement should be simplified to “care team members.”

Alignment of Objective with Standards

On p. 13719, the CMS proposed rule states that, “[t]ransmission can be any means of electronic transmission according to any transport standard(s) (SMTP, FTP, REST, SOAP, etc.).” We agree with this proposed flexibility and strongly support CMS’ position that many transport standards might be appropriate. However, on p. 13708, CMS proposes that, “[a]s with MU1, EPs, EHs, and CAHs must use the capabilities and standards that are certified to meet the objectives and measures for MU2. In meeting any objective of meaningful use, an EP, EH, or CAH must use the capabilities and standards that are included in certification.” We urge CMS to be explicit in the Final Rule that, for this objective and measure, its allowance for multiple transport methods and standards overrides this general statement from p. 13708 and would not require sole use of the ONC proposed rule standards 170.202(a)(1) and (a)(2).

We agree that choosing one minimum floor standard for certification is appropriate, but if an EP’s CEHRT supports other standards-based mechanisms more suited to their practice, those should also be permissible. We urge CMS to clarify the contradiction between the general statement on p. 13708 and the specific flexibility on p. 13719 in permitting the flexibility indicated.

Measurement

We have identified several measurement challenges with this objective.

Content

We agree that EPs should be able to exercise judgment about what to provide in a patient portal and what should be withheld until after an in-person visit or for other communication means, and that this withholding should not affect their numerators.

However, this appropriate flexibility introduces great complexity for reporting. CEHRT cannot determine if a lab result is being intentionally withheld until a visit or if a provider has simply failed to make it available within four business days of receipt.

Similarly, CEHRT cannot determine if some information is not provided to patients because it is not relevant (e.g., the patient has no current need for instructions), because it has simply not been provided, or because it was never entered in the chart. On p.

13720, CMS states that “[i]n circumstances where there is no information available to populate one or more of the fields previously listed, either because the EP can be excluded from recording such information (e.g., vital signs) or because there is no information to record (for e.g., no medication allergies or laboratory tests), the EP may have an indication that the information is not available and still meet the objective and its associated measure.” We are confused as to whether the expectation is that CEHRT will automatically generate an indication for patients that this information is not available, or if the expectation is that the provider will indicate this. We suggest the former, because the latter would be a large documentation burden, particularly for specialists who are excluded from recording such information. If an excluded EP must still enter “no information available” for every single relevant patient, that is not an effective exclusion.

On a separate note, growth charts are a visualization of data and not data elements themselves, and thus they should not be included in a consolidated CDA for download or transmission. We suggest the applicable data (height, weight) be included with the visualization removed from the content.

Including images for view, download and transmission is a complex requirement going significantly beyond the proposed menu objective to include view access to images for providers. Images are typically stored in a non-EHR system, introducing additional complexity to the task of including them in a patient portal. Second, the file size of images will present significant challenges for online viewing and downloading. Provision of images to patients is currently better suited to burning to a DVD. Therefore, we suggest images be deferred to a later stage.

Exclusions

We suggest clarification on the language around the exclusion “[a]n EP who neither orders nor creates any of the information listed for inclusion as part of this measure may exclude both measures.” Because the information listed includes the provider’s name and office contact information, exclusion seems categorically impossible. We assume the intention was to exclude providers not responsible for problem list entries, ordering procedures and lab tests, creating medication list entries, updating vital signs, updating smoking status, and creating care plans.

Additionally, we assume that the exclusion based on broadband availability will be based on attestation of the EP and not on CEHRT.

View

A patient portal (from an EHR or an HIE) might provide information to patients in formats best suited to the patient’s purpose. For example, a patient’s lab results might appear in one section where it is possible to view, in a graph, the lab results over time, as well as in another section that includes a visit summary because they are the lab results associated with that particular visit.

We also note that “view” is not defined for this measure. We do not believe it appropriate for this objective to limit measurement of “view” to simply when the patient views the clinical summary because a portal or HIE might provide more innovative or useful ways of viewing such information. Nor do we think that a “view” should be limited to only those times when a patient views the entirety of the information available in the portal.

We suggest that the best way to measure a view is to measure if a patient has logged in to a portal or HIE that is part of the provider’s CEHRT.

Download

We have not identified particular challenges with measuring downloads.

Transmit

We see various challenges and potential inaccuracy with the measurement of transmissions.

Transmission might have a variety of forms:

1. A patient takes a specific action to have his record transmitted electronically to a third party.
2. A patient provides authorization to the caregiver for his record to be transmitted electronically to a third party in certain circumstances (such as after each visit).

The measure seems to inadvertently encourage the second form because an ongoing authorization could lead to a transmission during each reporting period in which the provider sees that patient, without any actual engagement on the part of the patient – i.e., the patient might never log in to the third party portal to look at the information.

In addition, we are concerned that transmissions to third parties create many authentication challenges, as there is not sufficient Directory support for certificates.

Topic/Section: View, Download and Transmit (EHs) (FR 77 p. 13820)

Consistency of Numerator Wording

The wording of this numerator and denominator is inconsistent with the EP objective of the same name, and should be aligned for simplicity. We believe the EP wording is clearer than that for the EH because the EH wording seems to imply that the information would be available online but not available for access online. Also, we think the EP clarification that a patient’s authorized representative could also view, download or transmit the information is also important for EHs. We request clarification of consistency here and suggest using the language from the EP section in this section, as well.

EP:

Numerator 1: The number of patients in the denominator who have timely (within four business days after the information is available to the EP) online access to their health information

Numerator 2: The number of unique patients (or their authorized representatives) in the denominator who have viewed online or downloaded or transmitted to a third party the patient's health information

EH:

Numerator 1: The number of patients in the denominator whose information is available online within 36 hours of discharge.

Numerator 2: The number of patients in the denominator who view, download, or transmit to a third party the information provided by the eligible hospital or CAH online during the EHR reporting period

Consistency with Content in Clinical Summary

The EP objective cited should be consistent in the content required for "view, download, and transmit" with the content required for summaries of care provided at transitions in care. We think that such consistency is appropriate and should also be part of the EH objective. We are concerned that the variances in the content required for the EH view, download and transmit requirement introduce unnecessary additional complexity. Even small wording differences, such as the difference between "problem list" and "problem list maintained by the hospital" can introduce confusion and should be avoided. These kinds of variations raise the question of whether the problem list to be included in the summary of care document provided at transmissions is supposed to include more problems than just those that are maintained by the hospital, and how would those be incorporated.

We request clarification on some content intended to be provided in the portal.

1. Problem list maintained by the hospital on the patient
2. There appears to be unnecessary variation from other references to including the problem list in clinical documents. Obviously the problem list is the one for the patient who is accessing the information, and obviously it would be the one maintained by the hospital. We urge that CMS use a consistent name and definition for "problem list," and change the name of "problem list maintained by the hospital on the patient" to "problem list."
3. Relevant past diagnoses known by the hospital

Is this intended to be problems or diagnoses from previous admissions? We are uncertain what information this refers to and how it differs from the problem list maintained by the hospital. We suggest this item be clarified as it is inconsistent with

the content included in the summary of care document for transitions in care that uses the same standard, and the wording is confusing.

4. Medication list maintained by the hospital on the patient (both current admission and historical)

Does this item assume that the patient is currently admitted when viewing this portal? We are confused with the term “current admission” given that the requirement is only to make this available within 36 hours from discharge. Displaying all historical medications could be voluminous. We suggest instead focusing the requirement on just the current medication list. Other references in the EP objective of the same name and the transition in care objective reference the “medication list” or “active medication list.” This should be changed to be consistent with those simpler references.

5. Medication allergy list maintained by the hospital on the patient (both current admission and historical)

Again, we are confused by the term “current admission” given that the requirement is only to make this available within 36 hours from discharge. We think displaying (or transmitting) historical allergies could be confusing. Other references in the EP objective of the same name and the transition in care objective reference the “medication allergy list” or “active medication allergy list.” This should be changed to be consistent with those simpler references.

6. Laboratory test results (available at discharge)

Hospital patients can have enormous volumes of lab results, many of which can be abnormal and confusing. We suggest that EHs be permitted the discretion to filter the total lab test results to a reasonable subset, such as only the most recent results of a particular type, or results from the last 24 hours of admission.

