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October 10, 2018

Donald Rucker, MD
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Dr. Rucker,

On behalf of the 34 companies that are members of the Electronic Health Record Association (EHRA), we are pleased to submit the following comments on the Office of the National Coordinator for Health IT (ONC) on the 2015 Edition Certification Test Methods.

These comments reflect the expertise of health information and technology (IT) developers who focus on certification and delivery system reform, and are a result of EHRA's collaborative efforts to bring the value of our collective experiences to policymakers and, ultimately, our customers.

The following outlines our detailed comments on specific aspects of §170.315 (g)(2) Test Data.

The Association thanks you for this opportunity to provide our input. We appreciate ONC's openness to soliciting feedback from EHR stakeholders.

Sincerely,

Cherie Holmes-Henry
Chair, EHR Association
NextGen Healthcare

Sasha TerMaat
Vice Chair, EHR Association
Epic

HIMSS EHR Association Executive Committee

Hans J. Buitendijk
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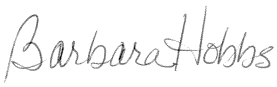

Barbara Hobbs
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About the EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of more than 30 companies that supply the vast majority of EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehra.org.

Required Test 13: ePrescribing of Schedule II Opioids

Denominator Questions

1. CMS states, "For both measures, we proposed to define opioids as Schedule II controlled substances under 21 CFR 1308.12, as they are recognized as having a high potential for abuse with potential for severe psychological or physical dependence." Is EHRA correct in understanding that even non-opioid Schedule II medications (such as stimulants) should be included in the denominator? Alternatively, has CMS provided a value set of Schedule II opioids to constitute the denominator?

2. We noted CMS' clarification on not limiting the denominator to discharge medications:

   "Response: The denominator for the measure is based on the Schedule II opioids that are electronically prescribed using CEHRT during the EHR reporting period rather than medications administered as the intent is to identify multiple provider episodes (physician shopping), prescriptions of dangerous combinations of drugs, prescribing rates and controlled substances prescribed in high quantities. In addition, we decline to revise the denominator of the measure as it could include prescriptions upon discharge as well as electronic prescriptions generated during the admission."

   We seek clarification on what would constitute an "electronic prescription" during an admission. Using this terminology is puzzling since typically prescriptions are only issued at discharge. Are opioids ordered and administered in the hospital facility considered "electronic prescriptions?" We see the logical choices as either:
   a. All inpatient orders for opioids (with the "electronic prescription" distinction removed);
   b. All electronically prescribed opioid discharge medications; or
   c. Both a. and b.

Numerator Questions

If the capabilities and standards for (a)(10) are to be used, please clarify the relevance of the preferred drug list standard identified.

1. The test data scenarios seem to allow one query to the PDMP per day to count toward the numerator when there are multiple eligible opioid prescriptions in the same day. However, this interpretation does not seem to be supported by the IPPS Final Rule; thus we seek clarification.

   As a test case: A patient is admitted on Day 1, a query happens and an opioid medication is ordered. On Day 2 of their admission, another opioid is ordered. Does the query have to be repeated on Day 2? What is the time frequency at which a second query is expected (e.g. 1 per admission, 1 per day, 1 per week, etc.)? Surescripts has limitations on how frequently medication histories can be retrieved, so some providers may be reluctant to query more than once per day.

2. Please confirm that the numerator should increment when the PDMP query occurs and is not reliant upon whether the PDMP query is successfully responded to or whether any physicians review the PDMP response.

3. We assume that the person triggering a query and/or reviewing the query data does not necessarily have to be the same staff person as the ordering user, as this would permit automated queries or delegation of queries to nursing staff.

If we count single sign-on (SSO):

1. What constitutes "data from CEHRT" in an SSO integration? Is knowing the provider's credentials (such as NPI) for SSO sufficient since this data is in the CEHRT?

2. Is there a distinction between SSO workflows that pass a patient context and those that do not? Passing a patient context saves the provider from having to perform a search.

3. Is launching an SSO session intended to count regardless of what is launched and whether further steps (such as patient lookup or navigation) are needed to see information? Alternatively, is some user attestation/acknowledgement/extra box to click necessary to report that this worked?

