

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 495

[CMS-0046-IFC]

RIN 0938-AR71

Office of the Secretary

45 CFR Part 170

RIN 0991-AB89

Health Information Technology: Revisions to the 2014 Edition Electronic Health Record Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program

AGENCY: Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services.

ACTION: Interim final rule with comment period.

SUMMARY: The Department of Health and Human Services (HHS) is issuing this interim final rule with comment period to replace the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule published on September 4, 2012 in the **Federal Register** with updated versions of those standards. This interim final rule with comment period also revises the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs by adding an alternative measure for the Stage 2 meaningful use (MU) objective for hospitals to provide structured electronic laboratory results to ambulatory providers, correcting the regulation text for the measures associated with the objective for hospitals to provide patients the ability to view online, download, and transmit

information about a hospital admission, and making the case number threshold exemption for clinical quality measure (CQM) reporting applicable for eligible hospitals and critical access hospitals (CAHs) beginning with FY 2013. This rule also provides notice of CMS's intention to issue technical corrections to the electronic specifications for CQMs released on October 25, 2012.

DATES: Effective Date: This interim final rule with comment period is effective

[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER.]

The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of **[INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

Comment Date: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on **[INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments, identified by RIN 0991-AB89 or RIN 0938-AR71, by any of the following methods (please do not submit duplicate comments).

- Federal eRulemaking Portal: Follow the instructions for submitting comments.

Attachments should be in Microsoft Word, Adobe PDF, or Excel; however, we prefer Microsoft Word. <http://www.regulations.gov>.

- Regular, Express, or Overnight Mail: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Steven Posnack, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies.

- Hand Delivery or Courier: Office of the National Coordinator for Health Information Technology, Attention: Steven Posnack, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT:

Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health Information Technology, 202-690-7151, for EHR technology standards and certification criteria issues.

Elizabeth Holland, (410) 786–1309, or Robert Anthony, (410) 786–6183, for Medicare EHR Incentive Program issues.

David Koppel, (410) 786–3255, for Medicaid EHR Incentive Program issues.

Maria Michaels, (410) 786–2809, for clinical quality measures issues.

SUPPLEMENTARY INFORMATION:

I. Background

A. Statutory Basis

1. Standards, Implementation Specifications, and Certification Criteria

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX – Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of HIT and electronic health information exchange.

Section 3004(b)(3) of the PHSA titled “Subsequent Standards Activity” provides that the “Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent” with the schedule published by the HIT Standards Committee. We consider this provision in the broader context of the HITECH Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HIT Standards Committee and endorsed

by the National Coordinator, as well as other appropriate and necessary HIT standards, implementation specifications, and certification criteria.

2. HIT Certification Programs

Section 3001(c)(5) of the PHSA provides the National Coordinator with the authority to establish a certification program or programs for the voluntary certification of HIT. Specifically, section 3001(c)(5)(A) specifies that the “National Coordinator, in consultation with the Director of the National Institute of Standards and Technology, shall keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria adopted under this subtitle” (that is, certification criteria adopted by the Secretary under section 3004 of the PHSA). The certification program(s) must also “include, as appropriate, testing of the technology in accordance with section 13201(b) of the [HITECH] Act.”

Section 13201(b) of the HITECH Act requires that with respect to the development of standards and implementation specifications, the Director of the National Institute of Standards and Technology (NIST), in coordination with the HIT Standards Committee, “shall support the establishment of a conformance testing infrastructure, including the development of technical test beds.” The HITECH Act also indicates that “[t]he development of this conformance testing infrastructure may include a program to accredit independent, non-Federal laboratories to perform testing.”

3. Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs

We described the legislative basis for the Medicare and Medicaid EHR Incentive Programs in our Stage 1 and 2 final rules. Such legislative basis remains the same for this interim final rule with comment period. We refer readers to the Stage 1 and 2 final rules

(75 FR 44316 through 44317; 77 FR 53970) for discussions of legislative basis, including sections 1848(o), 1853(l) and (m), 1886(n), 1814(l), 1903(a)(3)(F), and 1903(t) of the Social Security Act (the Act).

