September 14, 2021

Micky Tripathi, Ph.D., M.P.P.
National Coordinator for Health Information Technology
Department of Health and Human Services
330 C. Street, 7th Floor, Office 7009A, S.W.
Washington, DC 20201

Dear Dr. Tripathi,

On behalf of the nearly 30 member companies of the Electronic Health Record (EHR) Association, we are pleased to offer our comments to the Office of the National Coordinator for Health IT (ONC) and the Urban Institute on the Electronic Health Record Reporting Program. We appreciate this opportunity to provide input on the ONC's efforts to address information gaps in the health IT marketplace and provide insights on how certified health IT is being used.

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

The EHR Reporting Program duplicates some of the work currently being done in Real World Testing, which measures that a certified system continually demonstrates compliance with certification requirements. We recommend streamlining these two programs to optimize their qualitative and quantitative value.

We share your goal of creating high-value measures in which benefits outweigh the burden of collection. In many cases, we question the usefulness of the data requested in comparison to the overwhelming level of effort required to obtain it. For example, some metrics requested involve data EHR developers do not own and would require agreements with 3rd party application vendors or clients, while others are inaccessible from client-server installations. It is our position that the EHR Reporting Program is requiring too many measures from the start and should be scaled down. To ensure success, we recommend prioritizing the most impactful measures first and expanding the program over time.

Some metrics of the EHR Reporting Program focus more on quantitative usage data rather than how an EHR is qualitatively functioning, which we believe is the intended purpose of the program. Because this data is being used for comparative purposes, it will reflect poorly on an EHR that may have customers/patients using their product who have simply not utilized these features at the same level as another EHR. Utilization varies for many reasons outside of the control of the EHR, including geographic region, age of patient population, care setting, etc. We recommend prioritizing qualitative metrics, then evaluating the value of the data received before ramping up the program. We believe this will offer a better evaluation of how the EHR is functioning.

Our detailed comments follow. Thank you for considering our feedback.

Sincerely,

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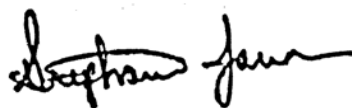
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Frequency of Reporting

Should developers report data on a quarterly, biannual, or annual basis?

The EHR Association recommends that all measures have an annual reporting frequency, but developers should retain the flexibility to pull data on their own prescribed frequency.

Level of Reporting

Which level of reporting is most appropriate (e.g., client, product, or developer level)?

The level of reporting should be guided by each developer's reporting capabilities. Variabilities include implementation (e.g., cloud versus client-server, etc.) and ownership of the data (App developer versus EHR developer). We recommend keeping the level of reporting flexible and allowing EHR developers to choose which level is most feasible for them.

Data Granularity and Distribution of Results

Are proposed subgroups appropriate (e.g., demographic characteristics, provider setting)?

The proposed subgroups are too onerous for this first set of measures. These stratifications add significant complexity. The EHR Association recommends either removing stratifications per measure, or limiting the number of measures. The program needs an achievable starting point; stratifications can be a future goal.

What are the implications of including measures that require data from developers' customers (e.g., reporting by characteristics)?

Overall, we feel strongly that data belonging to a consumer of CEHRT should be reported by the consumer. In many cases, it may not be possible for the developer to have full access or knowledge of the data in their customers' systems. This challenge is further complicated when the customer of an EHR developer uses an integrated health IT product across care settings. For example, an EHR developer is unlikely to know how to attribute an API call to the inpatient care setting versus the ambulatory care setting if the health system uses one system across those care settings.

Appropriateness of the Look-Back Period

Should the look-back period for active patients be by the past 12 months (or calendar year) or some longer timeframe (e.g., past 18 or 24 months) that would capture those who use care less frequently?

The reporting period should match the frequency of reporting. Therefore, we recommend a calendar year (CY) look-back period across all measures, which also aligns with the approach of quality reporting programs.

Clarity of Definitions and Measurement

We are particularly interested in feedback on measuring standards usage and on adding more precision to definitions or concepts that might be ambiguous.

We agree that clear and specific definitions are crucial. We are unclear, however, on the meaning of "measuring standards usage." Please define.

Benefit of Measures Relative to the Burden of Collecting the Data

Are developers already collecting this kind of data for any of the mentioned subgroups and estimates?

No, we are not.