7. Care transition summary and plan for next provider of care (for transitions other than home)

Other references in the EP objective of the same name and the transition in care objective reference the “care plan field, including goals and instructions.” The EH measure here should be changed to be consistent with those simpler references. Alternatively, a clearer expectation needs to be provided for a care transition summary and plan for the next provider of care. Also, we believe that this content would be more appropriate for the provider-to-provider transitions of care document (where it is not included) than for the provider-to-patient portal (where we suggest it should be removed).

Alignment of Objective with Standards

We note that transmission requirements are not addressed in the preamble discussion of the EH objective. We assume this omission is an oversight and that the requirements and allowed approaches are intended to be similar to the EP proposal. In addressing the EP

objective, on p. 13719, the proposed rule states, “[t]ransmission can be any means of electronic transmission according to any transport standard(s) (SMTP, FTP, REST, SOAP, etc.).” We agree with this proposed flexibility and strongly support that many transport standards might be appropriate. However, on p. 13708, it is proposed, “[a]s with [MU1], EPs, EHs, and CAHs must use the capabilities and standards that are certified to meet the objectives and measures for [MU2]. In meeting any objective of meaningful use, an EP, EH, or CAH must use the capabilities and standards that are included in certification.” We see several problems with this broad requirement which we will attempt to highlight. One problem is exemplified in this objective, as in ONC’s rule only standards 170.202(a)(1) and (a)(2) are specified.

We agree that choosing one minimum floor standard for certification is appropriate, but if an EH’s CEHRT supports other standards-based mechanisms more suited to its practice, those should also be permissible. We urge CMS to clarify the contradiction between the general statement on p. 13708 and the specific flexibility on p. 13719 in permitting the flexibility indicated.

Measurement

We have identified several measurement challenges with this objective.

Content

CEHRT cannot determine if some information is not provided to patients because it is not relevant (e.g., the patient has no current need for instructions), because it should have been provided but was not, or because a clinician at the EH has determined it was inappropriate to be released in that format. We note CEHRT cannot address those issues in measurement.

Exclusions

We assume that the exclusion based on broadband availability will be based on attestation of the EH and not on CEHRT.

View

A patient portal (from an EHR or an HIE) might provide information to patients in formats best suited to the patient’s purpose. For example, a patient’s lab results might appear in one section where it is possible to view, in a graph, the lab results over time, as well as in another section that includes a visit summary because they are the lab results associated with that particular visit.

We also note that “view” is not defined for this measure. We do not believe it appropriate for this objective to limit measurement of “view” to simply when the patient views the clinical summary because a portal or HIE might provide more innovative or useful ways of viewing such information. Nor do we think that a “view” should be limited to only those times when a patient views the entirety of the information available in the portal.

We suggest that the best way to measure a view is to measure if a patient has logged in to a portal or HIE that is part of the provider's CEHRT.

Download

We have not identified particular challenges with measuring downloads.

Transmit

We see various challenges and potential inaccuracy with the measurement of transmissions.

Transmission might have a variety of forms:

1. A patient takes a specific action to have his record transmitted electronically to a third party.
2. A patient provides authorization to the caregiver for his record to be transmitted electronically to a third party in certain circumstances (such as after an admission).

The measure seems to inadvertently encourage the second form because an ongoing authorization could lead to a transmission during each reporting period in which the provider sees that patient, without any actual engagement on the part of the patient – i.e., the patient might never log in to the third party portal to look at the information.

Topic/Section: Clinical Summaries for Office Visits (FR 77 p. 13715, 13819)

Content

We are concerned that the list of information to be included (p. 13716) in these summaries is quite lengthy and will generate an unwieldy clinical summary. Since starting MU1, we have heard numerous concerns that the summary provided after office visits is too long. We suggest CEHRT have the capability to provide all of the information suggested (noting our concerns below) but that providers have the explicit discretion to determine whether providing all or a subset of the information is most appropriate in each instance. In particular, we note that providers might want to provide only the most recent sets of information in an office visit clinical summary.

We request clarification on the following elements:

1. Current problem list and any updates to it

Updates are by definition included in a current problem list, so this phrasing seems unnecessarily complex. Is the intention to provide an indication of the change between the previous problem list and the problem list after the visit? This approach would introduce unnecessary complexity, especially with new patients (who do not have previous lists) or where previous lists might have come from other systems and require significant updates. We suggest simplifying to "current problem list."

2. Current medication list and any updates to it

See comment above on problem list.

3. Current medication allergy list and any updates to it

See comment above on problem list.

4. Vital signs and any updates

What does "and any updates" mean? We assume that the intention is to include the patient's vitals during the visit and suggest simplifying to "Vitals taken during visit".

5. List of diagnostic tests pending

What does "pending mean"? Does this wording mean ordered but not yet performed? Or performed but not yet resulted?

6. Clinical instructions

What are clinical instructions?

7. Future appointments and future scheduled tests

These might be stored in a scheduling system and not in an EHR. We suggest that if this information is not available in the EHR, the EP be excluded from having to provide it. Also, we request clarification of the difference between "future scheduled tests" and "pending diagnostic tests".

8. Demographics maintained by the EP

We assume this means any demographics in the EHR, not specifically ones updated by this particular EP. Our first concern is that EPs rarely update demographic information – it is almost always a staff member who updates the demographics. Second, establishing accountability for demographics maintenance introduces unnecessary complexity.

9. Care plan field, including goals and instructions

We think that this wording is inappropriately prescriptive, as the CEHRT might decide to structure care plans in ways other than one "field." Also, how are the instructions included with a care plan different from the separate section of clinical instructions? This seems duplicative.

10. Recommended patient decision aids

What are these? Please provide some examples.

Timeframe

Although we agree with CMS' assessment that most clinical summaries are provided at the close of a visit, some providers will continue to mail clinical summaries so requiring delivery in a 24 hour timeframe makes this basically impossible. We suggest that a timeframe of "by the close of the following business day" is more reasonable and, given variability of mail delivery, should clearly focus on the timing of provision (including mailing) and not receipt. Consider these examples:

1. Common practice for bulk mailing of clinical summaries is to print them all at the end of the business day and put them in the next day's mail. If a patient had an office visit at 9am on Tuesday, the clinical summary might be printed at 7pm on Tuesday but might not go into the mail until 11am on Wednesday, the next day's mail pickup. This seems like a reasonable effort to get the information to the patient in a timely fashion, but would not be within 24 hours.
2. Similarly, 24 hours might even exclude office visits close to a daily mail pickup. If a clinic has a mail pickup at 10am, and an office visit ends at 9:55am, it might not be possible to print and address the summary in time for that day's mail pickup. However, more than 24 hours have passed if the summary goes in the next day's mail pickup. This approach seems like a reasonable effort to get the information to the patient in a timely fashion, but would not be within 24 hours.

Considering the above scenarios above and the challenges of counting whether the summaries are mailed within 24 hours, we question whether reporting on this time lag can be sufficiently accurate. CEHRT might not be able to calculate the end time of an encounter relative to the time a summary was mailed to determine if it happened within 24 hours without introducing new and burdensome documentation requirements for entry of the precise end of the visit and the timestamp when the summary was mailed. Requiring someone to enter into the EHR the time a summary was mailed is certainly not meaningful use of an EHR and should be avoided. Reporting on whether the summary was mailed by the conclusion of the next full business day will be far less burdensome and more accurate, and therefore is much preferred.

Measurement

Provided

We request clarification on what it means to "provide" a clinical summary, especially when provision might be electronic. If a provider makes clinical summaries available to all patients on a patient portal immediately, does that indicate that they are at 100%? Or does the measure need to be limited by how many patients have current logins to the portal or actually view the summary? We recommend that the appropriate measurement for this objective would be to count successful placement of the patient summary on a patient portal where the patient has signed up for the service, and that the measure not assess any patient access of that information.

Multi-day Visits

It is almost impossible to report on whether a provider is excluded from providing a clinical summary due to a multi-day visit without adding documentation requirements for the EP to indicate, "not giving summary today because returning tomorrow for second part of multi-day visit." We do not think such documentation should be required as it does not have clinical relevance, and therefore we suggest that the threshold be low enough to accommodate multi-day visits without exclusions.

Refusals

In MU1, there have been varying clarifications on the exclusion related to a patient declining a clinical summary. This exclusion needs to be clarified in the Final Rule.

Content

CEHRT cannot distinguish between whether information is not provided in a clinical summary because it is not relevant, because a provider has exercised discretion to withhold it, or because it was mistakenly never entered in the chart. We suggest that it is more effective to independently measure whether information is populated, and therefore this objective should focus on whether the summary is provided.

