



Leaders in Applied Public Health Epidemiology

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CSTE is an organization that supports epidemiologists practicing at the state, territorial, tribal, and local levels.

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March 15, 2010

Charlene Frizzera

Acting Administrator

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David Blumenthal, MD, MPP

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RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program [CMS-0033-P]; Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology [RIN 0991-AB58]

Ms. Frizzera and Dr. Blumenthal:

This letter contains recommendations from the Council of State and Territorial Epidemiologists (CSTE), an organization of member states and territories representing public health epidemiologists. CSTE and all public health epidemiologists at state and local public health agencies have a vested interest in the successful implementation of health information technology and electronic health records as it will facilitate the timeliness and completeness of transfer of critical information from the clinical care sector to public health that is needed to recognize, monitor and respond to events of public health importance. This rapid and complete information sharing is critical to the collaboration of the clinical and public health sectors in responding to such events. The presence of public health requirements in all of the stages of implementation is crucial to achieve purpose 7 as specified in the HITECH Act, "improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks". CSTE has encouraged its members to submit individual state agency comments as we feel public health is extremely vested in the successful implementation of health information technology.

1. **Fully retain the proposed objectives and measures around reporting to public health agencies** under the Improve Population and Public Health policy priority area. We believe it is necessary, reasonable and justified to not reduce or in any way diminish these objectives and measures, such as offering the option for eligible professionals (EPs) and hospitals to defer until 2013, because:
 - The three objectives related to public health are already very limited in scope, requiring EPs and hospitals only to test the capability of their systems to report uni-directionally with public health. Actual reporting is already occurring across much of the country for laboratory and immunization data, and is growing in terms of syndromic surveillance data.
 - Both laboratory and immunization reporting are important for population health improvement and to support improvements in clinical care outcomes, coordination of care and other areas of interest to CMS and ONC. Experience during the recent H1N1 pandemic has shown the utility of real-time syndromic surveillance information to support public health, clinical decision-making and emergency response.
2. **Clearly confirm that CMS will approve State Health Agency adoption of actual submission criteria in Stage 1.** The CMS NPRM defines Stage 1 meaningful use criteria as focused “on electronically capturing health information in a coded format; and reporting clinical quality measures and public health information” [CMS NPRM preamble section II.A.2.c]. We believe that State Health Agencies (SHAs) which are now capable of receiving health information exchange (HIE) will want to require such submissions of public health information (e.g., immunization data, laboratory results, syndromic surveillance data) to occur. Proposed rule language of the population/public health objectives indicates that demonstration of actual submission is an appropriate state-specific more-stringent requirement in Stage 1: “Capability to submit electronic data to immunization registries and actual submission where required and accepted” [42 CFR part 495.6(c)(15)(i)], “Capability to provide electronic submission of reportable lab results (as required by State or local law) to public health agencies and actual submission where it can be received” [495.6(e)(6)(i)], and “Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice” [495.6(c)(16)(i)].
3. **Delete clauses in electronic laboratory reporting and syndromic surveillance allowing providers not to test capability to send.** Unlike the performance measure for immunization information [495.6(c)(15)(ii)], the performance measures for reportable lab results [495.6(e)(6)(ii)] and syndromic surveillance data [495.6(c)(16)(ii)] include the unnecessary clause “unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically”. CSTE recommends deleting this clause, which offers deferment based on current public health agency capacity, because it will be confusing for all parties; it may undermine the sense of urgency for public health agencies to be ready for the 2011 objectives, and potentially undermine EP/hospital commitment to public health reporting through this incentive program. The public health enterprise – local, state and federal – is committed to being ready for the 2011 objectives. Most states already have operational ELR systems.

4. We recommend that the rule specify acceptable methods for capability testing and verification in population/public health

A. We recommend that pre-certification capability testing be an acceptable method to demonstrate capability for immunization messaging. The CMS NPRM does not specify the method for a capability test. When immunization registries are enrolling a provider for participation, pre-certification (the process of evaluating incoming data quality of new submitters before allowing them to regularly add data) is required. Test files are sent as part of establishing the interface. The HL7 v2.3.1 immunization messaging Implementation Guide is available online;¹ the HL7 v2.5.1 immunization messaging Implementation Guide is pending.² Over 60% of immunization registries are currently capable of receiving HL7 v2.3.1 immunization messaging.³ As cited in the AIRA Data Quality Assurance for Incoming Data best practice guide,⁴ pre-certification review includes validation for integrity format (for the whole transmitted file), validation for mandatory data set (for each record), validation for coding, range, and format (for each data item), and cross-checks among data items. Capability testing for immunization registry HIE can be based upon this pre-certification procedure.