B. Regulatory History

1. Standards, Implementation Specifications, and Certification Criteria Rules

In the September 4, 2012 **Federal Register** (77 FR 54163), the Secretary issued a final rule (the “2014 Edition EHR certification criteria final rule”) that adopted the 2014 Edition EHR certification criteria and a revised Certified EHR Technology (CEHRT) definition. The standards, implementation specifications, and certification criteria adopted by the Secretary in the final rule established the capabilities that CEHRT must include in order to, at a minimum, support the achievement of meaningful use (MU) by eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in FY/CY 2014.

The Secretary previously issued an interim final rule (75 FR 2014, January 13, 2010) and final rule (75 FR 44590, July 28, 2010) which adopted an initial set of standards, implementation specifications, and certification criteria and a CEHRT definition to support MU (the “2011 Edition EHR certification criteria final rule”). In the October 13, 2010 **Federal Register** (75 FR 62686), an interim final rule with comment period was issued to remove certain implementation specifications related to public health surveillance that had been previously adopted in the final rule.

2. HIT Certification Programs Rules

In the 2014 Edition EHR certification criteria final rule previously mentioned above, ONC made revisions to the permanent certification program, including changing the program’s

name to the ONC HIT Certification Program. Previously, the Secretary issued a final rule on January 7, 2011 (76 FR 1262) establishing the permanent certification program's requirements (now called the ONC HIT Certification Program) and a final rule on June 24, 2010 (75 FR 36158) establishing the temporary certification program.

3. Medicare and Medicaid EHR Incentive Programs Rules

CMS's final rule (the "Stage 2 final rule") implementing Stage 2 of meaningful use appeared in the September 4, 2012 **Federal Register** (77 FR 53968). The final rule also contained some revisions to Stage 1 of meaningful use, beginning with EHR reporting periods in FY/CY 2013. A correction notice appeared in the October 23, 2012 **Federal Register** (77 FR 64755).

II. Provisions of the Interim Final Rule with Comment Period

A. Adoption and Incorporation by Reference of Newer Versions of the DEC and QRDA III Standards

1. Data Element Catalog

In the 2014 Edition EHR certification criteria final rule (77 FR 54163), we adopted the Data Element Catalog (DEC), August 2012 version, standard at 45 CFR 170.204(c) and incorporated the standard by reference at 45 CFR 170.299(m)(5). The DEC is included in the certification criterion at 45 CFR 170.314(c)(1), which requires EHR technology presented for certification to be able to electronically record all of the data identified in the DEC that would be necessary to calculate each clinical quality measure (CQM).

On October 25, 2012, CMS released the final 2014 CQM electronic specifications (e-specifications).¹ In preparation for that release, we performed a gap analysis to determine whether the DEC, August 2012 version (now referred to as “DEC version 1.0”) still appropriately specified all of the data that EHR technology would need to capture to support these final 2014 CQM e-specifications. Based on that analysis, we determined that the version of the DEC we adopted in the final rule needed to be updated in order to correctly align with data capture expectations expressed by numerous 2014 CQM e-specifications. Working with our colleagues at the National Library of Medicine (NLM), a new version of the DEC (version 1.1)² is now available that fully aligns with the final 2014 CQM e-specifications. By replacing the version of the DEC that is currently incorporated by reference at 45 CFR 170.299(m)(5) with an updated version (Data Element Catalog, Version 1.1 (October 2012)), EHR technology certified under the ONC HIT Certification Program will be capable of supporting the electronic capture of all of the necessary data for CQM calculation and submission by EPs, eligible hospitals, and CAHs for the Medicare and Medicaid EHR Incentive Programs. Based on our expectation that EHR technology testing and certification will begin in January 2013, if we do not act now to immediately update the version of the DEC currently incorporated by reference, EHR technology would be required to be tested and certified to DEC version 1.0 and thus capture, in some cases, less data than necessary to support the accurate calculation and reporting of the 2014 CQMs. As a consequence, CMS and the States would then receive incomplete CQM data from EPs, eligible hospitals, and CAHs. Therefore, we are replacing the version of the DEC that is currently incorporated by reference at 45 CFR 170.299(m)(5) with the updated version (DEC, Version 1.1

¹ http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/2014_ClinicalQualityMeasures.html

² <http://www.nlm.nih.gov/healthit/dec/>

(October 2012)) that we are adopting as the standard referenced by the 2014 Edition EHR certification criterion at 45 CFR 170.314(c)(1).

