

March 15, 2010

Department of Health and Human Services
Centers for Medicare & Medicaid Services (CMS)
Attention: CMS-0033-P
P.O. Box 8013
Baltimore, MD 21244-8013
File Code CMS-0033-P

Subject: PHDSC Response to the CMS NPRM on Medicare and Medicaid Electronic Health Record Incentive Programs and Meaningful Use Criteria

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 Notice of Proposed Rule Making (NPRM) by CMS on the Medicare and Medicaid Electronic Health Record Incentive Programs and Meaningful Use Criteria.

We want to acknowledge the efforts that both CMS and the Office of the National Coordinator for Health Information Technology (ONC) 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 CMS efforts to create the incentive programs called for in the ARRA- HITECH Act of 2009 aimed at ensuring the adoption and meaningful use of certified EHR technologies by eligible professionals and hospitals. We also applaud CMS decision to define first a series of health outcome policy priorities for the programs, identify then a series of care goals within each policy priority, and then propose a set of standards, certification criteria and meaningful use

measures for each these care goals (following recommendations from the HIT Policy Committee).

In particular, we want to applaud and strongly support CMS's decision to 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 meaningful use measures associated with this care goal to be achieved by users of certified EHR technologies in order to receive incentives from the program.

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. Support Staged Approach for Meaningful Use Criteria,

We strongly support CMS decision to use a staged approach to phase-in the requirements for demonstrating meaningful use. We believe it achieves an orderly, progressive, and incremental transition to adopting certified EHR technology and, more importantly, demonstrating its meaningful use.

Recommendation 1: Maintain the staged approach for meaningful use criteria.

2. 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 conditional or elective will significantly undermine efforts already underway to capture and exchange this information electronically.

Recommendation 2: 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.

3. Retain states' abilities to add additional objectives to the definition of meaningful use.

States should have the ability to add new objectives or refine how existing objectives are measured, given specific state health program priorities.

Recommendation 3: Retain states' ability to add additional objectives of meaningful use or modify how the existing objectives are measured.

SPECIFIC COMMENTS ON MEANINGFUL USE AND INCENTIVE PROGRAMS:

4. Change in the Recording Smoking Status MU Objective and Measure.

The current wording for the Recording Smoking Status MU objective and measure set lists the age requirement of patients at 13. We recommend reducing the age to 12 years or older, aligning the CMS measure with tobacco use statistics.

Recommendation 4: Reduce the patient age threshold for recording smoking status from 13 to 12 on both the MU Objective and Measure.

5. Change in the description of the Immunization Reporting MU Objective.

The current wording for the EP and Hospital reporting requirement to immunization registries Objective conditions the requirement to "... where required and accepted...". We recommend deleting the "required" portion of the provision, given that in many states, data exchange laws *allow* sharing of immunization data.

Recommendation 5: Delete the words 'where required and accepted' from the Immunization Data Objective, and adding "according to applicable law and practice." This is less confusing language and will make it consistent with the syndromic surveillance objective,: "Objective: Capability to submit electronic data to immunization registries and actual submission ~~where required and accepted~~, according to applicable law and practice"

6. Using consistent language on Immunization Reporting MU Measure.

We recommend adding the following wording to the end of the Immunization Reporting MU Measure: "according to applicable law and practice". This will make it consistent with the wording being used in the syndromic surveillance reporting MU Measure.

Recommendation 6: Add the following wording to the Immunization Reporting MU Measure: "Performed at least one test of certified EHR technology's capability to submit electronic data to immunization registries, according to applicable law and practice."

7. Eliminating the conditional provision on MU Measures for both Syndromic Surveillance and Lab Reporting to Public Health.

We recommend deleting the conditional clause on both MU Measures for Syndromic Surveillance and Lab Reporting to Public Health, as we believe this will be confusing for all parties; may undermine the sense of urgency for public health agencies to be ready for the 2011 objectives; and may potentially undermine EP/hospital commitment to public health reporting through this incentive program.