If we count completely un-integrated actions that don't happen in the EHR:

1. Will the other system take responsibility for reporting when queries happen? This would be the best method.

2. Alternately, does CMS expect users to document by checking extra boxes about actions they took in completely separate systems? We are very concerned this adds burden and does not promote interoperability.

Required Test 14: Verify Opioid Treatment Agreement

General Questions

1. The assumption is that the opioid treatment agreement would be sought within the CEHRT. If this assumption is correct, when would it ever <u>not</u> already be incorporated?

2. Please clarify the definition of incorporation. For example, is a PDF acceptable?

3. Suggest removing row 35 in Scenario 3 since all boxes are grayed out.

Denominator Questions

1. Please clarify whether ONLY patients from whom an electronic medication history request and response transaction can be fulfilled should be considered for the denominator? For example, if a matched medication history request is not found, regardless of the medications that are documented in the EHR, the patient should not count in the denominator.

2. Please confirm whether the expectation is for EHR developers to use the "days supplied" data from the medication history response for determining whether the patient has had "at least 30 cumulative days in the last 6 months."

3. Some PDMPs restrict access to medication history data in the EHR. How should EH/CAHs in those states report this denominator?

4. How are PRN prescriptions counted for "days supplied?" Is this used in the 30 cumulative day metric? Are developers required to use PRN prescriptions or simply allowed to do so?

Numerator Questions

1. In Scenario 1, Column K, the responses are N/A, No, Not Identified, and Incorporated. Please clarify that EHRA's understanding of these options is accurate; and, if so, that only options (c) and (d) would increment the numerator.
    a. N/A = Agreement was not sought
    b. No = Agreement was sought and found but not incorporated
    c. Not Identified = Agreement was sought but not found
    d. Incorporated = Agreement was sought, found, and incorporated

2. Can CMS confirm that there is no time limitation for how long it could take the provider to "incorporate" the opioid treatment agreement? Or does the provider need to incorporate the opioid treatment agreement within the reporting period? Or the performance year?

3. If a patient was seen today and signs the agreement tomorrow, and is seen again in three months, does the provider need another agreement? What if a previous agreement is outside the reporting period? We seek clarification on whether the presence of an opioid treatment agreement is sufficient or whether the EHR also must try to determine whether it exists within a valid date range.

4. The EHRA does not recommend that checkboxes be the primary way to track this data, we would like clarification on whether checkboxes are acceptable for tracking:
    a. Opioid treatment agreement sought;
    b. Opioid treatment agreement identified/found; and
    c. Opioid treatment agreement incorporated into the EHR

Required Test 15: Support Electronic Referral Loops by Receiving and Incorporating Health Information

General Questions

1. EHRA suggests that the language in columns I-K change from "during the calendar year" to "during the reporting period" to support the new 90-day reporting period allowance.

Denominator Questions

1. Based on the underlined section below, are we correctly understanding this to indicate that a single patient encounter has the potential to have multiple summary of care records qualify within this denominator?

   "the number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient."

   The overall measure is consistently referenced in the final rule as being a combination of the two measures (Request/Accept Summary of Care and Clinical Information Reconciliation Measure) in which the denominator for the Request/Accept measure is stated as the following:

   "Number of patient encounters during the EHR reporting period for which an EP, eligible hospital, or CAH was the receiving party of a transition or referral or has never before encountered the patient and for which an electronic summary of care record is available."

   We see a clear distinction between the previous denominator as compared to the new and would like clarification explicitly stating if the intent of the new measure is to allow for the possibility of multiple electronic summary of care records per one patient encounter to populate the denominator of this measure. We note that retaining the previous encounter-based denominator is simpler than transitioning to a document-based denominator.

2. The denominator definition states that new patient encounters should be counted in the denominator. Must providers receive a C-CDA for the patient in order for the encounter to be counted in the denominator?

3. When an EHR queries an HIE, or similar source of C-CDA documents, and the return data set is multiple C-CDA documents, are all documents expected to be reconciled to meet the measure, or is there flexibility for the EHR or the provider to determine which are the most relevant? What mechanisms for determining relevant documents would be reasonable?

Numerator Questions

1. Does reconciliation only count if an external C-CDA is received/used?