2. Quality Reporting Document Architecture (QRDA) Category III (QRDA III)

In the 2014 Edition EHR certification criteria final rule, we adopted the QRDA III, Release 1, standard at 45 CFR 170.205(k) and incorporated the standard by reference at 45 CFR 170.299(f)(14). The QRDA III is included in the certification criterion at 45 CFR 170.314(c)(3), which requires EHR technology presented for certification to be capable of electronically creating a data file for transmission of clinical quality measurement data in accordance with QRDA III and that can be electronically accepted by CMS.

As noted in the 2014 Edition EHR certification criteria final rule (77 FR 54232), we adopted QRDA III (specifically, Quality Reporting Document Architecture Category III, Release 1, Implementation Guide for CDA Release 2 (US Realm) Based on HL7 CDA Release 2.0, August 2012) even though it had not been balloted because we expected it to become a normative standard in the near future and agreed with CMS's decision to select this format rather than developing its own CMS-defined XML template because QRDA III is a product of several years of industry consensus work. The QRDA III standard has now been successfully balloted (specifically, HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1 (US Realm) Draft Standard for Trial Use, November 2012).³ The November 2012 balloted version of QRDA III clarifies ambiguities in the August version we adopted; specifically, certain data that would need to be included in any QRDA III file submitted to CMS, such as a provider's National Provider Identifier (NPI) or Taxpayer Identification Number (TIN) in order for the electronic submission to be properly

³ http://www.hl7.org/permalink/?CDAR2_IG_QRDA_CATIII_R1_NOV

processed. Additionally, some of the required components have been changed to optional in the November 2012 balloted version of the standard, which may reduce the burden for EHR technology developers. Finally, we are making this change because CMS intends to implement its electronic submission systems to receive QRDA III files formatted according to the November 2012 balloted version. For these reasons, we are replacing the version of the QRDA III that is currently incorporated by reference at 45 CFR 170.299(f)(14) with the November 2012 balloted version of QRDA III that we are adopting as the standard referenced by the 2014 Edition EHR certification criterion at 45 CFR 170.314(c)(3).

B. Revisions to the Medicare and Medicaid EHR Incentive Programs

1. Meaningful Use Criteria

a. Stage 2 Hospital Objective for Providing Electronic Lab Results to Ambulatory Providers

In the Stage 2 final rule (77 FR 54041 through 54043), we included the following objective and measure in the Stage 2 menu set for eligible hospitals and CAHs at 42 CFR 495.6(m)(6)(i) and (ii):

Objective: Provide structured electronic lab results to ambulatory providers.

Measure: Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received.

The measure denominator is limited to lab orders received electronically by the hospital. In our response to comments in the Stage 2 final rule (77 FR 54042), we recognized that this measure is based on some degree of electronic health information exchange taking place between the hospital and the ordering provider. The measure denominator assumes that if a hospital does not receive a lab order electronically, it would be less likely to send the results electronically to the ordering provider. Upon further consideration, however, in cases where hospitals send a

large number of lab results electronically in response to orders they receive through non-electronic means (for example, by phone or on paper), the measure might not capture a hospital's performance of the objective. In addition, a hospital that receives a very small percentage of its total lab orders electronically could have difficulty meeting the measure threshold regardless of the number of lab results it sends electronically to ordering providers. For example, if a hospital receives 10,000 lab orders and responds to 4,000 with structured electronic clinical lab results, but only 100 of those orders were received electronically and of those 18 were responded to with structured electronic clinical lab results, then the hospital would score 18/100 and fail to meet the measure's 20-percent threshold despite sending 4,000 structured electronic clinical lab results.