If the measure is implemented as proposed, what is the estimated level of effort required for developers to report on the measure at an aggregated level?

Overall, we find the program to be onerous and recommend that it be scaled back. The level of effort required of developers will vary by measure (whether data is currently being collected for quality programs, whether the infrastructure to collect the data exists, etc.) and type of system (e.g., cloud-based or not). This program will require a learning curve for all involved; its success will depend on a measured and practical implementation.

How to address potential interpretation challenges

Some measures might not be completely within a developer's control and can be influenced by local market conditions or customer and provider characteristics. Volume-based measures can also be difficult to interpret, because more is not necessarily better. We considered these limitations while developing our measures, but we welcome additional feedback in this area.

We agree that some of the measures are outside a developer's control. For example, metrics that cannot be provided by the CEHRT, but rather the App developers. We have identified these in comments.

Potential Burden on Users of CEHRT

Is there any potential burden on users of certified health IT? Would reporting unduly disadvantage small or start-up developers?

In response to the second question, this program is burdensome on all developers, not simply those that are small or start-up. Members of the EHR Association represent various-sized developers with previous certification experience and we collectively agree that the burden will be felt by all. However, the metrics that focus on counts rather than percentages may unfairly disadvantage smaller, specialty EHRs which simply do not have the adoption of features that may be seen in larger, general EHRs.

Itis also important to recognize that not all clinicians or EHRs work the same, and these differences are not indicative of variation in quality. Clinical specialties, provider workflows, and the populations we serve will impact the utilization of certain features. For some practices, using a feature may be more burdensome on them than it would be for others. We feel it would be inappropriate to ignore these variables and identify this as a characteristic of the EHR.

We agree with the importance of some of the proposed measures, but find the extensive nature of the reporting requirements involving far more substantial and complex development work. As we continue to evolve new measure standards and update our systems, these reporting requirements would impact prioritization of other requests from our users. We believe it would be best to start a new program by prioritizing the most important measures, defining them clearly and accurately, and then expanding the number of measures over time to add other priority measures. It is not feasible for developers to implement all the proposed measures across their customer base given the multitude of other regulatory obligations that developers of CEHRT must meet.

Value to Interoperability

What is the value of the measure to provide insights on interoperability, including to multiple stakeholders?

Clinovations is already working on a similar interoperability project with the ONC and there is also a requirement to create measures related to interoperability for the Real World Testing program. To reduce redundancy, we recommend using a single set of measures for all 3 programs.

Measurement Domain: Patient Access

This domain aims to assess the implementation of health IT provisions of the Cures Act by providing insight regarding whether patients are (1) electronically accessing data and (2) taking advantage of third-party applications (apps) to do so.

The proposed draft measures in this domain aim to address the following questions:

- **How are patients accessing their health information electronically (i.e., patient portals and third-party apps)? To what extent is usage sustained by method?**
- **To what extent are patient-facing apps registered via the certification criteria in section (g)(10) (under the Health IT Certification Program) being used? How many apps have sustained usage (versus drop-off after download)?**
- **To what extent do registered third-party patient-facing apps include comprehensive, publicly available privacy policies?**

Identifying by which method the patient accessed their information could be challenging. Reviewing audit logs would provide some information within current system audits; however, those audits may not define or be able to reflect the specificity that seems to be requested.

It is important to note that measuring quantity does not determine quality. This program is intended to determine the qualitative functions of certified products, whereas the proposed measures calculate quantitative metrics that do not enable a consumer to make quality comparisons among certified products. We are therefore unsure what value there is in this measurement domain.

Measure 1: Patient access to EHI: Percentage of patients who access their EHI using different methods and continue using those methods

Numerator 1: Number of patients that accessed their EHI
> **1a. Via 3rd party app only (authorization as a proxy for use)**
> **1b. Via patient portal or app given by healthcare provider for portal use only**
> **1c. Combinations of 3rd party app and web portal (e.g., 3rd party app, web portal, and /or healthcare provider app)**
> **1d. Neither (did not use patient portal or authorize access via an app)**

We have provided examples of how we expect EHR developers may be able to calculate each of these numerators for your consideration:

1a. Could use OAuth flow as the proxy to determine whether the app has been used

1b. Look at patient portal or portal's app audit logs to measure

1c. Patients who use 1a and 1b

1d. It is unclear what this is calculating (Den - (1a+1b)) we recommend removing this measure.