Recommendation 7.1: Remove conditional text from the Syndromic Surveillance Reporting MU Measure, as follows: “Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies ~~(unless none of the public health agencies to which the EP, eligible hospital or CAH submits such information have the capacity to receive the information electronically).~~”

Recommendation 7.2: Remove conditional text from the Lab Reporting to Public Health MU Measure, as follows: “Performed at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies ~~(unless none of the public health agencies to which the eligible hospital submits such information have the capacity to receive the information electronically).~~”

ADDITIONAL COMMENTS ON MEANINGFUL USE AND INCENTIVE PROGRAMS:

8. Additional demographic data elements

We strongly support the EHR requirement to *Record Demographics*, and the explicit call-out of 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 8: Include in the certification criteria for recording demographics the occupation and education status of patients

9. Capability to record Functional Status

We strongly recommend EHRs be required to have the ability to record, modify and retrieve Functional Status information about a patient.

Recommendation 9: Include a requirement for EHRs to electronically record, modify, and retrieve a patient's functional status.

10. Additional EHR requirements for Vital Records and Newborn Screening

We strongly recommend that the final rule on the incentive programs and meaningful use include two additional public health requirements for EHRs as follows:

Vital Records: To be able 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): To be able to capture and, report 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 requirements.

Newborn Screening (Early Hearing Detection and Intervention): To be able to capture and, report newborn hearing test data electronically to public health early hearing detection and intervention programs consistent with reporting requirements; 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 10.1: Include a meaningful use objective for users of certified EHR technologies to electronically record and retrieve medical data needed to be reported to public health agencies.

Recommendation 10.2: Include a meaningful use objective for users of certified EHR technologies to electronically record and retrieve information needed to support certification of cause of death.

Recommendation 10.3: We recommend that the electronic transmission standards for birth certificate information to public health agencies be included in the Stage 2 - 2013 standards.

Recommendation 10.4: 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 10.5: 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.

11. Definition of Preferred Language

We applaud the decision by CMS to require EHRs to capture and transmit the 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 11.1: Provide a definition of preferred language. It is not clear what is the meaning of “preferred language”, nor is the process for capturing it (who collects it, from whom, etc) clear.

Recommendation 11.2: Provide educational and outreach opportunities for the industry to understand, widely adopt, and be able to implement the standard for preferred language.

12. 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 set¹ 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 12: Require in the final regulations that to codify insurance type, eligible professionals and hospitals must use the Source of Payment Typology developed by the Public Health Data Standards Consortium.

13. We recommend setting a certification process and developing testing tools to enable certification of EHR products for Meaningful Use to support electronic data exchanges with public health authorities.

The NPRM specifies provider’s self-attestation as a way to certify ability to submit electronic data to public health information systems (immunization registries, public health information

¹ Public Health Data Standards Consortium (PHDSC). Source of Payment Typology. URL: <http://www.phdsc.org/standards/payer-typology.asp>

systems that will receive electronic laboratory data, syndromic surveillance systems). To enable self-attestation, there are needs to set up the certification process including the audit capacities, and develop conformance and compliance testing tools for public health reporting/information exchanges with EHR systems. State and local public health agencies need to participate in this effort to assure that local needs for information exchanges are met in the certified HIT products. We recommend the following activities to enable a public health component in HIT product certification and testing:

- **Setting Certification Process:** include public health representatives in developing and implementing the certification process for HIT products;
- **Develop Compliance Testing Tools:** Support participation of public health representatives in the ISO TS 14441 Effort – Security and Privacy Requirements for Compliance Testing of EHR Systems
- **Develop Conformance Testing Tools:** Support participation of public health information systems in the IHE Connectathon to test interoperability between EHR systems and public health information systems

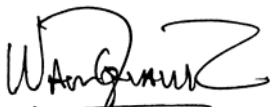
14. Establishing 2013 meaningful use metrics that demonstrate the adoption and use of ICD-10 code sets by provider EHR systems

We strongly recommend that CMS consider establishing meaningful use metrics for 2013 to ensure that EHR systems adopted by providers are utilizing the ICD-10 code sets. A corresponding set of recommendations related to certification criteria and standards were made to ONC.

Recommendation 8: Establish 2013 meaningful use metrics that demonstrate the adoption and use of ICD-10 code sets by providers in their EHR systems.

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,



Walter G. Suarez, MD, MPH
President

cc Board of Directors
ONC - RIN 0991-AB58