ONC HIT CERTIFICATION PROGRAM
Program Policy Guidance #14-01

I. Introduction

Program Policy Guidance #14-01 contains our annual guidance to ONC-Authorized Certification Bodies (ONC-ACBs) for the calendar year 2015 (CY15) surveillance period. ONC-ACBs are expected to conduct surveillance of the Complete EHRs and/or EHR Modules that they have certified. We issue annual guidance to ONC-ACBs to identify priority topics and specific elements of surveillance that we believe should be addressed in their annual surveillance plans. As outlined below, we expect CY15 surveillance and surveillance plans to cover the same aspects and prioritize the same elements as the CY14 surveillance plans while also including refinements and improvements based on ONC-ACBs' experiences implementing their CY14 surveillance plans.

We refer ONC-ACBs to Program Policy Guidance #13-01,[1] which remains applicable and provides general program guidance related to surveillance as well as our annual guidance for the CY14 surveillance plans. See also Establishment of the Permanent Certification for Health Information Technology; Final Rule, 76 Fed. Reg. 1262, 1281-1285 (Jan. 7, 2011).

II. Submission of Annual Surveillance Plan

ONC-ACBs must submit annual surveillance plans as required by 45 CFR 170.523(i). Annual surveillance plans describe an ONC-ACB's surveillance approach for the following calendar year. CY15 surveillance plans must be submitted to ONC by **September 30, 2014**. Extensions may be granted in limited circumstances and must be requested in writing with accompanying rationale. ONC will only accept electronic submissions of surveillance plans and requests for extensions. Plans and requests for extensions must be submitted via onc.certification@hhs.gov.

III. ONC-ACB Surveillance and Surveillance Plan Elements

The elements recommended by ONC for ONC-ACBs' CY15 surveillance plans are the same as those outlined below and explained in greater detail in Guidance #13-01 as applicable for CY14 surveillance plans.

A. ONC-ACB Surveillance Approach

An ONC-ACB's surveillance approach includes the assessment of whether the products (i.e., Complete EHRs and EHR Modules) it has certified continue to function as intended after they have been

[1] Guidance #13-01 (July 2013), available at http://www.healthit.gov/sites/default/files/onc-acb_2013annualsurveillanceguidance_final_0.pdf.

implemented in a production or "live" environment.[2] Guidance #13-01 describes the activities that we expect ONC-ACBs to include as part of their surveillance approach. These include:

- Conduct surveillance initiated by complaints received from users of products the ONC-ACB has certified.[3]

- Conduct surveillance upon the issuance of a repeated number of inherited certified status requests.

- Systematically obtain and synthesize feedback from users of products the ONC-ACB has certified to determine if certain capabilities should be evaluated with the technology developer or with the user in the field, or both.

CY15 surveillance plans should describe in detail how the ONC-ACB will address these and other aspects of surveillance for the CY15 surveillance period. Within the overall approach identified, ONC-ACBs should describe how they will address (at a minimum) the detailed aspects of surveillance prioritized below in III.B. In addition, we expect that CY15 surveillance plans will incorporate refinements and improvements based on ONC-ACBs' experiences implementing their CY14 surveillance plans.

B. CY 2015 (CY15) Surveillance Plan Elements

For CY15, we expect ONC-ACBs to prioritize (at a minimum) the elements we identified as a priority in our CY14 surveillance guidance (Guidance #13-01, section III.C.). These include the nine capabilities specified within the following four categories, as described in Guidance #13-01, section III.C.: (1) exchange, (2) safety-related, (3) security, and (4) population management. We expect ONC-ACBs to cumulatively address these nine capabilities throughout the entire calendar year, meaning that each of these nine capabilities should be assessed at least once during the calendar year. The elements also include the ONC-ACB's assessment of EHR technology developers' complaint processes.

For the reasons we stated previously,[4] these elements continue to be of substantial interest to ONC. Therefore, we expect that CY15 surveillance plans submitted by ONC-ACBs will, in addition to describing an overall approach to surveillance, specifically address these prioritized items. ONC-ACBs should refer to Guidance #13-01 for a full listing and description of the prioritized items and detailed guidance for incorporating them in their CY15 annual surveillance plans.

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[2] In consultation with the HHS Office for Civil Rights, we clarified that ONC-ACBs meet the definition of a "health oversight agency" under the HIPAA Privacy Rule when they conduct surveillance in accordance with the requirements of their accreditation and the ONC HIT Certification Program rules at 45 CFR 170 Subpart E. See ONC Regulation FAQ #45 [12-13-045-1] (available at http://www.healthit.gov/policy-researchers-implementers/45-question-12-13-045).

[3] When ONC receives a user complaint about certified EHR technology, ONC's general practice is to forward the complaint to the ONC-ACB responsible for performing surveillance for that product under the ONC HIT Certification Program.

[4] See Guidance #13-01 at p.3, n.2.

IV. Submission of Annual Surveillance Results

ONC-ACBs must annually report surveillance results to the National Coordinator as required by 45 CFR 170.523(i). We expect that the procedures developed by ONC-ACBs for performing surveillance will provide EHR technology developers with an opportunity to give input to an ONC-ACB, where appropriate, regarding surveillance results prior to reporting the results to the National Coordinator. We strongly encourage ONC-ACBs to work with developers to review and validate surveillance results prior to submission to ONC.

Guidance #13-01 describes the information we expect ONC-ACBs to document and report annually as part of its surveillance results, including information about developers' complaint processes, identifying information about the products that the ONC-ACB surveilled during the surveillance period, and, where applicable, the reasons for the failure of these products to function properly. We expect CY15 surveillance plans to provide for the accurate recordation and reporting of this information, as described my fully in our earlier guidance.

A. Content Limitation

In reporting the results of its surveillance, an ONC-ACB should **NOT** under any circumstances include information in its surveillance results that would identify a health care provider(s) or practice site. For further instructions, see Guidance #13-01.

B. Due Date and Submission Method

CY15 surveillance results are due to ONC by **February 29, 2016**. Extensions may be granted in limited circumstances and must be requested in writing with accompanying rationale. ONC will only accept electronic submissions of surveillance results and requests for extensions. Surveillance results and requests for extensions must be submitted via onc.certification@hhs.gov.

V. ONC HIT Certification Program Transparency

ONC-ACBs are strongly encouraged to make their annual surveillance plans and surveillance results publicly available after submission to ONC. We believe making this information publicly available will help strengthen the overall value stakeholders will be able to get from the ONC HIT Certification Program. We will continue to work with ONC-ACBs and the ONC-Approved Accreditor to mature and refine this portion of the ONC HIT Certification Program and may issue additional guidance as necessary.