If these examples do not align with the intent of the measures, we recommend clarifying them.

Availability of an app is more a measure of the app than of EHR capabilities. As a result of necessity and business need, more apps are developed to interact with some EHRs than others. Additionally, many factors, including patient population (e.g., access, propensity to use internet technology), type of practice, region, etc. could impact utilization of existing patient portals and apps.

Numerator 2: Number of patients that accessed their data more than once (i.e., sustained use) by method listed above

We suggest eliminating this numerator for a number of reasons. Historically, CMS measures that have focused on patient action have been challenging to collect, report, and accurately evaluate. Repeated patient access is not relevant across all care settings. The definition of sustained use is problematic; a patient logging in twice in one day may not be as valuable in some cases as logging in over several months. Finally, this numerator is more complex than proposed numerators 1a-1c, thereby creating a higher development burden.

Denominator: Number of individuals with an encounter (i.e., active patients)

This denominator lacks clarity. We recommend changing "individuals" to "patients" and clarifying the definition of an encounter. For example, do vaccine-only visits count? Telehealth visits?

Measure 2: Percentage of 3rd party, registered patient-facing apps with a minimum number of users (i.e., patients who have authorized access to their EHR data) and extent to which those apps continue to be used

Numerator 1: Number of 3rd party, registered patient-facing apps with a minimum number of patients who authorized access to their data (by category)

Today, there is very low adoption of third party consumer apps that connect to CEHRT, which will limit the insight this measure offers. We recommend considering this measure for future updates to the program when there is more substantial usage of apps across many care settings.

Measure 3: Percentage of 3rd party, registered patient-facing apps that include a publicly available privacy policy

Screening questions: Does the developer collect whether 3rd party patient-facing apps have a publicly available privacy policy as part of the registration process? If yes, proceed to report on Numerator 1.

EHR developers are not the best fit to evaluate privacy policies of 3rd party apps, nor does this measure evaluate the EHR in any way. Additionally, it is duplicative to ask every EHR developer to answer questions about the same apps. The HITAC's EHR Reporting Program Task Force recommended removing this measure; the EHR Association agrees.

Targeted Feedback on Patient Access Measures

What are the appropriate categories for the number of users and reauthorized users?

Assuming this points to Measure 2, we recommend lowering the categories, as we believe there is only one app with more than 1,000.

Does assessing whether patients accessed their data more than once during the calendar year (i.e., sustained use) provide valuable insights beyond looking at access by method? Similarly, does looking at the number of apps that were not reauthorized by a majority of users provide useful insights into what apps are valued?

The focus of this measure seems to be on whether apps are useful rather than of evaluating the EHRs. The EHR Association recommends removing this metric as an EHR measure.

What is the appropriate threshold for the number of times a patient should access their data within 12 months to be considered sustained use? Is 12 months appropriate for the reauthorization measure, or should the look-back period be longer (e.g., 18 months)?

We note this measure seems to assume a certain demographic of patients that is seen multiple times annually. Patients who are young and healthy may only see physicians annually. Alternatively, other patients only see certain specialists (e.g., dermatology) infrequently. Other factors include patients' access to the internet, technical literacy, etc. None of these factors fairly represent the quality of the EHR, nor would it allow a customer to fairly compare EHRs. If the objective is to understand drop off after download or actual use, a threshold of one will start to demonstrate overall sustained use for a provider organization.

By which patient characteristics should we collect the measures? Would EHR developers have access to data reflecting these characteristics? If so, are the data (e.g., related to race and ethnicity) from EHRs reliable for reporting?
» The currently proposed characteristics are age group, patient versus caregiver, and race and ethnicity.

These stratifications add significant complexity. The EHR Association recommends either removing stratifications per measure, or limiting the number of measures. The program needs an achievable starting point; stratifications can be a future goal.

Measurement Domain: Health Information Exchange

Measure 1: Percentage of vaccinated individuals who immunization data were sent electronically to an IIS

Numerator: Number of individuals whose immunization information was electronically submitted to the registry (e.g., via HL7v2.5.1 transactions)

We recommend simplifying this to count the number of immunizations transmitted to registry to capture the quantity of immunizations transmitted to a registry rather than a single patient's information. The way the numerator currently reads, if a patient received 5 immunizations in a single visit, they would only count once in the numerator rather than each of the 5 immunizations triggering the count.