Topic/Section: Patient Education (FR 77 p. 13720, 13819, 13820)

Denominator

We agree with the proposal that EPs who do not have office visits with patients might not have the opportunity to provide educational materials. However, EPs who see patients for many follow up visits on the same condition might not need to provide repetitive education at each office visit.

Also, providing education is more patient-centric than visit-centric. Measuring by unique patients will account more accurately for non-visit-specific methods of providing education, such as making educational materials available in a patient portal or messaging patients about suggested education.

We suggest that the measure be changed to consider unique patients who have had at least one office visit with the EP.

Measurement

One measurement challenge is the provision of education that is not visit specific, as described above.

Topic/Section: Secure Messaging (FR 77 p. 13728, 13819)

Messages Sent to Staff of EP

The objective is worded “the number of patients who send a secure electronic message to the EP.” We suggest rewording “...to the EP or a member of the EP’s staff.” As with other meaningful use objectives, tasks within CEHRT might be performed by the EP or by members of his staff, and messages might be commonly answered or triaged by a nurse or care manager. These messages should still be counted.

Relevant Health Information

We agree that it is not reasonable to expect CEHRT to determine whether a message includes relevant health information, and we suggest this element be deleted from the objective, since it would not be practical to have an EP or his staff label all incoming messages with an indication as to whether they include relevant health information or not. Some messages might be questions about a condition or the instructions given to a patient, but some might also be requests for an appointment, requests to refill a prescription, or questions about a bill. Since the goal is to engage patients in this new technology, we suggest that all messages be counted toward the 10% measure, regardless of content.

We note that some messages might vary in type. If a provider sends a patient a questionnaire (such as a health risk assessment) and the patient fills it out and sends it back to the provider, that this would also be a message and should count.

We also note that “relevant health information” is described in the objective but not in the specific measure, and assume that this matches our suggestion above to count all messages regardless of content.

Alternate Measurement Options Proposed

Given concerns about how the 10% threshold was established and whether all providers would be able to meet such a threshold given varying patient populations, we suggest alternate forms of measurement that might be more appropriate for MU2.

1. Attestation that such a feature is enabled. This approach could be combined with a threshold-less measure of what percentage of patients send a message that could be used to inform a threshold for Stage 3.
2. Requiring the EP or his staff to send a message to at least 10% of patients, rather than the reverse.
3. Measuring the percent of patient messages that an EP or his staff respond to.

Topic/Section: Medication Reconciliation (FR 77 p. 13721, 13819, 13820)

How to Report on Transitions of Care

In MU1, EHR Association members and their customers have experienced difficulties report on transitions of care because it is not always clear or indicated when a transition is taking place. Providers, in fact, do not always know if a transition is happening (e.g., if a patient sees another provider and does not report this). And even when it is known, this

status change is not always entered into the EHR. Without this information to construct an accurate denominator, reporting on this objective will be inconsistent and inaccurate. We also agree with the CMS assessment that determining all relevant encounters for medication reconciliation is too subjective to be measured.

We suggest that additional manual documentation, such as requiring a notation that an encounter or admission is a transition, could be avoided by instead focusing on actions that can be measured accurately with minimal disruption to workflow. For example, we think there is general consensus that these situations would be clear transitions where medication reconciliation should take place:

- A first encounter with a new patient
- An admission to a hospital
- A visit to the Emergency Department (ED)

We suggest that we focus on the three scenarios above and learn from these first efforts before expanding this measure. We considered several other scenarios in which medication reconciliation is useful, but difficulty of reporting consistently and accurately precluded us from recommending these be included:

- Returning outpatient who might have seen another provider in the interim
- Infrequent visits to the same physician
- First outpatient visit to any EP after an inpatient stay or ED visit

For simplicity of reporting and accuracy across CEHRT with different reporting capabilities, we suggest that measurement of medication reconciliation be narrowed to first encounters with new patients (for EPs, if the visit is creating a new chart for the patient at the organization) and to all admissions (for EHs).

EPs and EHs would be encouraged to also perform medication reconciliation at other appropriate opportunities, of course, but we do not recommend measuring beyond the first two outlined above for reasons of simplicity and consistency.

Relation to CEHRT

We agree with CMS' assessment on p. 13721 that "[w]hile we believe that an electronic exchange of information following the transition of care of a patient is the most efficient method of performing medication reconciliation, we also realize that it is unlikely that an automated process within the EHR will fully supplant the medication reconciliation conducted between provider and patient. Therefore, the electronic exchange of information is not a requirement for medication reconciliation."

However, on p. 13708, it is proposed, "[a]s with [MU1], EPs, EHs, and CAHs must use the capabilities and standards that are certified to meet the objectives and measures for [MU2]. In meeting any objective of meaningful use, an EP, EH, or CAH must use the

capabilities and standards that are included in certification." We see several problems with this broad requirement which we will highlight.

In this case, the functionality required for certification presumes that electronic exchange is the method of medication reconciliation. The functionality needed to perform that type of medication reconciliation might be more complex than is needed for simpler medication reconciliation, when a nurse or EP asks a patient if she is still taking a particular medication and marks it as active or not active. We suggest, given the disparity between the more sophisticated certification requirement and the realities of current practice, that CMS not require EPs and EAs to use only that more sophisticated functionality in all cases, even when it may not be relevant. CMS should clarify that this is not the expectation.

Measurement

Significant measurement challenges and lack of clarity exists with identifying transitions in care, as described above. For example, is a transition only a change from one type of setting to another (e.g., hospital to long-term care) or from one setting to another (e.g., hospital A to hospital B)?

Topic/Section: Summary of Care at Transition in Care (FR 77 p. 13722, 13819, 13821)

The EHR Association has a long record of supporting standards that enable secure information exchange among collaborating provider organizations as an essential building block for effective care coordination.

Required fields

We request clarification as to the content of the summary of care to be provided and how this affects measurement. For example, CMS refers to the "care plan" and "team members, including PCP" as "required fields." We suggest there might be some confusion as to the nature of a summary of care document, which is not a form filled out at the time of a transition (that could have required fields) but rather a document generated by the EHR based on information previously documented in the chart.

Additionally, an important point related to this measure is that depending on the design of the CEHRT, the generation of a summary of care document might not involve user intervention but rather happen automatically in certain circumstances (e.g., an electronic records request from another HIPAA-covered entity with patient authorization). This scenario provides another reason that the concept of a "required field" in a form, as generally known, is not applicable. We assume that the intention is, rather, that the content of these previously populated fields be included in the summary of care document, and we request that this be clarified.

Care plan definition

CMS defines care plan in the context of this objective. We note that care plans are also defined, with slight variation, in other parts of the rule (we have observed variant definitions on p. 13716 and 13722, and there were perhaps others). We suggest that, to avoid confusion, one single definition of care plan (and care transmission summary, if that is the same) be provided in the final rule and that the single definition be referenced consistently.

No information available

We appreciate the clarification that, in circumstances where there is no information available about one of the listed fields because the EP or EH is excluded from documenting that information or because there is no information to record, that the fields can be blank and still satisfy the measure. Our understanding is that if any of the fields specifically for problem list, medication list, or allergy list is blank, the EP or EH will not meet the measure, but that if any other information is blank, the EP or EH will still meet the measure. Clarification on this point and reinforcement of our understanding outlined above will be helpful for accurate measurement.

Include the most recent information known

We are confused by the wording that the EP or EH must “verify that these three fields for problem list, medication list and allergy list are not blank and include the most recent information known by the EP or EH at the time of generating the summary.” This requirement seems to imply that there is a required manual review process at the time of each summary generation, which is not appropriate. As described above, some CEHRT might have the capability of automatic generation of a summary, and requiring manual signoff that the information is the most recent known would be inefficient and should not be required. The fact is that CEHRT will automatically include the current problems, medications and allergies in the summary of care when it is generated. Measurement of the objective could exclude from the numerators summaries where one of these three is blank.

How to Report on Transitions of Care

In MU1, we have experienced significant difficulties reporting on transitions of care because it is not always indicated when a transition is taking place. Providers do not always know if a transition is happening (e.g., if a patient has seen another provider and does not report this), and even when it is known, this is not always entered into the EHR. Without this information to construct an accurate denominator, reporting on this objective will be inconsistent and inaccurate.

