ONC HIT CERTIFICATION PROGRAM
Program Policy Guidance #13-01

I.   Introduction

In the Permanent Certification Program Final Rule ("PCP Final Rule"), we stated that ONC-Authorized Certification Bodies (ONC-ACBs) would be expected to conduct surveillance of the Complete EHRs and/or EHR Modules that they have certified. 76 FR 1282. We explained that surveillance is a requirement of ISO Guide 65[1] (incorporated by reference in 45 CFR §170.599), the international standard to which ONC-ACBs must conform in order to obtain and maintain accreditation under the ONC HIT Certification Program. We also stated that we expected to issue annual guidance to ONC-ACBs to identify ONC priority topics and specific elements of surveillance that we believe should be addressed in their annual surveillance plans. 76 FR 1283. We noted that "…guidance could include topics that would be consistent from year to year, but that it might also include specific focus areas in certain cases, such as when a new certification criterion has been adopted that we believe is important to assess."

Program Policy Guidance #13-01 provides additional general program guidance related to surveillance and ONC's annual guidance for ONC-ACB calendar year (CY) 2014 surveillance plan submissions.

II.   Submission of Annual Surveillance Plan

A. Background

Section 170.523(i) within title 45 of the Code of Federal Regulations (CFR) requires an ONC-ACB to submit an annual surveillance plan to the National Coordinator.

B. "Annual" Performance Period Defined

While ONC-ACBs must develop surveillance plans for the purposes of accreditation, we intend for the annual surveillance plans referenced in 45 CFR 170.523(i) to cover a calendar year (e.g., CY 2014). Thus, any annual surveillance plan submitted by an ONC-ACB in accordance with section 170.523(i) should cover a calendar year.

C. Due Date and Submission Method

Surveillance plans must be submitted to ONC by the last business day in September of each year preceding the next calendar year that is covered by the surveillance plan. For example, CY 2014 surveillance plans must be submitted by September 30, 2013. Extensions will be granted in limited circumstances and must be made 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.

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[1] ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, incorporated by reference in 45 CFR §170.599.

III. ONC-ACB Surveillance and Surveillance Plan Elements

A. Background

In the PCP Final Rule, we stated that we anticipated issuing guidance on an annual basis in order to identify specific elements of surveillance that we consider to be a priority. 76 FR 1283. We also stated that "…the guidance could specify as a priority specific capabilities required by an adopted certification criterion (e.g., electronic prescribing) or categories of capabilities required by adopted certification criteria (e.g., 'safety-related' capabilities, which could include computerized provider order entry (CPOE); clinical decision support (CDS); drug-drug, drug-allergy interaction checks; electronic prescribing; and other similar capabilities required by adopted certification criteria)."

Additionally, we stated our expectation that annual surveillance plans submitted by ONC-ACBs "will be based on and consistent with the requirements of an ONC–ACB's accreditation." 76 FR 1284. Thus, this guidance is meant to complement and does not alter the conditions under which the ONC-ACB was granted its accreditation by the ONC-Approved Accreditor (ONC-AA). Per 45 CFR 170.503(e), the ONC-AA is charged (among other responsibilities) with: "verify[ing] that ONC-ACBs are performing surveillance in accordance with their respective annual plans;" and "review[ing] ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs with the conditions of their respective accreditations."

Last, in the Health Information Technology (HIT) Patient Safety Action & Surveillance Plan issued by ONC, we stated that we would provide guidance to ONC-ACBs on their surveillance responsibilities associated with the complaint records that EHR technology developers are required to keep and make available to them as a condition of their accreditation under the ONC HIT Certification Program. We noted that ONC-ACBs are accredited to Section 15 of ISO Guide 65, which instructs an ONC-ACB to ensure that an EHR technology developer "keeps a record of all complaints made known to the [EHR technology developer] relating to a product's compliance with requirements of the relevant standard and to make these records available to the certification body when requested." Section 15 also requires that the EHR technology developer "take appropriate action with respect to such complaints and any deficiencies found in products or services that affect compliance with the requirements for certification; and document the actions taken."

B. ONC-ACB Surveillance Approach

We stated in the PCP Final Rule our expectation that part of an ONC-ACB's surveillance approach would involve the assessment of whether the Complete EHRs and EHR Modules it had certified continue to function as intended after they have been implemented in a production environment (i.e., "live" in the field by eligible professional, eligible hospital, or critical access hospital). 76 FR 1282.

To further illustrate as part of this guidance the full breadth of activities that we expect to be part of an ONC-ACB's surveillance approach, we request that ONC-ACBs address the following aspects of surveillance in their annual surveillance plans. ONC-ACB should explain how they will:
- Conduct surveillance initiated by complaints received by an ONC-ACB from a user (e.g., doctor, hospital, group practice) of an EHR technology the ONC-ACB has certified. We expect ONC-ACBs to address in their plans how and when such complaints would require an evaluation of the EHR technology as implemented in the field.

