

March 15, 2010

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology (ONC)
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave., SW.
Washington, DC 20201
RIN 0991-AB58

Subject: PHDSC Response to ONC's IFR on Standards, Implementation Specifications and Certification Criteria for Electronic Health Record Technology

The *Public Health Data Standards Consortium* (PHDSC, The Consortium) is a national non-profit membership-based organization of federal, state and local public health agencies, professional associations, academia, public and private sector organizations, international members, and individuals. The Consortium is committed to bringing a common voice from the public health community to the national efforts of standardization of health information technology and population health data in order to improve individual and community health.

On behalf of the Consortium and its members, we appreciate the opportunity to review and comment on the recently published Interim Final Rule (IFR) by ONC on Standards, Implementation Specification and Certification Criteria for Electronic Health Record Technology.

We want to acknowledge the efforts that both ONC and the Centers for Medicare & Medicaid Services (CMS) have made to develop a comprehensive and coordinated set of regulations covering both the standards and certification criteria and the meaningful use and incentives program related to the adoption and use of certified EHR technology. The unprecedented level of cross-agency coordination to address such an extensive, complex and sensitive area, within a very tight timeframe, and in such a careful and detailed manner is quite well reflected throughout the two sets of regulations.

We applaud ONC efforts to define a set of national interoperable electronic standards and implementation specifications that are applicable to electronic health record systems and health

information technology in support of the electronic exchange of health information. We also appreciate ONC efforts to define a series of base-level criteria for the certification of EHRs.

In particular, we want to applaud and strongly support ONC's decision to 1) include "***improve population and public health***" as one of the health outcome policy priorities of the program; 2) define "***communicate with public health agencies***" as a care goal for this policy priority; and 3) define a set of standards, implementation specifications and certification criteria associated with this care goal required in order to certify EHR technologies.

While we have several comments on more specific issues noted below, we want to provide here some overarching, high priority items for consideration.

GENERAL COMMENTS:

1. Ensure that the three population and public health priority areas already included in both regulations are maintained for Stage 1.

We strongly support the decision by ONC and CMS to focus, during Stage 1 of the program, on three main priority areas within the overall health outcome policy priority of improving population and public health. Namely, the ability to electronically submit data to immunization registries, reportable lab results to public health agencies, and syndromic surveillance data to public health agencies. We believe that these activities are some of the most fundamental and foundational data exchanges between clinical care and public health, support patient care as well as population and public health improvements, and can significantly benefit from wide adoption of the standards being adopted and the meaningful use requirements being proposed. Furthermore, we believe many public health agencies are ready (and many more can become ready by the time of implementation) to support these data exchanges. We also believe that any attempts to drop, eliminate, or make these basic three requirements elective will significantly undermine efforts already underway to capture and exchange this information electronically.

Recommendation 1: Maintain the three population and public health priority areas for which standards, certification criteria and meaningful use requirements are set for Stage 1 of the program and do not drop or eliminate them or make any of the three elective. Furthermore, we recommend that a percentage of all federally funded HIE/HIT projects is set aside to address these three public health priority areas.

2. Use the HL7 EHR Functional Model Conformance Criteria to identify data sets that support EHR-based clinical health information exchanges as well as clinical and public health information exchanges.

With the support from the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), the PHDSC has been facilitating the re-evaluation of the HL7 EHR Functional Model from Public Health perspectives.¹ Over 100 public health professionals

¹ Public Health Data Standards Consortium (PHDSC). Electronic Health Record – Public Health Task Force. Re-evaluation of the HL7 EHR Functional Model from Public Health Perspectives. URL: http://www.phdsc.org/health_info/ehr-task-force.asp

participate in this project. In this effort, participants have been re-evaluating data elements that need to be collected in EHR systems for public health reporting. These include demographic data, risk factor data (e.g., smoking status), occupational data, functional status data, birth and death records data, test data and others. The participants recommend that the HL7 EHR Functional Model Conformance Criteria should serve as a framework for supporting data sets for health information exchanges (HIEs) between clinical EHR systems and public health information systems. This approach in identifying, assembling and maintaining clinical and public health data sets can enable an organized, standard-based way of managing information exchange content within the most commonly used information exchange standard (HL7).

Recommendation 2: We recommend that ONC, the HIT Policy Committee, the HIT Standards Committee, NCVHS and other appropriate federal advisory committees use the HL7 EHR Functional Model Conformance Criteria for future definition of data sets that support EHR-based clinical data exchanges, including electronic exchanges of health information between clinical care and public health.

COMMENTS ON CERTIFICATION CRITERIA:

3. Support adopted certification criteria related to public health reporting

We strongly support the adopted EHR certification criteria in the IFR related to the three public health reporting requirements. We believe they are appropriately discussed and defined. Our only recommendation is to add the word ‘modify’ to all three criteria.

Recommendation 3 We recommend including ‘modify’ to each of the three certification criteria (immunization reporting, reportable lab reports, syndromic surveillance data), as follows: “Electronically record, modify, retrieve, and transmit...”