We suggest that additional manual documentation (such as a notation that an encounter or admission is a transition) should be avoided by focusing on things that can be measured accurately but with minimal disruption to workflow. For example, we think there

is general consensus that the following would be clear points of transitions where a summary of care should be provided:

- A patient is referred to another provider
- A patient is discharged from the hospital
- After an ED visit

Other transitions are more difficult to track and report via the CEHRT.

EPs and EHRs would be encouraged to also perform medication reconciliation at other appropriate opportunities, of course, but we do not recommend measuring beyond the first two outlined above for reasons of simplicity and consistency.

Determination of Internal v. External Transitions

We agree with the CMS assessment that when the recipient of a transitioning patient has “access to the medical record maintained by the referring provider, then the summary of care would not need to be provided and that patient should not be included in the denominators of the measures.” However, we highlight that whether the recipient of a transition has access to the same record is not always known. Some EHRs might not include this indication for reporting, and even EHRs that include it might not always have it be filled out. For example, many times a patient might be offered choices of specialists within network. If the referral recipient is not known at the time the transition is initiated, it will not be possible to report accurately out of the EHR. We suggest that these transitions be excluded only when known, with the understanding that they will not always be known, and that thresholds remain reasonable given uncertainty due to patient choice.

MU1 Requirements

We agree with CMS’ assessment that the MU1 requirement to perform a test of the capability to exchange between systems has been generating confusion and not providing significant value. We agree that providers will be better served by focusing on actual exchange between systems, as will be needed in MU2, with tests as needed during MU1 to prepare for required MU2 exchange.

Transport Standards

CMS requests comment on whether use of NwHIN Exchange standards (such as those using SOAP standards as presented by ONC as an optional transport mechanism) should be counted toward this objective in addition to Direct standards identified in ONC’s certification rule. We strongly support the inclusion of NwHIN Exchange standards as counting toward the numerator of the electronic exchange measurement. We think that NwHIN Exchange standards are appropriate for exchange use cases not covered as well by the Direct standards, and use of either standard should be counted.

Providers and organizations that are part of the NwHIN Exchange or other organizations using these standards should receive credit for those exchanges in meeting

interoperability measures. Given that the NwHIN-type of connection might not be point-to-point, we believe that CMS should allow an alternative to the 10% exchange measure as in an NwHIN-type model (whether from a provider officially part of the NwHIN Exchange or simply relying on the approach), where records might be exchanged Directly, shared through a Health Information Exchange organization or published to a registry and/or repository but not specifically sent to a specific provider.

Feasibility Challenges in Particular Areas

It is noted in the NPRM that there might be feasibility challenges in certain areas with meeting the measure of 10% exchange outside of one's organization with different certified EHRs from different vendors. For example, CMS cited examples where the majority of providers in one area use EHRs from only a few vendors. CMS requests comments on possible exclusions or alternate measures for this case.

We understand the intent behind the proposed measure and we support appropriate information exchange between all providers, where clinically relevant, regardless of the EHR used by that provider. We agree, though, that there are likely many areas of the country where EPs might not be able to achieve this meaningful use measure due to these and related factors and were unable to find alternatives. We agree with the CMS statement in the preamble that all those currently achieving MU1 should be capable of achieving MU2, and we suggest that this requirement needs modification for this reason. The EHR vendor selected by providers in a particular geographic area is not always within the control of and may not even be known to all EPs or EHs who will be affected by the decision or knowable by the EHR. If the proposed measure is preserved, this could be an inadvertent discouragement for those providers who have achieved MU1 from ongoing participation in the program.

It is also important to consider the active mergers and acquisitions environment currently at play in the industry. It is not uncommon for EHR companies to merge with or acquire other EHR companies, and what might have previously been EHRs from different vendors could suddenly be EHRs provided by the same vendor. This situation would again pose feasibility challenges for EPs and EHs that are beyond their control.

Not only would such a measure be challenging to implement and measure, it might have the unintended consequence of artificially pushing providers to send referrals outside of an organization or coordinated care network in order to meet the 10% threshold, which could endanger the success of care delivery organizations, including the accountable care models that CMS is working to encourage through other programs. We believe that even unintentionally changing referral patterns is outside the scope of an EHR incentive program and also not desirable given CMS's other goals for accountable care.

For these reasons, we suggest breaking the measure into two separate measures:

1. A measure intended to foster general inter-organizational data exchange so info is flowing between providers, even if they use the same EHR. For this measure, we

propose that of transitions of care and referrals taking place between providers in different organizations, 10% should be done electronically.

Denominator: The number of transitions in care and referrals:

- to recipients outside the organization
- made during the EHR reporting period
- for which the EP or EH was the transitioning or referring provider

Numerator: The number of transitions of care and referrals in the denominator where a summary of care record was electronically transmitted using CEHRT

Models of Exchange

We note separately that the proposed measurement in the NPRM only recognizes one model of interoperability —the push of a message. As indicated above in the discussion of the NwHIN option, other methods of data exchange are also useful. For example, if a patient presents in a hospital emergency department, it is clearly valuable to query other providers for information about that patient to pull relevant records. This type of interoperability and exchange should also be encouraged, and we urge CMS to develop measures that credit providers who are engaging in all forms of exchange.

We note that one method of accommodating this model would be to count when a hospital pulls a record for patients who have presented in the emergency department. Consideration would have to be given to the construction of an appropriate denominator, or perhaps it could be measured without a threshold in MU2 to construct a threshold for Stage 3.

Measurement

Earlier sections described several measurement challenges around identifying transitions in care and other information suggested for reporting, distinguishing between transitions within and outside of an organization, appropriate accounting for different models of exchange, and feasibility issues. We have suggested alternate measures above.

Topic/Section: Immunization Registry (FR 77 p. 13819, 13821)

Transport Mechanisms

We are concerned that there are no transport methods for certification and that the transport methods required by an immunization information system (IIS) might not be supported by CEHRT. EPs and EHs should be excluded in these cases.

Exclusions

We agree with the CMS proposal to exclude EPs and EHs from submitting if they do not administer immunizations to any populations for which data is collected. However, we are concerned that even though an EP or EH might not generally administer such immunizations, or might not have in the previous reporting period, there is always the chance that such an immunization would be provided unexpectedly, without opportunity

to immediately connect to a registry (e.g., if an EP rarely sees adults but renders care for a single patient over 18). Therefore, we suggest this exclusion be based on either a previous reporting period or on giving fewer than some small quantity of immunizations.

We also agree that EPs and EHs should be excluded if they operate in a jurisdiction where there is no immunization registry or no registry capable of receiving data in the format generated by the provider's CEHRT. However, we note that it might take three to six months to implement a connection to an immunization registry. Therefore, the exclusion should indicate that the EP or EH is excluded if the registry is not capable of acceptance in the correct format as of six months prior to the reporting period. If a registry becomes capable of accepting in the correct format the day before the reporting period, all affected EPs and EHs will not be able to instantaneously connect, but they would no longer be excluded in the current wording.

Measurement

We think that attestation is appropriate as a measurement for this objective, and we agree that letters from public health agencies would be reasonably applied. We note that ONC has proposed a certification criterion suggesting that CEHRT "would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed." Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

1. It is not clear what "enabling" of "ongoing submission" might look like and, since it might vary, we are not sure how CEHRT would audit it, especially since transport mechanisms will vary. Some registries might accept real-time submissions while others might accept batch files of information on a periodic basis such as weekly, monthly, or quarterly. These permutations will be better addressed by attestations from the EP and EH and the registry rather than by automated tracking the EHR.
2. Submission might be facility-specific rather than provider-specific. For example, if a provider practices in two clinics, one that submits to the registry and one that does not, how will CEHRT report if the provider has this capability enabled?
3. Ongoing submission might be temporarily disabled while performing system maintenance (e.g., if a registry is upgrading to new interface standard). We are concerned that this is not accounted for in the requirement for ongoing submission.

We agree that CEHRT can provide helpful information about how frequently immunization messages are executed. However, frequency of execution is ultimately irrelevant to the proposed measurement of this objective.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that ongoing submission was enabled throughout the reporting period. Attestation measurement and auditing will need to be based on the expectation of

this being a human judgment call. The main objective is to send applicable immunizations by electronic means to the appropriate immunization registries, and enablement / disablement would seem to be a distraction here rather than a focus on the actual transmission of the immunization data.

Public Health Exclusions

We note that a public health agency can change standards at any point, which might mean that an EP or EH who was submitting successfully is suddenly unable to continue submitting for the rest of the reporting period. This should be accounted for.