Denominator: Number of individuals with an immunization administered

We recommend simplifying this to count the number of immunizations administered to capture the quantity of immunizations administered rather than the quantity of patients who received an administered vaccine to align with the recommended changes to the above numerator.

Measure 2: Percentage of IIS queries made per individual with an encounter

Numerator: Number of immunization forecasts and histories received from IIS into EHR

We recommend simplifying this to count the number of query responses to better align with the CEHRT's ability to track this information.

Denominator: Number of individuals with an encounter

We recommend simplifying this to count the number of visits. The current denominator definition would result in any individual with an encounter during the timeframe specified, whereas the number of visits would demonstrate a high denominator. The first would measure a single patient whereas the recommended change would measure the volume of visits/encounters.

Targeted Feedback on HIE Measures

Which individual characteristics should we collect the measures by? Would HIT developers have access to data on these patient characteristics (e.g., age)?

These stratifications add significant complexity. The EHR Association recommends either removing stratifications per measure, or limiting the number of measures. The program needs an achievable starting point; stratifications can be a future goal.

Queries via portals would be excluded from Measure 2. To what extent is this a limitation?

If the immunization registry has a portal from which immunization history can be accessed, then clinician access to the portal would not necessarily be logged in the EHR resulting in the measure undercounting whether a patient's immunization forecast or history was accessed The measure would continue to reflect whether the information was interoperably exchanged between the IIS and the EHR.

For Measure 2, should the denominator be encounters, E&M visits, or vaccinated individuals?

None of these options would adequately work for inpatient products, unless "encounters" were specifically and clearly defined to include them.

Measurement Domain: Clinical Care Information Exchange

Measure 1: Percentage of SOC records viewed by end users and clinicians (broken out by parsing/integration of records)

Numerator 1: Number of unique SOC records received using CEHRT that are viewed by end users and clinicians

Denominator 1: Number of unique SOC records received using CEHRT

The EHR Association recommends removing this numerator and denominator, as they are very similar to CMS' Promoting Interoperability measures related to transition of care documents. It is redundant for developers to report on the same measures our customers are reporting.

Numerator 2: Number of unique SOC records received using CEHRT that are parsed, integrated, and viewed by end users and clinicians

Denominator 2: Number of unique SOC records received using CEHRT that are parsed and integrated

This measure requires clarification. Specifically, the terms parsed, integrated, and end users would all need specific definitions to ensure EHR developers count actions correctly when reporting numerators and denominators. For example, it is unclear if elements must be parsed and integrated as a prerequisite for viewing the information, and how this measure would be impacted if only some data elements from the SOC were integrated into the record.

The EHR Association recommends a shift in focus to what the CEHRT does, which is to allow users to not only view a received document, but to also ingest and reconcile discrete data elements into the patient's record in the EHR.

Measure 2: Percentage of registered, 3rd party clinician-facing apps with active users (as defined by end users and clinicians authorizing access)

Numerator 1: Number of registered, 3rd party clinician-facing apps with a minimum number of users (see potential categories/subgroups)

This measure focuses on 3rd party apps, rather than measuring quantitative or qualitative EHR functionality. EHRs are unable to ascertain the number of active users for a 3rd party app.

Instead, we recommend the following:
Denominator: Number of apps registered with the API server
Numerator: Number of apps deployed by 1 or more clients
Bonus attribute: Average number of apps deployed per client for each product

Measurement Domain: Standards Adoption and Conformance

Measure 1: Number and percentage (relative share) of calls for individual Core and non-Core FHIR profiles by clinician-facing apps

Numerator: Number of calls by clinician-facing registered apps for each distinct FHIR profile (both Core and non-Core)

What is meant by "non-Core" and what does this measure hope to accomplish? It is likely more appropriate to evaluate FHIR Resources rather than Core versus non-Core FHIR profiles; non-Core may not even be a capability of the CEHRT.

Denominator 2: Number of clinician-facing 3rd party apps registered via 170.315(g)(10)(III) with a minimum number of users (see clinical exchange Measure 2 in Table 3)

For clinician-facing apps, it would be especially challenging to achieve a minimum number of users, as there may be only one or two eligible users within a practice. Because of this, we suggest the minimum number of users is inapplicable. However, it seems this measure may expect developers to aggregate across all sites, which would make minimum user expectations more feasible.

