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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 170

RIN 0991-AB91

2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of “Common Meaningful Use (MU) Data Set”

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises one paragraph in the Common Meaningful Use (MU) Data Set definition at 45 CFR 170.102 to allow more flexibility with respect to the representation of dental procedures data for electronic health record (EHR) technology testing and certification.

DATES: Effective date: This regulation is effective on [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [**INSERT DATE 60 DAYS AFTER DATE OF 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-AB91, by any of the following methods (please do not submit duplicate comments):

- Federal eRulemaking Portal: You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” and

enter the filecode to find the document accepting comments. Attachments should be in Microsoft Word, Adobe PDF, or Excel; we prefer Microsoft Word.

- Regular, Express, or Overnight Mail: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Steven Posnack, Patriots Plaza III Building, Suite 310, 355 E Street SW., Washington, DC 20024. Please submit one original and two copies.

- Hand Delivery or Courier: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Steven Posnack, Patriots Plaza III Building, Suite 310, 355 E Street SW., Washington, DC 20024. Please submit one original and two copies. (Because access to the interior of the Patriots Plaza Building is not readily available to persons without federal government identification, commenters are encouraged to request an escort from an ONC staff member at the security desk in the main lobby of the building.)

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.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period will be available for viewing by the public, 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 on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

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 above to arrange for inspection).

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 health information technology (health IT or HIT) and electronic health information exchange.

Section 3004(b)(3) of the PHSA entitled, “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 for Health Information Technology (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, 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.”

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 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 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 under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in Federal Fiscal Year/Calendar Year 2014.

The 2014 Edition Final Rule adopted a definition for the term Common MU Data Set at 45 CFR 170.102. The definition was created to reduce the repetitiveness of certification criteria and to make the certification criteria more concise. The definition includes types of data that are common among five certification criteria (the “view, download, and transmit to a 3rd party,” “clinical summary,” “transitions of care—receive, display, and incorporate transition of care/referral summaries,” “transitions of care—create and transmit transition of care/referral summaries,” and “data portability” certification criteria) and meant to mirror the data specified by the Centers for Medicare

& Medicaid Services (CMS) in the MU objectives and measures to which these certification criteria correlate.

2. HIT Certification Programs Rules

In the January 7, 2011 **Federal Register** (76 FR 1262), the Secretary issued a final rule establishing the permanent certification program and its requirements. In the 2014 Edition Final Rule mentioned above, ONC made revisions to the permanent certification program, including changing the program's name to the "ONC HIT Certification Program."

II. Issue Addressed by This Interim Final Rule

A. Background

The Common MU Data Set definition adopted at 45 CFR 170.102 identifies sixteen kinds of data and (where applicable) associated vocabulary standards. The definition's fifteenth paragraph (Paragraph 15) identifies the required and optional vocabulary standards for representing "procedures" data for the purposes of testing and certification.

Paragraph 15 requires that (in all certification criteria in which this definition is referenced) EHR technology must demonstrate for testing and certification that it can represent procedures in "[a]t a minimum, the version of the standard specified in § 170.207(a)(3) or § 170.207(b)(2)." In other words, procedures can be represented in Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) or the combination of Health Care Financing Administration Common Procedure Coding System (HCPCS) and Current Procedural Terminology, Fourth Edition (CPT-4) vocabularies.

In Paragraph 15, we also provide the option for EHR technology developers to represent procedures in either the Current Dental Terminology (CDT) (the standard specified at § 170.207(b)(3)) or International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) (the standard specified at § 170.207(b)(4)) in addition to, but not in lieu of, the required vocabulary standards mentioned above.

B. Revision to Common MU Data Set Definition

In the 2014 Edition Final Rule (77 FR54178), we responded to a commenter who recommended that we should adopt CDT to represent dental procedures. Instead of accepting the commenter's suggestion, we designated CDT as an "optional" standard so that it could be used for testing and certification but only in addition to, and not in lieu of, SNOMED CT® or CPT-4/HCPCS. As discussed below, we have determined after further consideration that this "optional" designation does not appropriately reflect that CDT is best suited to represent dental procedures in EHR technology. The revision to the Common MU Data Set definition made by this interim final rule is intended to improve regulatory flexibility and remove an unintended burden on EHR technology developers who develop products for customers that need a precise and comprehensive standard in which to record dental procedures.

On July 29, 2013, the HIT Standards Committee transmitted a recommendation to the National Coordinator stating that we should adopt CDT as a "required" vocabulary standard for EHR technology testing and certification.¹ It is our understanding that this recommendation sought to emphasize that the EHR technology testing and certification process should support and make available as a pathway for certification the

¹ <http://www.healthit.gov/facas/FACAS/health-it-standards-committee/health-it-standards-committee-recommendations-national-coordinator>

representation of dental procedures using CDT alone, rather than its current “optional” designation as a standard to be used in addition to SNOMED CT® or CPT-4/HCPCS. In consideration of that recommendation, we conducted fact-finding with experts in CDT and EHR technology developers who develop products that use this terminology to better understand how our decision to designate CDT as “optional” has impacted EHR technology testing and certification. We also sought to determine whether either of the two required vocabulary standards adopted to represent procedures (namely, SNOMED CT® or CPT-4/HCPCS) is sufficiently equivalent to CDT such that a regulatory change would be unnecessary.