Topic/Section: Reportable Labs (FR 77 p. 13821)

Inappropriate Requirement

Reporting lab results is fundamentally a laboratory information system (LIS) feature, not an EHR feature, so this requirement is not appropriate for a program on meaningful use of EHRs. Rather, it should be incorporated into a regulatory program for lab systems.

Normally, an LIS determines whether a lab result is reportable to public health and will send, in addition to the message to the EHR, an appropriate message to the public health agency. For purposes of satisfying the certification requirements for an EHR, either the LIS has to become an EHR module, or the message to public health has to be routed through the EHR. Neither is a necessary nor desirable configuration from the perspective of value to the patient or provider workflow. We therefore strongly suggest removal of this objective from the EHR Incentive Program and ask CMS to work through CLIA to ensure that laboratories perform this reporting, whether part of a hospital environment or stand-alone/independent.

Transport Mechanisms

We are concerned that there are no transport methods for certification and that the transport methods required by a public health agency might not be supported by CEHRT. EHs should be excluded in these cases.

Exclusions

We also agree that if the EH operates in a jurisdiction where there is no public health agency capable of receiving data in the format generated by the provider's CEHRT that these EHs should be excluded. However, we note that it might take three to six months to implement a connection to a public health agency. Therefore, the exclusion should indicate that the EH is excluded if the registry is not capable of acceptance in the correct format as of six months prior to the reporting period. If a registry becomes capable of accepting in the correct format the day before the reporting period, all affected EHs will not be able to instantaneously connect, but they would no longer be excluded in the current wording.

Differing Definitions of Reportable Labs

Each agency varies in how they define which labs are considered reportable, and this can impose EHR feature requirements. We suggest that if an agency's definitions of reportability as of six months prior to the reporting period are not accommodated by CEHRT, the EH also be excluded from this measure.

Alternately, we suggest that the measure remain menu.

Measurement

We think that attestation is appropriate as a measurement for this objective, and we agree that letters from public health agencies would be reasonable. We note that ONC has proposed a certification criterion suggesting that CEHRT "would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed." Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

1. It is not clear what "enabling" of "ongoing submission" might look like, and since it might vary, we are not sure how CEHRT would audit that enablement, especially since transport mechanisms will vary. Some agencies might accept real-time submissions while others might accept batch files of information on a periodic basis such as weekly, monthly or quarterly. These permutations will be better addressed by attestations from the EH and the registry rather than by automated tracking through the EHR.
2. Ongoing submission might be temporarily disabled while performing system maintenance (e.g., if an agency is upgrading to new interface standard). We are concerned that this is not accounted for in the requirement for ongoing submission.

In summary, human judgment will be necessary to establish that ongoing submission was enabled throughout the reporting period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Public Health Exclusions

We note that a public health agency can change standards at any point, which might mean that an EH who was submitting successfully is suddenly unable to continue submitting for the rest of the reporting period. This should be accounted for.

Topic/Section: Syndromic Surveillance (FR 77 p. 13819, 13821)

Menu for EPs

We agree that this objective is not ready to be a core objective for EPs due to the lack of an implementation guide and low adoption currently. Even as a menu objective, we have serious concerns that EPs will be required to choose one measure among (1) syndromic surveillance (2) submitting to cancer registries, or (3) submitting to specialty registries,

all of which seem significantly challenging with outside dependencies beyond an EP's control.

Transport Mechanisms

We are concerned that there are no transport methods for certification and that the transport methods required by a public health agency might not be supported by CEHRT. EPs and EHs should be excluded in these cases.

Exclusions

We agree that if the EP or EH operates in a jurisdiction where there is no agency or no agency capable of receiving data in the format generated by the provider's CEHRT that these EPs and EHs should be excluded. However, we note that it might take six to nine months to implement a connection to a public health agency. Therefore, the exclusion should indicate that the EP or EH is excluded if the agency is not capable of acceptance in the correct format as of six months prior to the reporting period. If an agency becomes capable of accepting in the correct format the day before the reporting period, all affected EPs and EHs will not be able to instantaneously connect, but they would no longer be excluded in the current wording.

Measurement

We think that attestation is appropriate as a measurement for this objective, and we agree that letters from public health agencies would be reasonable. We note that ONC has proposed a certification criterion suggesting that CEHRT "would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed." Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

1. It is not clear what "enabling" of "ongoing submission" might look like, and since it might vary, we are not sure how CEHRT would audit that enablement, especially since transport mechanisms will vary. Some agencies might accept real-time submissions while others might accept batch files of information on a periodic basis such as weekly, monthly or quarterly. These permutations will be better addressed by attestations from the EP and EH and the agency rather than by automated tracking the EHR.
2. Submission might be facility-specific rather than provider-specific. For example, if a provider practices in two clinics, one that submits to the agency and one that does not, how will CEHRT report if the provider has this capability enabled?
3. Ongoing submission might be temporarily disabled while performing system maintenance (e.g., if an agency is upgrading to new interface standard). We are concerned that this is not accounted for in the requirement for ongoing submission.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that ongoing submission was enabled throughout the reporting

period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Public Health Exclusions

We note that a public health agency can change standards at any point, which might mean that an EP or EH who was submitting successfully is suddenly unable to continue submitting for the rest of the reporting period. This should be accounted for.

Topic/Section: Protect Health Information (FR 77 p. 13716, 13819, 13821)

Similarities to MU1

We support the general consistency with the MU1 approach, and the additional focused on data at rest, and suggest that this objective and measure remain unchanged in the Final Rule from what was in the Proposed Rule.

Suggested Education

In MU1, our experience has been that EPs and EHs have some confusion about their responsibility relative to use of the specific certified capabilities of CEHRT that are linked to this objective, since the CEHRT features are not directly related to their obligation to complete a risk assessment. Clarification or education on this point will be hugely helpful.

With the change to the objective from MU1 and the addition of the need to address encryption, we suggest that additional education on what it means to address encryption would be beneficial.

Measurement

We agree that EPs and EHs are most equipped to attest to this measure and that it cannot be reported by CEHRT.

Topic/Section: Advance Directives (FR 77 p. 13731, 13821)

Focus on EHs

We agree with not extending this requirement to EPs based on challenges with EPs taking on this documentation work.

Menu

We support this requirement remaining menu.

Measurement

We do not see significant challenges with measurement of this objective.

Topic/Section: Imaging Results (FR 77 p. 13819, 13821)

“Accessible Through”

We support the CMS proposal to not require images to be stored within the EHR, but to just be accessible through the EHR, such as by a link. It is not common to store such images within an EHR. More customary is that the EHR would have a link that activates a separate image viewing application for viewing; the viewer is not part of the EHR, but it can be made convenient in the EHR.

Limitations of Non-EHR Systems

We are concerned that this objective has dependencies on functionality that is not required to be certified. For example, an EP or EH might have a certified EHR that supports single sign-on capabilities. However, if they have a PACS system that does not support that single sign-on, they will not be able to access images from their EHR via a link without signing on again. This scenario is not a limitation of their EHR and should not prohibit them from being able to achieve meaningful use.

Language

Some of the language used in this objective is confusing, particularly the word "scan," which frequently applies to actions and concepts other than certain types of images. We suggest that the words "scan" and "test" be removed for clarity, and that the denominator and numerator be simplified:

- Denominator: Number of tests (whose result is one or more images) ordered by the EP or an authorized provider on behalf of the EH or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period
- Numerator: The number of tests ordered in the denominator whose result (including images and narrative text/reports) is accessible through certified EHR technology

We are also confused by the exclusion for providers who do not perform diagnostic interpretation of scans. Is the accessibility to images intended to be for specialists (such as a radiologist reading an image and providing a diagnosis) or for generalists (such as a family practitioner placing an imaging order)? This exclusion needs clarification and might appropriately be changed to "providers who do not order scans or images intended for diagnostic interpretation."

We also believe that the definition of images should be clarified and made explicit.

Measurement

We are concerned that it is not always known whether a result will produce an image. In some areas, such as radiology, such output might be very predictable, but in other areas, such as anatomic pathology, an order might or might not produce an image as a result. The denominator might not be more difficult to measure for this reason because of the need to know whether one or more image was generated. Here again, the definition of image for this measure could use clarification.

As proposed, too, the numerator measures results, and the denominator measures "scans and tests" which seems like an error; we propose a consistent approach above to the numerator and denominator language.