4. Modify certification criterion on Immunization Reporting

As described in the Standards and Implementation Specification Comments section below, we support the standards adopted in the IFR for electronic submission of immunization data, including for content the HL7 2.3.1 and, alternatively, HL7 2.5.1, and for vocabulary the CVX code, version 2009.

We are concerned that during Stage 1 there will be two standards for messaging (HL7 2.3.1 and HL7 2.5.1) and that the certification criteria allow the support of either of the two standards OR the ‘applicable state-designated standard format’. We strongly recommend eliminating the option of a state-designated standard format from this certification criterion, and only allowing the two content standards adopted in the IFR (HL7 2.3.1 or HL7 2.5.1).

Recommendation 4: Eliminate from the text of the description of the certification criterion for immunization data submission the option of allowing ‘applicable state-designated standard format’.

5. Include additional demographic data elements

We strongly support the EHR certification criteria related to *Record Demographics*, and explicitly calling out preferred language, insurance type, gender, race, ethnicity, and date of birth. We recommend, though, that two additional elements be called out: current occupation and education status

Recommendation 5: Include in the certification criteria for recording demographics the occupation and education status of patients

6. Include the capability to record Functional Status

We strongly recommend that EHR certification criteria include the ability to record, modify and retrieve Functional Status information about a patient.

Recommendation 6: Include a certification criterion that requires EHRs to enable users to electronically record, modify, and retrieve a patient's functional status in accordance with the standard recommended below (see Comments on Standards)

7. Include additional certification criteria related to Vital Records and Newborn Screening

Vital Records: We strongly recommend that certification criteria be added to ensure that EHRs enable users to record and retrieve medical data for the birth certificate and submit such data electronically to public health agencies, consistent with birth certificate reporting requirements. It is important to point out that not all information needed to populate the birth certificates will come from EHRs. Similarly, we strongly recommend that certification criteria be added to ensure that EHRs are capable of providing information needed to prepare a certification of cause of death.

Newborn Screening (Bloodspot Testing): We also strongly recommend that certification criteria be added to ensure that EHRs enable users to record laboratory orders for the newborn bloodspot testing, to submit such data electronically to laboratories including public health laboratories, and retrieve laboratory results consistent with newborn screening reporting and information exchange requirements.

Newborn Screening (Early Hearing Detection and Intervention): We also strongly recommend that certification criteria be added to ensure that EHRs enable users to capture and report newborn hearing test data electronically to public health early hearing detection and intervention programs consistent with reporting requirements; and to be able to retrieve care plans for children with abnormal test results, with risk factors for delayed and progressive hearing loss, or whose hearing screening was not completed.

Recommendation 7.1: Include a certification criterion that requires EHRs to enable users to electronically record, retrieve and electronically submit appropriate medical data on the birth certificate to public health agencies.

Recommendation 7.2: Include a certification criterion that requires EHRs to enable users to electronically record and retrieve information needed to support certification of cause of death.

Recommendation 7.3: We recommend that the electronic transmission standard for birth certificate information to public health agencies be included in the Stage 2 - 2013 standards.

Recommendation 7.4: We recommend that the electronic transmission standards for exchange of newborn bloodspot screening information with public health agencies be included in the Stage 2 - 2013 standards.

Recommendation 7.5: We recommend that the electronic transmission standards for exchange of newborn hearing information with public health agencies be included in the Stage 2 - 2013 standards.

8. Establishing 2013 certification criteria for EHR systems to support and use ICD-10 code sets

We strongly recommend that ONC formally establish certification criteria for 2013 for EHRs to support and use ICD-10 code sets as one of the defined national content/vocabulary standards for 2013, consistent with the current HIPAA requirements (see below a related recommendation on the Standards and Implementation Specification section of the letter).

Recommendation 8: Establish certification criteria for EHR systems to support and use ICD-10 code sets in 2013.

COMMENTS ON STANDARDS AND IMPLEMENTATION SPECIFICATIONS:

9. Support adopted standards for immunization data reporting to immunization registries

We strongly support the standards adopted in the IFR for electronic submission of immunization data, including for content the HL7 2.3.1 and, alternatively, HL7 2.5.1, and for vocabulary the CVX code, version 2009. We are concerned that during Stage 1 there will be two standards for content and that the certification criteria allows the support of either of the two content standards OR the ‘applicable state-designated standard format’. We have made recommendations above related to the certification criterion (eliminating the state-designated standard format option). We understand that having two adopted standards will be the most practical and achievable approach for Stage 1, but strongly recommend that a single standard be adopted for Stage 2 and that the certification criteria for Stage 2 be appropriately adjusted to match such one single national standard.

Recommendation 9: Define a single standard for electronic submission of immunization data for Stage 2 – 2013 of the program.