While we continue to believe that most hospitals will find it advantageous to use the existing measure, for the reasons discussed previously, we are adding an alternative measure for this objective. Hospitals can meet either the existing measure or the alternative measure to satisfy the objective. The alternative measure is "Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of lab orders received" at §495.6(m)(6)(ii)(B). The denominator, numerator, and threshold for this alternative measure are as follows:

- Denominator: The number of lab orders received from ambulatory providers.
- Numerator: The number of lab orders in the denominator for which structured electronic clinical lab results were sent to the ordering provider.
- Threshold: The resulting percentage must be greater than 20 percent.

The existing measure of "Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received" will be

redesignated as 42 CFR 495.6(m)(6)(ii)(A). We clarify the numerator, denominator, and threshold of the existing measure as follows:

- Denominator: The number of electronic lab orders received from ambulatory providers.
- Numerator: The number of lab orders in the denominator for which structured electronic clinical lab results were sent to the ordering provider.
- Threshold: The resulting percentage must be greater than 20 percent.

b. Stages 1 and 2 Hospital Objective for View, Download, and Transmit

In the Stage 2 final rule (77 FR 54041 through 54043), we included the following objective and two associated measures in the Stage 2 core set for eligible hospitals and CAHs at 42 CFR 495.6(l)(8)(i) and (ii). We also included the objective and measure in the Stage 1 core set for eligible hospitals and CAHs at 42 CFR 495.6(f)(12)(i)(B) and (ii)(B).

Objective: Provide patients the ability to view online, download, and transmit information about a hospital admission.

Measures: (A) More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge; and

(B) More than 5 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH (or their authorized representative) view, download or transmit to a third party their information during the EHR reporting period.

In the Stage 2 final rule (77 FR 53968), we inadvertently omitted the word “unique” from the regulation text for the two measures. We described in the preamble of the final rule

(77 FR 54040) the denominators of the measures as “Number of unique patients discharged from an eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period.” However, the regulation text for these measures incorrectly refers to “all patients” instead of “all unique patients.” Because we intended for the regulation text to be consistent with the measure specifications as described in the preamble, we are correcting the regulation text at §495.6(f)(12)(ii)(B), (l)(8)(ii)(A), and (l)(8)(ii)(B) to clarify that these measures are based on the number of unique patients discharged from a hospital’s inpatient or emergency department during the EHR reporting period.

2. Case Number Threshold Exemption for CQM Reporting for Hospitals

In the Stage 2 proposed rule, CMS solicited comments on whether a case number threshold would be appropriate for hospital clinical quality measures reporting, given the apparent burden on hospitals that very seldom have the types of cases addressed by certain measures. We requested comments on whether such thresholds should be established for 2013, noting that the issue would be mitigated beginning in 2014 by our proposal to establish a larger menu set of CQMs from which hospitals would select.

As we stated in the Stage 2 final rule (77 FR 54080), many commenters noted that the implementation of a case number threshold for hospital CQM reporting would help reduce the burden placed on hospitals that very seldom have cases that would be counted in the denominator of certain CQMs. Commenters suggested a variety of possible implementation mechanisms, but all commenters responded to the premise that the threshold would be in effect in FY 2013.

In the Stage 2 final rule, we adopted a policy that would apply beginning in FY 2014. Under such policy, eligible hospitals and CAHs with 5 or fewer inpatient discharges per quarter

or 20 or fewer inpatient discharges per year (Medicare and non-Medicare combined), as defined by a CQM's denominator population, would be exempted from reporting on that CQM. We stated that the exemption would be available in all stages of meaningful use beginning in FY 2014, but that eligible hospitals and CAHs that submit CQMs through attestation (because they are demonstrating meaningful use for the first time) would not be able to qualify for the exemption. We explained that the burden of submitting aggregate population and sample size counts in order to qualify for the exemption would be at least equal to the effort required to obtain and attest to the calculated CQM data.