Measure 2: Percentage (relative share) of calls for individual Core and non-Core FHIR profiles by patient-facing apps

Numerator: Number of calls by clinician-facing apps for each FHIR profile (both Core and non-Core)

We assume that in this measure "clinician-facing" should read "patient-facing."

What is meant by "non-Core" and what does this measure hope to accomplish? It is likely more appropriate to evaluate FHIR Resources rather than Core versus non-Core FHIR profiles; non-Core may not even be a capability of the CEHRT.

Denominator 2: Count of patient-facing 3rd party apps registered via 170.315(g)(10)(III) with a minimum number of users (see patient access Measure 2)

It is common for patient-facing app developers to register test apps with only one or two users. Because of this, the EHR Association recommends having a minimum number such as 10 or 50 to determine an app is active. Recommend that the minimum only applies to the aggregated numbers.

Measure 3: Usage of SMART/HL7 FHIR bulk data access to enable data export in enterprise-to-enterprise transactions

Numerator 1: Number of SMART/HL7 FHIR bulk calls across EHR installations

Numerator 2: Number of SMART/HL7 FHIR bulk calls related to export data on all individuals across EHR installations

Numerator is infeasible based on ease of EHRs determining this metric. We recommend removing this numerator at this time.

Numerator 3: SMART/HL7 FHIR bulk calls related to export of all data for individuals within a specified group (e.g., accountable care cohort research group, health plan members)

This numerator hints at b10 EHI Export functionality rather than g10 functionality. Given b10 functionality will not impact all CEHRT, nor is it required until the end of 2023, the EHR Association recommends modifying this numerator to more clearly indicate g10 functionality, or removing it entirely.

Numerator 4: Number of SMART/HL7 FHIR bulk calls related to full system-level export of all resources

Numerators 2 and 4 are ambiguous and we are unable to determine how they are functionally and practically different.

Denominator: Number of distinct EHR installations

This denominator does not give a good sense of volume, and will result in some cases of the numerator being larger than the denominator (i.e., the number of bulk calls across installations will be higher than the number of distinct EHR installations). The EHR Association recommends modifying this denominator.

Potential Future Measures

Patient Access Measure: Percentage of patients using write-back functionality on 3rd party registered patient-facing apps

Numerator: Number of patients who have used write-back functionality on 3rd party, registered patient-facing apps

Writing into the EHR is not part of certification, so the EHR Association questions whether this is an appropriate basis for evaluation of the EHR.

Denominator: Number of patients who have authorized access to their information via 3rd party apps (this number is also collected via numerator from patient access Measure 1)

The EHR Association recommends that this information should be requested from the 3rd party app vendors as EHR developers do not necessarily have access to this data.

Public Health Measure: Submission of data to 3rd party apps or APIs

Numerator: Number of EHR installations submitted data to PHAs using APIs of 3rd party apps (e.g., eCR Now) related to (f) criteria: f1-3, f5-6

This measure requests data regarding API interface rather than EHR functionality. The CEHRT is unable to monitor what a 3rd party submits or determine the purpose of data submitted using APIs. As a result, the EHR Association recommends removing this numerator or modifying it to reflect what a CEHRT would be capable of monitoring.

Denominator: Number of health IT installations

What is the definition of "health IT installations"? Is it the number of client sites, or the number of providers at the client site?

Data quality and completeness measure: By data element, percentage of data complete (i.e., not missing)

Numerator: For each data element selected, number of active patients with complete information for that data element

We recommend this be a provider measure since it evaluates how a user is utilizing the system rather than functionality provided by the EHR. Most of the cited data elements are already standard in the industry, some of which are required fields.

> Race, Ethnicity, Gender, DOB: Required for Demographics and CCDA criteria, so those EHRs certified to this criterion would support them.

> Address: Required for CCDA criteria, so those EHRs certified to those criteria would support it.

> Mother's Maiden Name: Not required for certification. In our experience, mother's maiden name is not used in matching patient records. Other data elements are more valuable, including address and phone number.

> First Name/Last Name: Part of USCDI. However, we cannot conceive that a patient record could be created without a patient's first and last name. Internationally, not having a first name listed might be common, but not in the US.

> Gender: How is this being defined? Is it sex assigned at birth (natal sex), gender identity, or other?