- Conduct surveillance upon the issuance of a repeated number of inherited certified status requests (pursuant to 45 CFR 170.545(d) and 45 CFR 170.550(f)). For example, after the issuance of the fifth inherited certified status request to an EHR technology.
- Systematically obtain and synthesize feedback from users of EHR technology that the ONC-ACB has certified to determine if certain capabilities should be evaluated with the EHR technology developer or with the user in the field, or both.

For all of these aspects, we expect ONC-ACBs to, at a minimum, prioritize the elements specified in section III.C directly below as part of their overall surveillance approach.

C. CY 2014 (CY14) Surveillance Plan Elements

ONC has prioritized the following four categories of capabilities adopted as part of the 2014 Edition EHR certification criteria for ONC-ACBs to include in their CY14 surveillance plans: (1) exchange capabilities; (2) safety-related capabilities; (3) security capabilities; and (4) population management capabilities.[2] For these four categories, we clarify that we expect ONC-ACBs to cumulatively address the nine capabilities specified within these four categories throughout the entire calendar year. That is, an ONC-ACB may perform surveillance according to a subset of the capabilities when performing surveillance of a particular EHR technology, but should assess each of these nine capabilities at least once during the calendar year. For example, an ONC-ACB could conduct surveillance on EHR technology A to three of the nine capabilities listed, three different on EHR technology B, and the final three on EHR technology C.

1. Exchange

The following certification criteria related to care coordination are prioritized for CY14 ONC-ACB surveillance plans:
- 45 CFR 170.314(b)(2) (Transitions of care–create and transmit transition of care/referral summaries).
- 45 CFR 170.314(e)(1) (View, download, and transmit to 3rd party).

These certification criteria focus on facilitating care coordination through the secure electronic exchange of health information between multiple providers and between providers and patients.

2. Safety-related

The following safety-related capabilities are prioritized for CY14 ONC-ACB surveillance plans:
- 45 CFR 170.314(a)(1) (Computerized provider order entry).
- 45 CFR 170.314(a)(2) (Drug-drug, drug-allergy interaction checks).[3]
- 45 CFR 170.314(b)(4) (Clinical information reconciliation). For this certification criterion we recommend that ONC-ACBs focus their surveillance on medication reconciliation.

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[2] These capabilities were prioritized based on several factors, including the likelihood that most eligible health care providers would have adopted EHR technology certified to these criteria to meet the Certified EHR Technology definition at 45 CFR 170.102; the capability's significance to interoperability, patient engagement, patient safety, and privacy and security as part of the Medicare and Medicaid EHR Incentive Programs; and recommendations to ONC from HHS' Office of the Inspector General (http://oig.hhs.gov/oas/reports/other/180930160.pdf).

[3] High-priority drug-drug interactions are those which involve drugs that should never be prescribed together. For the purposes of performing surveillance of EHR technology to the drug-drug, drug-allergy interaction checks certification criterion, we strongly encourage ONC-ACBs to review the high-priority drug-drug interactions identified by Phansalkar S, et al., J Am Med Inform Assoc 2012;19:735-743 and 2013;20:489-493 (available at http://jamia.bmj.com/content/19/5/735.full and http://jamia.bmj.com/content/20/3/489.long, respectively).

In the 2014 Edition Standards and Certification Criteria Final Rule ("2014 Edition Final Rule"), we concluded that the above capabilities are among those that "pose the greatest risk for patient harm and therefore the greatest opportunity for error prevention." 77 FR 54187. For this reason, we designated these and other similar capabilities as among those to which user-centered design (UCD) processes must be applied in order to obtain certification. 45 CFR 170.314(g)(3) (Safety-enhanced design).

3. Security

The following security capabilities are prioritized for CY14 ONC-ACB surveillance plans:
- 45 CFR 170.314(d)(2) (Auditable Events and Tamper-Resistance).
- 45 CFR 170.314(d)(7) (End-User Device Encryption).

These certification criteria establish security capabilities for EHR technology that protect patient health information and track unauthorized access to patient health information.

4. Population Management

The following certification criteria related to population management are prioritized for CY14 ONC-ACB surveillance plans:
- 45 CFR 170.314(c) (2) (Clinical quality measures – import and calculate). With regard to this specific criterion, surveillance plans could focus on the calculation of one or more specific clinical quality measures (CQMs).
- 45 CFR 170.314(a)(14) (Patient list creation).

These certification criteria focus on the EHR technology capabilities necessary to accurately calculate clinical quality measures as well as better understand the specific needs of certain patient populations.

EHR Technology Developer Complaint Processes

In addition to the four categories prioritized above, we have prioritized the assessment of EHR technology developers' complaint processes. We expect that CY14 surveillance plans submitted by ONC-ACBs will, in addition to describing an overall approach to surveillance, specifically address the surveillance of these prioritized items, which are of substantial interest to ONC.