Upon further review of this policy, we believe there are valid reasons to make this policy applicable for EHR reporting periods in FY 2013, as well as for eligible hospitals and CAHs that are submitting their CQMs through attestation. For FY 2013, eligible hospitals and CAHs are required to submit information on each of the 15 CQMs that were finalized for FYs 2011 and 2012 in the Stage 1 final rule (75 FR 44418 through 44420). Because they do not have a choice as to which CQMs to report for FY 2013, hospitals may experience the burden of revising workflow in order to accurately report on CQMs for which they have fewer than 20 cases per year. In addition, after considering the workflow redesign costs that could be incurred by training staff to input data used in calculating low-volume CQMs, we have re-assessed the burdens of attesting to calculated CQM data and submitting aggregate population and sample size counts in order to qualify for the exemption.

Therefore, we are finalizing a case threshold exemption that is applicable for eligible hospitals and CAHs in all stages of meaningful use beginning with FY 2013. Eligible hospitals and CAHs that are demonstrating meaningful use for the first time and submitting their CQMs using attestation would be able to qualify for the exemption. Eligible hospitals and CAHs with 5

or fewer discharges during the relevant EHR reporting period (if attesting to a 90-day EHR reporting period), or 20 or fewer discharges during the year (if attesting to a full year EHR reporting period) as defined by the CQM's denominator population would be exempted from reporting on that CQM.

In FY 2013, since the reporting requirement is to report all 15 of the CQMs finalized in the Stage 1 final rule, invoking the case threshold exemption would reduce the number of CQMs a hospital would be required to report by the number of CQMs for which it does not meet the case threshold of discharges as described earlier. For example, if the hospital submitted aggregate population and sample size data reflecting 4 stroke patients discharged in FY 2013, then the hospital would be exempt from reporting the CQMs that include stroke patients as part of the denominator population (that is, the 7 stroke CQMs out of the total 15 CQMs). Therefore, this hospital would successfully meet the CQM reporting requirements in FY 2013 if they submit the 8 remaining CQMs. If a hospital does not reach the case threshold for all 15 CQMs, the hospital would be exempt from reporting all CQMs.

Beginning in FY 2014, the reporting requirement is to report 16 CQMs covering at least 3 domains from a list of 29 CQMs. The hospital would follow the same process as in FY 2013, but in order to be exempted from reporting fewer than 16 CQMs it would need to qualify for the case threshold exemption for more than 13 of the 29 CQMs. If the hospital does not meet the case threshold for 13 or fewer CQMs, the hospital would be able to report at least 16 CQMs. Likewise, if the CQMs for which the hospital can meet the case threshold of discharges do not cover at least 3 domains, the hospital would be exempt from the requirement to cover the remaining domains. For example, if the hospital does not meet the case threshold of discharges

for 13 CQMs, and thus could report 16 CQMs, but the 16 CQMs cover only 2 of the 3 domains, then the hospital would be exempt from covering the third domain.

To be eligible for the exemption, Medicare-eligible hospitals and CAHs must use the same process outlined in the Stage 2 final rule (see 77 FR 54080), including submitting aggregate population and sample size counts for Medicare and non-Medicare discharges as defined by the CQM's denominator population for the EHR reporting period no later than November 30 after the end of the fiscal year containing the EHR reporting period (for example, November 30, 2013 for the hospital's EHR reporting period that occurs in FY 2013). Medicaid-only hospitals, including children's hospitals, must report this same information to the state to which they attest, in a manner specified by that state.

3. Technical Corrections to CQM Electronic Specifications

During the time period since the final 2014 CQM e-specifications were released on October 25, 2012, we have identified technical errors in a few of the e-specifications that, if not corrected, would produce inaccurate results. In order to maintain the integrity of the CQM(s) affected by such errors, and to allow for accurate reporting of the measure(s), CMS will issue technical corrections to the e-specifications released on October 25, 2012. We expect to issue these corrections on or around December 21, 2012. In order to meet this date, we are encouraging individuals and organizations (in particular, vendors and system implementers) that have identified logic or other technical issues with any of the e-specifications released on October 25, 2012 to submit the issues to the following email address no later than December 10, 2012 (HIT_quality_measurement@CMS.hhs.gov). The corrected e-specifications will be required both for certification and reporting purposes.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of the rule take effect in accordance with section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). However, we can waive the notice and comment procedure if the Secretary finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the final notice or rule that is issued.