Image Exchange

We agree with the CMS assessment that introducing image exchange for MU2 as a menu item would likely discourage many EPs from pursuing this objective. If included, we suggest that image exchange be a separate menu objective for those providers who prioritize such a capability. We foresee significant measurement problems with establishing how frequently particular scans need to be shared, as well as with assigning responsibility for sharing them to a particular EP. It might be more appropriate to measure scans accessed by a provider (rather than scans shared), as scans accessed would be more likely to eliminate duplicative orders for additional imaging.

For image exchange, we are concerned that the Direct point-to-point standards might not be as successful as they can prove to be with the exchange of clinical documents due to the size of image files.

Topic/Section: Family History (FR 77 p. 13727, 13819, 13821)

Limitation to and Definition of First-Degree Relatives

We do not understand why this requirement is limited to first-degree relatives. We suggest that any documented family history should count toward satisfying this objective, because a patient's grandparents or other distant relatives might be more medically pertinent. In addition, rather than using a genetics-based definition of first-degree relatives, if CMS chooses to retain this concept, it should simply indicate parent, child, sibling or other relative.

We appreciate that CMS is not calling for any electronic exchange of information related to family history.

Required Information

We support inclusion of a family history certification criterion, but we believe that the proposed criterion should be modified to allow for the use of unstructured data to record family health history, as such a format is the most widely used method of data collection. As such, we oppose the requirement in the meaningful use objective for structured data recording. It is essential that CMS clarify what is expected for this requirement.

New Requirement

We suggest that this new requirement be phased in with a low threshold to allow those providers who've previously captured family history but not in a structured format to re-document the information.

Topic/Section: Cancer Reporting (FR 77 p. 13819)

Menu for EPs

We agree with CMS that this objective is not ready to be a core objective. Even as a menu objective, we have serious concerns that EPs will be required to choose one of (1)

syndromic surveillance (2) submitting to cancer registries, or (3) submitting to specialty registries, all of which seem significantly challenging with outside dependencies beyond an EP's control.

New Objective

We have many questions about this objective since it is new. Oncologists we have talked with indicate that previously most submission has come from hospitals. Cancer outpatients, though, have many physicians, and it is unclear who is responsible for submitting to the registry.

Additionally, we are not sure that the standard chosen, which requires that very specific oncology information be reported, will deliver the general information about cancer diagnoses that many in the industry have been alluding to.

Exclusions

We agree that if the EP operates in a jurisdiction where there is no agency or no agency capable of receiving data in the format generated by the provider's CEHRT, these EPs should be excluded. We note, however, that it might take many months to implement a connection to a cancer registry. Therefore, the exclusion should indicate that the EP or EH is excluded if the agency is not capable of acceptance in the correct format as of six months prior to the reporting period. If an agency becomes capable of accepting in the correct format the day before the reporting period, EPs will not be able to all instantaneously connect, but they would no longer be excluded in the current wording.

Measurement

Attestation is appropriate as a measurement for this objective, and we agree that letters from cancer registries would be reasonable. We note that ONC has proposed a certification criterion suggesting that CEHRT "would need to be able to record the date and time and enable a user to create a report that indicates when each capability was enabled, and disabled, and/or executed." Our comments to ONC will include details on why we think the complexity of this proposal has been drastically underestimated. For purposes of determining measurement of this objective, we include the following comments here:

1. It is not clear what "enabling" of "ongoing submission" might look like, and since it might vary, we are not sure how CEHRT would audit that enablement, especially since transport mechanisms will vary. Some agencies might accept real time submissions while others might accept batch files of information on a periodic basis such as weekly, monthly or quarterly. These permutations will be better addressed by attestations from the EP and the agency rather than by automated tracking the EHR.
2. Submission might be facility-specific rather than provider-specific. For example, if a provider practices in two clinics, one that submits to the agency and one that does not, how will CEHRT report if the provider has this capability enabled?

3. Ongoing submission might be temporarily disabled while performing system maintenance (e.g., if an agency is upgrading to new interface standard). We are concerned that this is not accounted for in the requirement for ongoing submission.

In summary, we suggest that while CEHRT can provide insight, human judgment will be necessary to establish that ongoing submission was enabled throughout the reporting period. Attestation measurement and auditing will need to be based on the expectation of this being a human judgment call.

Cancer Reporting Exclusions

We note that a cancer registry can change standards at any point, which might mean that an EP who was submitting successfully was suddenly unable to continue submitting for the rest of the reporting period. This should be accounted for.

Topic/Section: Specialty Reporting (FR 77 p. 13819)

Support for Specialists

Conceptually, we like the idea of including objectives that are more flexible and appropriate to particular specialist meaningful users. However, we have serious concerns about the actual level of support that will be available for this menu objective, for the following reasons.

Challenges

No standards

There are no standards proposed by ONC for this objective, and yet on p. 13728 it states that EPs operating in a jurisdiction where no registry is capable of receiving electronic case information in the specific standards required for MU2 are excluded. This seems to be an error, as it would exclude all EPs.

We are not certain that there is an applicable standard, given the wide variance of needs between specialties and registries.

Development

Submission requirements vary dramatically, and as EHR developers our experience with working on registry submissions is that each type of submission could require significant development effort, perhaps equivalent to the effort an EHR developer would place on a specialty module.

Although there are hundreds of possible recipients (greater than a dozen per specialty), an EP might find that his CEHRT only supports submission to one or two registries, if that, given the amount of individual programming effort per registry. This might mean that no registries relevant to the EP are supported.

Fees

Some registries charge EHR vendors fees to submit, and sometimes substantial ones. Such fees (along with the development required) are a limiting factor on the registries that can be supported by one EHR.

Additional licensing

EPs might have to purchase additional software, either from their CEHRT vendor or from other vendors, in order to capture all of the required data elements and submit in the format required by a registry. Many of these additional modules work using abstracted data. Encouraging abstraction workflows, however, does not seem like meaningful use of an EHR.

Due to these challenges, we estimate that this menu objective will not be achievable by many EPs. We suggest that the public health menu set needs to be constructed for EPs assuming that it will not be widely available and many EPs will not have this objective as an option. Nonetheless, for the specialists who do have this option, it will provide nice flexibility.

Measurement

We think that attestation is appropriate as a measurement for this objective, and we agree that letters from public health agencies would be reasonable. As with other public health objectives, we do not think CEHRT will supplant human judgment in determining whether such a capability is enabled throughout the reporting period.

Specialty Reporting Exclusions

We note that public health agencies can change standards at any point, which might mean that an EP who was submitting successfully was suddenly unable to continue submitting for the rest of the reporting period. This should be accounted for.

Not proposed – Hospital Labs to EPs

We strongly agree that this potential objective and measure should not be proposed. Reporting lab results is fundamentally a LIS feature, not an EHR feature, and this requirement is not appropriate for a program on meaningful use of EHRs. It should not be an objective of meaningful use of EHRs because it is unrelated to use of an EHR. We agree this should not be proposed.

Although a hospital-based LIS is clearly part of an EH/CAH health IT environment, the LIS is not *part* of an EHR, but rather a feeding system and complement to the EHR. Many hospital-based laboratories service both the inpatient and ambulatory laboratory test requests from the provider community. In that flow, it is not appropriate for ambulatory test results to be communicated to the requesting provider through the EHR of the hospital that the laboratory is part of. This objective, if it were adopted, would require the implementation and configuration of data flows that are not helpful and potentially

requires ambulatory test data to be stored in the hospital's EHR where the patient has not been seen. This requirement, if adopted, would impose unnecessary responsibilities onto the EH/CAH EHR.

We therefore suggest that CMS works through CLIA to ensure that laboratories supporting EPs provide the results using the standards proposed by ONC for §495.6(j)(7) and §495.6(l)(6).

We agree with the reasoning that such a requirement would disadvantage hospital labs as compared to their competitors (independent labs). Such requirements should be applied to all labs together through other mechanisms such as CLIA or NwHIN.

If adopted, the requirement would also unintentionally discourage labs from accepting electronic lab orders.

Not proposed – Patient Preferences

We agree that no such measure should be included, as we support limiting the overall number of objectives for EPs and EHs to report on.

Not proposed – Care Plans

We agree that no such measure should be included, as we support limiting the overall number of objectives for EPs and EHs to report on.

Not proposed – Care Team

We agree that no such measure should be included, as we support limiting the overall number of objectives for EPs and EHs to report on.

Not proposed – Electronic Notes

We agree that no such measure should be included, as we support limiting the overall number of objectives for EPs and EHs to report on.