Our fact-finding uncovered two important points. First, stakeholders confirmed that CDT is specifically designed for and used to represent dental procedures. Additionally, they stated that although SNOMED CT® and CPT-4/HCPCS as clinical terminologies are best for most other medical settings, those standards sparingly include dental procedure codes. Stakeholders indicated that CDT was far and above the best-suited standard to represent dental procedures because of its depth, breadth, and specific focus on these unique types of procedures. Second, they indicated that the current wording of Paragraph 15(i) in the Common MU Data Set definition would cause undue burden, and unnecessary work and costs for EHR technology developers who develop EHR technologies primarily to record dental procedures. Additionally, they asserted that the revision of this portion of the Common MU Data Set definition would significantly improve their ability to complete the testing and certification process in a timely manner. Further, stakeholders indicated that because Paragraph 15(i) requires EHR technology (designed either as comprehensive or stand-alone/supplemental offering) to represent

procedures using SNOMED CT® or CPT-4/HCPCS, EHR technology developers who primarily develop products for doctors of dental surgery and dental medicine would have to build those standards into their products, even though CDT would be more appropriate to represent dental procedures and better support these customers' specific coding needs.

Given the HIT Standards Committee's recommendation and the related fact-finding we conducted, we have decided to revise Paragraph 15 in the Common MU Data Set definition. This revision will allow EHR technology that has been primarily developed to record dental procedures to be tested and certified to CDT alone (for either a Complete EHR or EHR Module certification), rather than in addition to SNOMED CT® or CPT-4/HCPCS. Moreover, this change will enable EHR technology developers who serve customers with a need to record specific dental procedures to develop and seek testing and certification for EHR technologies without the previously mentioned burden and cost associated with supporting additional and less precise standards in their products. We emphasize, however, that this limited revision to the regulation is intended only for EHR technology that has been primarily developed to record dental procedures. In all other cases, EHR technology must continue to be tested and certified using SNOMED CT® or CPT-4/HCPCS to represent procedures.

Accordingly, we have revised Paragraph 15 of the Common MU Data Set definition at § 170.102 to include CDT in Paragraph 15(i) as a vocabulary standard to which EHR technology can be tested and certified to represent dental procedures (instead of SNOMED CT® or CPT-4/HCPCS) in the limited circumstance where EHR

technology is primarily developed to record dental procedures. ICD-10-PCS (now Paragraph 15(ii)) continues to be designated optional for testing and certification.

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 (5 U.S.C. 553(b)). However, we can waive the notice and comment procedure if we find good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporate a statement of the finding and the reasons in the final notice or rule that is issued (5 U.S.C. 553(b)(3)(B)).

Based on the HITSC's recommendation and our own fact-finding discussed above, we believe it would be contrary to the public interest to undergo notice and comment rulemaking to revise Paragraph 15 of the Common MU Data Set definition at § 170.102. It is our understanding from stakeholders that if this revision is not made in a timely manner, some EHR technology developers may not be able to achieve certification at all for their products and, as a result, may forgo seeking certification altogether. Such a result could significantly curtail the market for certified EHR technology developed to meet the needs of certain types of health care professionals (for example, doctors of dental surgery and dental medicine). Additionally, in cases where these EHR technology developers would forge ahead to get their products certified based on the current Common MU Data Set definition, we anticipate that they would incur unnecessary costs (which potentially could be passed on to customers) associated with incorporating SNOMED CT® or CPT-4/HCPCS into their products solely because they must

demonstrate compliance with these standards for certification. This change to the regulation will relieve a burden on some developers by allowing their products to be certified to CDT alone.

From the broader perspective of the Medicare and Medicaid EHR Incentive Programs, we believe that this revision to the Common MU Data Set definition will mitigate the risk that some EHR technology developers would limit or cease development of EHR technology specifically designed for doctors of dental surgery and dental medicine. If certified EHR technology designed to meet their specific needs is not available, these EPs may not qualify for EHR incentive payments and could be subject to future downward payment adjustments under Medicare. Additionally, the expected time it would take to complete the notice and comment rulemaking process could compromise the timely availability of 2014 Edition certified EHR technologies for doctors of dental surgery and dental medicine seeking to participate for the first time or continue their participation in the Medicare and Medicaid EHR Incentive Programs.

For the reasons stated, we believe that a notice and comment period would be contrary to the public interest. We therefore find good cause for waiving the notice and comment period to revise the Common MU Data Set definition.

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 does not need to 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 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 (RFA) (5 U.S.C. 601 et seq.), section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), and Executive Order 13132 on Federalism (August 4, 1999).

In following Executive Orders 12866 and 13563, we have determined that this interim final rule does not reach the economic threshold (\$100 million or more in any one year) such that a regulatory impact analysis (RIA) needs to be prepared. Thus, this rule is not considered a major rule and an RIA has not been prepared. This rule is not being treated as a “significant regulatory action” under section 3(f) of Executive Order 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget.

Similarly, with respect to the RFA, we do not believe that the change in this interim final rule with comment period alters any of the prior analyses we performed for the 2014 Edition Final Rule; and therefore, the Secretary certifies that this interim final rule with comment period will not have a significant economic impact on a substantial number of small entities.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues 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.

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 one year of \$100 million in 1995 dollars, updated annually for inflation. The current inflation-adjusted statutory threshold is approximately \$141 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.

List of Subjects in 45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Health care, Health information technology, Health records, Hospitals, Reporting and recordkeeping requirements, Public health.

For the reasons set forth in the preamble, the Department amends 45 CFR subtitle A, subchapter D, part 170 as follows:

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

1, 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.

2. Section 170.102 is amended by revising paragraph (15) of the Common MU Data Set definition to read as follows:

§ 170.102 Definitions.

* * * * *

Common MU Data Set

* * * * *

(15) Procedures –

(i) (A) At a minimum, the version of the standard specified in § 170.207(a)(3) or § 170.207(b)(2); or

(B) For EHR technology primarily developed to record dental procedures, the standard specified in § 170.207(b)(3).

(ii) Optional. The standard specified at § 170.207(b)(4).

* * * * *

Dated: October 24, 2013. _____

Kathleen Sebelius,

Secretary.

BILLING CODE: 4150-45-P

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