A. Adoption of Newer Versions of the DEC and QRDA III Standards

Under the regulatory framework we have established, EHR technology will be certified under the ONC HIT Certification Program and subsequently used by EPs, eligible hospitals, and CAHs to participate in the Medicare and Medicaid EHR Incentive Programs. We believe it would be contrary to the public interest if EHR technology is required to be certified to the versions of the DEC and QRDA III standards that we adopted in the 2014 Edition EHR certification criteria final rule. With respect to the DEC standard, the EHR technology would not be fully capable of electronically capturing all potentially necessary CQM data for electronic submission to CMS or the States under the Medicare and Medicaid EHR Incentive Programs. With respect to the QRDA III standard, the August 2012 version did not specify certain data that would need to be included in a QRDA III file submitted to CMS in order for the electronic submission to be properly processed. As we noted in section II.A.1 of this interim final rule with comment period, this update is necessary to prevent EHR technology from being required to be tested and certified to DEC version 1.0 and thus capture, in some cases, less data than necessary to support the accurate calculation and reporting of the 2014 CQMs. As a consequence, this would lead to CMS and the States receiving incomplete CQM data from EPs, eligible hospitals, and CAHs. Similarly, with respect to our adoption of the November 2012 balloted version of

QRDA III, we believe that this step is necessary for a number of reasons, including: (1) the changes in the November 2012 version provide necessary clarifications that reduce implementation ambiguity and ensure that the data CMS needs to properly process electronically submitted QRDA III files is captured and transmitted; and (2) CMS's intentions to implement its electronic submission systems to receive QRDA III files formatted according to the November 2012 balloted version. Accordingly, by adopting the new versions of the DEC and QRDA III standards in this interim final rule with comment period to replace the previously adopted versions, we can facilitate the development and certification of EHR technology to standards that can fully support the electronic capture and electronic submission of CQM data under the Medicare and Medicaid EHR Incentive Programs, which benefits the public interest.

Finally, because testing and certification of EHR technology to the 2014 Edition EHR certification criteria is expected to begin in January 2013, updating these standards in advance would avoid the scenario where EHR technology would be certified to different versions of these standards, and consequently, some EHR technology may need to be re-developed and re-certified to meet the new versions of the standards. Based on this timeframe for EHR technology developers, and the additional time providers will need for adoption and implementation of certified EHR technology, we believe it would be impracticable and contrary to the public interest to undergo notice and comment rulemaking to adopt the new versions of the DEC and QRDA III standards.

B. Modifications to Meaningful Use Hospital Objectives

The alternative measure for the Stage 2 hospital objective of “provide structured electronic lab results to ambulatory providers” (42 CFR 495.6(m)(6)) that we are finalizing in this rule relieves a restriction on eligible hospitals and CAHs. The correction of the regulation

text for the measures associated with the hospital objective of “provide patients the ability to view online, download, and transmit information about a hospital admission” (42 CFR 495.6(f)(12)(i)(B) and 495.6(l)(8)(i)) is necessary to ensure accurate certification of EHR technologies. It would also be impracticable and contrary to the public interest to engage in notice and comment rulemaking to finalize these modifications. Because these measures are percentage-based, they are linked to the certification criteria that ONC has adopted at 45 CFR 170.314(g)(1) and (g)(2). Thus, if we did not institute these changes in a timely manner, it could potentially delay the certification of EHR technology to the 2014 Edition EHR certification criteria, which as noted in the preceding section is expected to begin in January 2013. A delay in the availability of certified EHR technology could negatively affect hospitals’ ability to make informed purchasing decisions and shorten their timeframe to implement EHR technology certified to the 2014 Edition EHR certification criteria. We believe many hospitals would benefit from the certainty of knowing these changes as they begin their planning and analysis in advance of purchasing and updating their EHR technology. Furthermore, if there were to be a delay in the certification of EHR technology to the criteria adopted at 45 CFR 170.314(g)(1) and (g)(2), it could prevent hospitals from adopting and using 2014 Edition EHR technology to meet the CEHRT definition in FY 2013. For these reasons, there is good cause to make the changes to the objectives and measures effective prior to receiving public comment.