Topic/Section: Meaningful EHR User (FR 77 p. 13702)

CMS proposes to include clinical quality measure reporting as part of the definition of "meaningful EHR user" instead of as a separate meaningful use objective under 42 CFR 495.6. This change is explained in section II.A.3.d. in the context of the proposed MU2 criteria for meaningful use.

EHR Association Comment:

We agree with this proposal.

Topic/Section: Certified EHR Technology (FR 77 p. 13743)

CMS proposes that EPs, eligible hospitals and CAHs must only submit clinical quality measures that their Certified EHR Technology is explicitly certified to calculate according to 45 CFR 170.314(c)(2) in ONC's proposed rule and to meet the meaningful use requirement for reporting clinical quality measures.

EHR Association Comment:

We agree with this requirement, and we feel that it aligns with all stakeholders' efforts to ensure the accuracy of the measure calculations.

Topic/Section: Criteria for Selecting Clinical Quality Measures (FR 77 p. 13700, 13743, etc.)

For EPs, CMS proposes a set of clinical quality measures beginning in 2014 that align with existing quality programs, such as those measures used for the Physician Quality Reporting System (PQRS), CMS Shared Savings Program and the National Council for Quality Assurance (NCOA) for medical home accreditation, as well as those proposed under the Children's Health Insurance Program Reauthorization Act, (CHIPRA) and under ACA Section 2701.

For eligible hospitals and CAHs, the set of CQMs CMS proposes beginning in 2014 would align with the Hospital Inpatient Quality Reporting (HIQR) and the Joint Commission's hospital quality measures.

EHR Association Comment:

We applaud CMS for its commitment to aligning measures among reporting programs for both the EP and EH/CAH program. We urge CMS to also seek alignment in other areas of quality measurement, such as the technical specifications and data reporting methods. We also call attention to the duplicate effort required of providers to collect data for both manually abstracted measures and eMeasures, and we ask CMS to consider ways to continue to reduce this burden.

Topic/Section: Measure Specifications and Management (FR 77 p. 13744)

CMS does not intend to use notice and comment rule-making as a means to update or modify clinical quality measure specifications. It states that a clinical quality measure that has completed the consensus process has a measure steward who has accepted responsibility for maintaining and updating the measure. In general, it is the role of the measure steward to make changes to a measure in terms of the initial patient population, numerator, denominator, and potential exclusions. CMS states that it recognizes that it may be necessary to update measure specifications after they have been published to ensure their continued relevance, accuracy, and validity. Measure specifications updates may include administrative changes, such as adding the NOF endorsement number to a

measure, correcting faulty logic, adding or deleting codes as well as providing additional implementation guidance for a measure. These changes would be described in full through supplemental updates to the electronic specifications for EHR submission provided by CMS.

The complete measure specifications would be posted on the CMS website (https://www.cms.gov/QualityMeasures/03_ElectronicSpecifications.asp) at or around the time of the final rule.

Measure specification updates should be released at least six months prior to the effective date (p.13745).

EHR Association Comments Regarding the Lack of Specifications for the 2014 Measures

We are enormously concerned about the CMS stated intent not to use notice and comment rule-making related to the clinical quality measure specifications.

We feel strongly that since most of the proposed measures do not have publicly available final electronic specifications, it is unreasonable to expect an adequate evaluation and related comments on whether they are indeed feasible and can be efficiently implemented for data collection and submission. Furthermore, the proposed release date for the CQM specifications does not provide enough lead time for review, development and certification efforts by EHR vendors along with implementation by providers. The expected publication date will allow only slightly more than 12 months during which vendors must analyze the specifications; update software for user interfaces, data models, and workflow; and certify their EHRs. Providers must implement that upgraded software, and then they must train caregivers on the requisite data collection and any associated workflow changes in order to be ready to begin data collection by October 1, 2013. This timeframe is unrealistic, and there is risk of unintended consequences through the need to truncate normal testing, validation and training processes. Additionally, this could negatively impact the vendors' ability to appropriately focus on usability and conduct User Centered Design.

We urge CMS to give preference to those measures that have final existing HQMF criteria and specifications, that are both MAP and NQF endorsed, and that only require data elements that would be expected to be found in most EHRs. We again want to reiterate that eMeasures should be put through a rigorous test process prior to including them in meaningful use.

As defined in the HIMSS eMeasures recommendations sent to HHSS in January 2012, both controlled testing and field testing of the eMeasure specification should be part of the measure development and endorsement process. Controlled testing of the eMeasure specification should ensure the feasibility, validity and accuracy of each eMeasure when implemented in an EHR. The eMeasure testing process should also include a testing site

with a set of sample data, testing examples and an Implementation Guide that can be used by vendors during their implementation and testing.

Field testing of the eMeasure specification should be done in order to validate at least the following:

- The eMeasures specifications are accurate, with the correct clinical category defined and mapped to the correct vocabulary standards (taxonomy) and codes, along with the correct attributes and state(s).
- The eMeasures are tested for validity and reliability against the measure's intent.
- Required data elements can be efficiently and accurately gathered in the healthcare provider workflow, if at all possible using data elements that are already collected as a byproduct of the care process and stored in the EHR.
- CQM reports based on eMeasures accurately reflect the care given by the applicable healthcare provider(s).

Because of all of the above considerations, the EHR Association strongly urges CMS to consider finalizing far fewer measures for MU2 than have been proposed, and to be more selective regarding the measures chosen based on the criteria we have defined.

EHR Association Comments Regarding the Management of Specifications and Updates

We appreciate the improved management of specifications and updates, but we still note that depending on the extent of updates, six months may not be sufficient time to implement changes. Although this timeframe has worked well for manually abstracted measures that have limited impact on the information technology used to support patient care, it is an insufficient time to deploy and adequately test upgrades that may affect clinician workflows and, hence, patient safety.

The measure specification release process must be improved so we are assured of having accurate specifications for certification. This change could be accomplished by a public comment period, more lead time for analysis of the measure specifications and appropriate timing for release of measure specifications. We also ask for additional clarity regarding how newly released measure specifications interact with the certification process. For example, how do revised specifications affect our already certified EHRs? We think it is important that certification retain meaning throughout the certification period, and that updating previously certified software to new measure specifications be optional.

We recommend that the ongoing measure specification release process follow a regular schedule that incorporates a public comment period in order to allow time for analysis of the measure specifications and implementation guides. This approach will ensure that all vendors have accurate specifications for implementation, certification and deployment to

our customers, and will provide greater confidence in the measure calculations, analyses and outcomes.

Topic/Section: Clinical Quality Measures Proposed for Eligible Professionals for CY 2014 (FR 77 p. 13745)

CMS is seeking public comment on two proposed options for selection of the 12 required quality measures for eligible providers.

Option 1a: EPs can report on 12 CQMS selected from Table 8 must select at least one CQM from each of the five domains of care listed in the National Quality Strategy: Patient & Family Engagement; Patient Safety; Care Coordination; Efficient Use of Healthcare Resources; Population and Public Health; and Clinical Processes and Effectiveness.

Option 1b: EPs can report on 11 core CQMs (found in Table 6 on p. 181 of the proposed rule) and select one menu CQM from Table 8.

EHR Association Comment:

We believe that option 1b provides several advantages:

- As providers collectively report on the same measures, there will be more population-level data across the same measures for better comparative data.
- Finalizing a core set of 11 CQMs allows vendors and providers to prioritize their efforts on integrating a smaller set of measures effectively into physician workflow while remaining focused on usability.

Topic/Section: Clinical Quality Measures Proposed for Eligible Professionals for CY 2014 (FR 77 p. 13746)

EPs participating in the Physician Quality Reporting System (PQRS) program at CMS can report on the PQRS-required measure set using a certified EHR Technology (CEHRT) that is also PQRS qualified and receive both Meaningful Use incentives and PQRS reimbursement

EHR Association Comment:

The EHR Association endorses a consolidated approach to reporting across multiple programs, specifically the PQRS and ACO programs, but we are concerned about the additional burden on EHR vendors that stems from dual certification/qualification programs. We also point out that the programs have mismatched application timelines for providers participating in both programs. We encourage CMS and ONC to work together on some form of joint product certification or deemed status that would remove this additional burden, which is a sizable one.