We expect an ONC-ACB's surveillance plan to identify how the ONC-ACB will assess EHR technology developers' complaint processes specifically related to complaints submitted in reference to safety-related capabilities (i.e., the eight certification criteria specified by the safety-enhanced design certification criterion, 45 CFR 170.314(g)(3)). ONC expects ONC-ACBs' surveillance plans to address how the ONC-ACB will assess whether an EHR technology developer's complaint process conforms to ISO Guide 65's Section 15 requirements. Further, we expect an ONC-ACB to confirm during its surveillance that the complaint process identified to the ONC-ACB (when the EHR technology was issued a certification) is the complaint process in place and that such process was followed when complaints were made. Last, we expect ONC-ACBs to determine, as best they can, the frequency of complaints made to EHR technology developers associated with the prioritized capabilities in Section III.C.1 through III.C.4.

D. The CY14 Surveillance Plan

In summary, ONC expects ONC-ACBs' CY14 Surveillance Plans to include a discussion of the following:
- The aspects of their surveillance approach identified in Section III.B
- How they will reflect the evaluation of the prioritized elements in Section III.C within the different aspects of surveillance identified in Section III.B

IV.   Submission of Annual Surveillance Results

A. Background

Pursuant to 45 CFR 170.523(i), an ONC-ACB must annually report surveillance results to the National Coordinator.

B. Opportunity for EHR Technology Developer Input Prior to Submission of Surveillance Results

As we stated in the PCP Final Rule, 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 the surveillance results obtained by the ONC-ACB prior to it reporting such results to the National Coordinator." 76 FR 1284. Thus, we reiterate in this guidance and strongly encourage ONC-ACBs to work with developers to review and validate surveillance results prior to the ONC-ACB's submission to ONC.

C. Surveillance Results Reporting

1. Prioritized Capabilities

When submitting annual surveillance results in accordance with 45 CFR 170.523(i), ONC-ACBs are responsible for identifying the certified Complete EHR or certified EHR Module that was subject to surveillance and, where applicable, "the reason(s) behind a Complete EHR or EHR Module's failure to function properly, such as an implementation error, a misapplication by a user, or other factors." 76 FR 1283. ONC-ACBs should document an affirmative finding based on all available evidence and describe the substantial factors that, in its assessment, may have caused or contributed to the failure (or apparent failure) of the Complete EHR or EHR Module to function properly. This assessment should indicate whether the Complete EHR or EHR Module did in fact fail to function as expected. In situations where the EHR technology developer whose Complete EHR or EHR Module was subject to surveillance offers an explanation for the EHR technology's actual (or apparent) failure, the ONC-ACB should indicate its concurrence (or non-concurrence) with the developer's explanation. If an ONC-ACB is unable to determine fully the reason(s) behind a Complete EHR or EHR Module's failure to function properly, it should provide an explanation as to why the results of its surveillance were inconclusive. In addition, ONC-ACBs should identify whether surveillance was initiated randomly or due to the receipt of a complaint from an EHR technology user.

When identifying each certified Complete EHR or certified EHR Module that was subject to surveillance, we encourage and recommend that ONC-ACBs identify each certified Complete EHR or certified EHR Module by its Certified Health IT Products List (CHPL) product number. Alternatively, an ONC-ACB may identify each certified Complete EHR and certified EHR Module by product name, developer, product classification (Complete EHR or EHR Module), product type (ambulatory or inpatient), and product version.

2. Complaint Processes

When submitting annual surveillance results, ONC-ACBs are expected to identify for each EHR technology developer whose EHR technology was subject to surveillance during the applicable calendar year:

- The extent to which the EHR technology developer followed its complaint process, and any observed deficiencies with its process;
- The frequency of complaints made to EHR technology developers associated with the prioritized capabilities in Section III.C.1 through III.C.4

This applies to all EHR technology developers whose EHR technology was subject to surveillance during the applicable calendar year, regardless of the circumstances that triggered surveillance (e.g., whether the surveillance was conducted at random or in response to a complaint from an EHR technology user).

3. Content Limitations

The contents of an ONC-ACB's annual surveillance results should be limited solely to those aspects that pertain to the EHR technologies subjected to surveillance during the calendar year covered by the surveillance plan. In instances where an ONC-ACB conducts surveillance of EHR technology implemented or used by a specific health care provider at their practice site, or where the ONC-ACB has reviewed complaints submitted to an EHR technology developer by one or more health care providers, the ONC-ACB should **NOT** under any circumstances include any information in its surveillance results that would identify the health care provider(s) or practice site.

D. Due Date and Submission Method

Annual surveillance results are due to ONC by the last business day in February of the year following the calendar year that is covered by the surveillance plan. For example, CY14 surveillance results will be due on February 27, 2015. Extensions will be granted in limited circumstances and must be made 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. Given that this is the first year in which ONC has issued surveillance guidance under the ONC HIT Certification Program and also the first time ONC-ACBs will have had to develop and submit surveillance plans and surveillance results, we will continue to work with ONC-ACBs and the ONC-Approved Accreditor (American National Standards Institute (ANSI)) to mature and refine this portion of the ONC HIT Certification Program.