C. Case Number Threshold Exemption for CQM Reporting

The low case number threshold exemption we are finalizing in this rule relieves a restriction on eligible hospitals and CAHs. It also is contrary to the public interest, impracticable, and unnecessary to engage in notice and comment rulemaking to finalize this exemption. As CMS already received comments regarding the exemption being available for

those hospitals reporting CQMs beginning in FY 2013, we believe it would be unnecessary to engage in another round of comments. In addition, eligible hospitals and CAHs require immediate notification of the exemption to be able to invoke it for EHR reporting periods in FY 2013; it would not be possible to engage in notice and comment rulemaking in time. It also benefits the public interest if eligible hospitals and CAHs, to the extent possible, do not encounter the burden of complying with reporting on CQMs for which they have case numbers beneath our thresholds. For these reasons, there is good cause to make the case number threshold exemption effective prior to receiving public comment.

IV. Response to Comments

Because of the number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

VI. Regulatory Impact Statement

We have examined the impact of this interim final rule with comment period as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2011), the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), section 1102(b) of the Social Security Act,

section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

A. Executive Orders 12866 and 13563 – Regulatory Planning and Review Analysis

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This interim final rule with comment period does not reach the economic threshold and, thus, is not considered a major rule. Therefore, an RIA has not been prepared.

B. Regulatory Flexibility Act and Social Security Act Section 1102(b)

The Regulatory Flexibility Act (RFA) requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. Similarly, CMS is also required by section 1102(b) of the Act to prepare an RIA if a rule will have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. We do not believe that the changes in this interim final rule with comment period alter any of the prior analyses we performed for the 2014 Edition EHR certification criteria final rule or the Stage 2 final rule; and therefore, the Secretary certifies that this interim final rule with comment period will not have a significant impact on a substantial number of small entities.

C. Executive Order 13132 – Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule (including an interim final rule) that imposes substantial direct

requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. Because this interim final rule with comment period does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

D. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately \$139 million. This interim final rule with comment period will not impose an unfunded mandate on state, local, and tribal governments or on the private sector that will reach the threshold level.

The Office of Management and Budget reviewed this interim final rule with comment period.

List of Subjects

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 495 and the Department amends 45 CFR subtitle A, subchapter D, part 170 as set forth below:

Title 42--Public Health

**PART 495--STANDARDS FOR THE ELECTRONIC HEALTH RECORD
TECHNOLOGY INCENTIVE PROGRAM**

1. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Section 495.6 is amended as follows:

a. In paragraph (f)(12)(ii)(B), by removing the phrase "all patients who are discharged" and adding in its place the phrase "all unique patients who are discharged".

b. In paragraphs (l)(8)(ii)(A) and (B), by removing the phrases "all patients who are discharged" and adding in its place the phrases "all unique patients who are discharged".

c. By revising paragraph (m)(6)(ii).

The revision reads as follows:

§495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs.

* * * * *

(m) * * *

(6) * * *

(ii) Measures. Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of --

(A) The electronic lab orders received; or

(B) The lab orders received.

Title 45–Public Welfare

**PART 170 – HEALTH INFORMATION TECHNOLOGY STANDARDS,
IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND
CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY**

3. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

4. Amend § 170.299 by revising paragraphs (f)(14) and (m)(5) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(f) * * *

(14) HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category III, DSTU Release 1 (US Realm) Draft Standard for Trial Use, November 2012, IBR approved for § 170.205.

* * * * *

(m) * * *

(5) Data Element Catalog, Version 1.1, October 2012, IBR approved for § 170.204.

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Section 3004 of the Public Health Service Act and Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program);

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance;
and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 3, 2012

Marilyn Tavenner,
Acting Administrator,
Centers for Medicare & Medicaid Services.

Dated: December 3, 2012

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

BILLING CODE: 4150-45-P

[FR Doc. 2012-29607 Filed 12/04/2012 at 4:15 pm; Publication Date: 12/07/2012]