Topic/Section: Clinical Quality Measures Proposed for Eligible Professionals for CY 2014 (FR 77 p. 13746)

CMS is proposing clinical quality measures in Table 8 that would apply to all EPs for the EHR reporting periods in CYs 2014 and 2015 (and potentially subsequent years), with the same number of measures to be reported on, regardless of whether an EP is in MU1 or MU2.

EHR Association Comment:

This proposal, and a similar one for EH/CAH providers, imposes a significantly greater burden on providers seeking to reach MU1 meaningful use in CY/FY 2014 than those who have done so in earlier years. Public testimony from providers has consistently indicated that more than half of the effort involved in reaching MU1 is associated with clinical quality measurement. CMS is proposing to double the scope for EPs and a 60% increase for the much more complex EH/CAH measures, with a very narrow implementation window, as discussed above.

We recommend retaining the existing MU1 measure reporting requirements and measures but implementing them using the 2014 edition of the specifications where applicable.

Topic/Section: Proposed Reporting Methods for Medicare EPs in CY 2013 (FR p. 13757)

In the CY 2012 Medicare Physician Fee Schedule final rule, CMS established a pilot program for Medicare EPs for CY 2012 that is intended to test and demonstrate its capacity to accept electronic reporting of MU1 clinical quality measure data (76 FR 73422 through 73425). The title of this pilot program is the Physician Quality Reporting System – Medicare EHR Incentive Pilot, and it capitalizes on existing quality measures reporting infrastructure. The EHR Incentive Program Registration and Attestation System is located at <https://ehrincentives.cms.gov/hitech/login.action>.

EHR Association Comment:

The Electronic Reporting Pilot program is working with QRDA and individual patient data, and we believe that it should be working with aggregate data. One challenge with the current approach is the lag time between when the standards are finalized and when they become available. QRDA category III work is currently in process, as well as a QRDA category I refresh. For reporting, we are very constrained by this lack of appropriate standards. The EHR Association recommends an electronic reporting pilot using aggregate data in 2013.

Topic/Section: Proposed Reporting Methods for Medicaid EPs in CY 2013 and CY 2014 (p. 13757)

For Medicaid EPs, States are, and will continue in MU2 to be, responsible for determining whether and how electronic reporting would occur, or whether they wish to allow reporting through attestation. If a State does require such electronic reporting, the State is responsible for sharing the details on the process with its provider community. We anticipate that whatever means States have deployed for capturing MU1 clinical quality measures electronically would be similar for reporting in CY 2013. However, we note that subject to prior approval, this is within the States' purview. Beginning in CY 2014, the States will establish the method and requirements, subject to CMS' prior approval, for electronic reporting.

EHR Association Comment:

We urge a common national data submission standard in order to limit the burden on providers and vendors operating in multiple states. We recommend that the states align with the same electronic reporting requirements as CMS, including the transport method.

Topic/Section: Group Reporting Option for Medicare and Medicaid Eligible Professionals Beginning with CY 2014 (FR77 p 13758)

Beginning with CY 2014, CMS is proposing three group reporting options to allow eligible professionals within a single group practice to report clinical quality measure data on a group level. All three methods would be available for Medicare EPs, while only the first one would be possible for Medicaid EPs, at states' discretion.

EHR Association Comment:

We applaud CMS for this change, which will be of value to many of our customers, and we recommend its inclusion as one reporting option.

One concern that we have is that we have not seen separate group-level measures or the method to assign the attribution to a group from an individual provider, and we are concerned regarding the associated possible burden on vendors to accurately reflect the group assignment. We are also concerned about the requirement that all physicians must be past their first year of meaningful use to report as a group. In large practices, it is likely that new physicians are continually joining the practice. How would this process be managed by both the provider and the EHR software? The intent of group reporting should be to simplify this process, but it is actually more complicated as proposed. We believe that if everyone in 2014 is reporting on the same measures, this requirement (to be past the first year of participation) is unnecessary.

CMS is proposing to change the reporting requirement beginning with FY 2014 to require eligible hospitals and CAHs to report 24 clinical quality measures from a menu of 49 clinical quality measures, including at least 1 clinical quality measure from each of the 6 domains. The 49 clinical quality measures would include the current set of 15 clinical quality measures that were finalized for FYs 2011 and 2012 in the MU1 final rule as well as additional pediatric measures, an obstetric measure, and cardiac measures.

Aside from the previous threshold discussion, CMS is proposing clinical quality measures in Table 9 that would apply for all eligible hospitals and CAHs beginning with FY 2014, regardless of whether an eligible hospital or CAH is in MU1 or MU2.

EHR Association Comment:

In our previous comments in this document, the EHR Association strongly recommends that only measures with existing eSpecifications, that are both NOF and MAP endorsed, and that require data elements that would be found in most existing EHRs be adopted. We recognize that current eSpecifications will be updated at approximately the same time as the release of the Final Rule, and we have commented on our concerns regarding this. We also strongly recommend that prior to finalization, all adopted measures be subjected to a rigorous harmonization process to ensure they all use common concepts, taxonomies and value sets.

Because of all of the above considerations, CMS should consider finalizing far fewer measures for MU2, and we recommend that CMS be more selective regarding the measures chosen according to the criteria that we have outlined here.

In addition, regarding the EH/CAH providers who are in MU1 in FY 2014, we reiterate our comments made in the section regarding the Clinical Quality Measures proposed for EPs for CY 2014, as they also apply to the EH/CAH providers that are in MU1. This proposal, and a similar one for EH/CAH providers, imposes a significantly greater burden on providers seeking to reach MU1 meaningful use in CY/FY 2014 than those who have done so in earlier years because CMS is proposing to double the scope for EPs and a 60% increase for the much more complex EH/CAH measures, with a narrow implementation window, as discussed above. Public testimony from providers has consistently indicated that more than half of the effort involved in reaching MU1 is associated with clinical quality measurement.

For MU1 EH/CAHs, we recommend retaining the existing MU1 measure reporting requirements but implementing them using the 2014 edition versions of the specifications.

Topic/Section: Proposed threshold for EH and CAH (FR77 p. 13759)

CMS' experience from MU1 in implementing the current set of 15 clinical quality measures in specialty and low volume eligible hospitals has illuminated several challenges. For example, children's hospitals rarely see patients 18 years or older. CMS is considering whether a case number threshold would be appropriate, given the apparent burden on hospitals that very seldom have the types of cases addressed by certain measures. Hospitals that do not have enough cases to exceed the threshold would be exempt from reporting certain clinical quality measures

EHR Association Comment:

We support the concept of case number thresholds, and we also remind CMS that some measures require additional implementation on the part of the provider. Therefore, in order to reduce the burden on providers, we recommend that any affected measures should be removed from the measure set that the provider has to implement and report against.

Topic/Section: Clinical Quality Measures Reporting Proposed for Eligible Hospitals and CAHs for FY 2014 (FR77 p. 13764)

For MU2 EHs and CAHs reporting, CMS is proposing to use an aggregate XML- based format specified by CMS similar to the IQR/Electronic Reporting Pilot. EHs and CAHs have two proposed options for reporting:

1. Submit the selected 24 measures in aggregate XML-based format through a CMS web portal. The measure data is output from Certified EHR Technology (CEHRT.)
2. Submit the selected 24 CQMs through the CMS EHR Incentive Program Electronic Reporting Pilot Eligible Hospitals.

CMS is seeking comments on four options for data submission characteristics:

- All patients from the Medicare population only
- All patients regardless of payer
- Sample of patients-Medicare population only
- Sample of patients from all payers

EHR Association Comment:

For the first question, we strongly favor aggregate reporting and thus support option two, "Submit the selected 24 CQMs through the CMS EHR Incentive Program Electronic Reporting Pilot Eligible Hospitals".

In regard to the four options for data submission characteristics in the second question, we support the option of all patients from all payers, in order to be consistent with the current method of attribution and to simplify the reporting aspect for both providers and vendors.

Topic/Section: Electronic Reporting of Clinical Quality Measures for Medicaid Eligible Hospitals (FR77 p. 13764)

Hospitals participating in the Medicaid EHR incentive program will report on the same set of 24 measures; however, each state has the authority to establish its own system of electronic reporting. Each state is responsible for informing the EHs and CAHs about the selected system, which CMS anticipates will be similar to the mechanisms each state selected for MU1.

EHR Association Comment:

See comments under the Electronic Reporting of CQMs for Medicaid EPs. We urge a common national data submission standard in order to limit the burden on providers and vendors operating in multiple states. We recommend that the states align with the same electronic reporting requirements as CMS, including the transport method.