10. Support adopted standards for lab results reporting to public health

We strongly support the standards adopted in the IFR for electronic submission of lab results to public health agencies, including for content the HL7 2.5.1, and for vocabulary the LOINC codeset version 2.27 (when such codes were received within an electronic transaction from a laboratory).

Recommendation 10: Support standard adopted for lab reporting

11. Support adopted standards for surveillance or reporting submissions to public health

We support standards adopted in the IFR for electronic submission to public health agencies for surveillance or reporting, namely the HL7 2.3.1 and, alternatively, the HL7 2.5.1.

We are concerned that the standard applies to both surveillance-related submissions (for which the IFR specifically adopts a certification criterion) and ‘reporting’ related submission. We recommend clarification of the meaning of ‘reporting’ in this context.

Recommendation 11: Clarify the meaning of ‘reporting’ to which the adopted standard will apply.

12. Adopt a standard for Functional Status (to go along with certification criteria noted above)

We recommend that ONC adopt the International Classification for Functioning, Disability and Health (ICF) from the World Health Organization to codify functional status. This will support the earlier recommendation to include a certification criterion for EHRs to enable users to record, modify, retrieve and transmit functional status of patients.

Recommendation 12: Adopt the International Classification for Functioning, Disability and Health (ICF) from the World Health Organization to codify functional status.

13. Definition of Preferred Language

We applaud the decision by ONC to require EHRs to enable users to capture and transmit preferred language of patients. While not explicitly noted in the IFR, we understand that the Secretary has named the ISO 639 standard for this data element. We also believe that there is no clear understanding of what preferred language is. Finally, we believe there is a deep lack of knowledge about the standards for preferred language.

The PHDSC representatives on the National Uniform Billing Committee (NUBC) have already championed changing the ANSI X12N Claim / Reporting transaction (837) to include **Preferred Language** data element. The change has been approved by ANSI X12. We are currently working with industry groups to develop an unambiguous definition for **Preferred Language** to be incorporated into the UB Specifications maintained by the NUBC.

We recommend the following:

Recommendation 13.1: Formally name in this regulation the ISO 639 as the standard to be used to document preferred language.

Recommendation 13.2: Provide a definition of preferred language. It is not clear what the meaning of preferred language is, nor the process for capturing it (who collects it, from whom, etc).

Recommendation 13.3: Provide educational and outreach opportunities for the industry to understand, widely adopt and be able to implement the standard for preferred language.

14. Naming ICD-10 code sets (ICD-10-CM and ICD-10-PCS) as standard vocabulary for 2013

We strongly recommend that ONC formally adopt the ICD-10 code sets as one of the defined national content/vocabulary standards for 2013, consistent with the current HIPAA requirements.

Recommendation 14: Adopt the Source of Payment Typology as the standard for codifying insurance type.

15. Naming the PHDSC Source of Payment Typology as the standard for the Insurance Type data element

The NPRM identifies **Insurance Type** data element for EHR meaningful use in stage 1 objectives for eligible professionals and hospitals.

The PHDSC created Source of Payment Typology value set² that has been recognized as an approved externally maintained standard by (HL7) and ANSI X12. There is also ongoing work to incorporate this value set in any future version of ANSI X12 implementation guides. Several state data organizations (Georgia, Oregon, and New York) have already implemented the PHDSC Source of Payment Typology. Their reason for choosing the PHDSC Typology as the replacement for other value sets is its hierarchical structure of the relationship among payer categories. These relationships provide the basis for states to use the typology and to add lower levels of granularity for state-specific purposes while still maintaining a standard that can be used to compare data across states or for combining states' data to make national data sets. Another significant advantage of the PHDSC Typology over existing value sets is the comprehensive definition of terms that does not exist in any of the existing value sets we have examined.

Recommendation 15: Adopt the Source of Payment Typology as the standard for codifying insurance type.

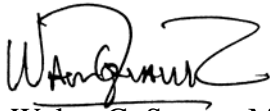
While not specifically related to this IFR, one additional comment and recommendation we would like to offer is related to the State HIE Cooperative Agreements currently being implemented by ONC. We strongly believe that state HIE plans should adequately address public health capacity for electronic health information exchanges, in particular those related to

² Public Health Data Standards Consortium (PHDSC). Source of Payment Typology. URL: <http://www.phdsc.org/standards/payer-typology.asp>

the three priority areas defined in this IFR and the CMS NPRM regulations. Thus, we recommend that ONC consider requiring that state HIE plans include assurances that public health agencies will have the support to achieve HIE capabilities in support of, at least, the three states objectives.

We appreciate again the opportunity to offer these comments and recommendations. Should you have any questions about any of the items covered in this letter please do not hesitate to contact Dr. Anna Orlova, Executive Director of the Consortium at 410-614-3463 or aorlova@jhsph.edu.

Sincerely,

A handwritten signature in black ink, appearing to read 'Walter G. Suarez', with a stylized flourish at the end.

Walter G. Suarez, MD, MPH
President

cc Board of Directors
CMS Attn CMS-0033-P