B. We recommend that evaluation of HL7 conformance, completeness and accuracy of test messages sent to a State public health agency be an acceptable method to demonstrate capability for electronic laboratory reporting. Capability testing for electronic laboratory reporting can include use of test files and simulation tests (analogous to standard lab QA procedures), wherein fictional positive test results are inserted into a hospital lab LIS (flagged as “TEST”), transmitted from LIS to hospital EHR, then to the SHA public health unit. Test files are examined for HL7 conformance, and completeness and accuracy of data fields; the HL7 v2.5.1 ELR Implementation Guide is available.⁵

¹ CDC National Center for Immunization & Respiratory Diseases, Immunization Information Systems Support Branch. *Implementation Guide for Immunization Data Transactions using Version 2.3.1 of the Health Level Seven (HL7) Standard Protocol*, Implementation Guide Version 2.2. Atlanta: CDC, June 2006. <http://www.cdc.gov/vaccines/programs/iis/stds/downloads/hl7guide.pdf>.

² Health Level Seven, International. *HL7 Version 2.5.1 Implementation Guide: Immunization Messaging (US Realm)*, Implementation Guide Release 1.0. Ann Arbor, MI: HL7 International, March 2010. <URL pending>

³ CDC National Center for Immunization & Respiratory Diseases. Immunization Information Systems Annual Report (IISAR) Data. <http://www.cdc.gov/vaccines/programs/iis/rates/default.htm>.

⁴ AIRA Modeling of Immunization Registry Operations Workgroup (eds.). *Data quality assurance in Immunization Information Systems: Incoming Data*. Atlanta, GA: American Immunization Registry Association. February, 2008. http://www.immregistries.org/pdf/AIRA_MIROW_Chap3_DQA_02112008.pdf.

⁵ Health Level Seven, International. *HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health*, Release 1 (US Realm). Ann Arbor, MI: HL7 International, February 2010. Available without charge to HL7 members, or can be purchased at <https://www.hl7.org/store/>.

C. We recommend that test messages sent to a State or local health agency and examined for HL7 conformance, completeness, and accuracy be an acceptable test of capability to transmit syndromic data. Capability testing for syndromic surveillance data can include use of test files and simulation tests. For example, HL7 messages containing fictional emergency department (ED) visit data can be generated from a hospital EHR system (flagged as “TEST”) and transmitted to the SHA public health unit. Test files are examined for HL7 conformance, and completeness and accuracy of data fields. The HITSP Biosurveillance Interoperability Specification is available.⁶

D. We recommend that the process used for verification of capability attestation involve consultation with State Health Agencies (SHA). The CMS NPRM does not specify methods to be used for verification of capability attestation. SHAs may want to challenge attestation in selected instances. It is preferable for SHA to be an active participant in routine verification procedures. Hospitals and EPs can attest to immunization registry enrollment, ELR simulation testing or syndromic surveillance enrollment, and CMS compliance review verification (and state Medicaid verification) can be conducted as confirmation by consultation with the SHA public health unit.

5. We recommend that the rule specify an acceptable method for performance testing and verification of actual submission of immunization information. Many states have established expectations for immunization registry participation in terms of data completeness, accuracy and timeliness. In 2008, 75% of all U.S. children aged <6 years (approximately 18 million children) participated in an Immunization Information System (IIS); the proportion of children in the statewide IIS was over 95% in 19 states.⁷ The AIRA Data Quality Assurance for Incoming Data best practice guide (noted above) provides standard principles and business rules. The HITSP Immunizations and Response Management Interoperability Specification is available.⁸ Where states require submission of immunization information as part of their state-specific meaningful use criteria, EPs and hospitals can attest to actual submission, and CMS compliance review verification (and state Medicaid verification) can be conducted as confirmation by consultation with the SHA public health unit. This verification method for performance uses the same logic as verification of capability.

6. We recommend that the rule specify acceptable methods for performance testing and verification of actual submission for Electronic Laboratory Reporting (ELR)

⁶ Healthcare Information Technology Standards Panel. *Biosurveillance Interoperability Specification*, Version 3.2. HITSP, December 2008. <http://www.hitsp.org/>.

⁷ CDC. Progress in Immunization Information Systems --- United States, 2008. *MMWR* 2010;59(05):133-135. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5905a3.htm?s_cid=mm5905a3_e.

⁸ Healthcare Information Technology Standards Panel. *Immunizations and Response Management Interoperability Specification*, Version 1.0. HITSP, December 2008. <http://www.hitsp.org/>.

- **We recommend that SHA data review be an acceptable method to verify actual submission of electronic laboratory reporting.** Many states have established expectations for ELR in terms of data completeness, accuracy and timeliness. Lacking a method to identify reportable lab results that were not transmitted electronically, SHA data review may reward hospitals that use ELR, even if their reporting is incomplete; however, we believe that this is a rare scenario. Importantly, this method of assessing completeness is easy to conduct in SHAs which use the CDC-provided NEDSS Base System (NBS), as well as other similar systems. Assessment of timeliness is standardized using stratification by condition; delays in reporting are greater problems for some conditions than for others. Assessment of ELR accuracy is generally done by examination of individual data fields; as noted above, the HL7 v2.5.1 ELR Implementation Guide is available. Operational ELR systems initially require dual submission (of electronic and paper results) during a run-in phase; hospitals which are in this dual-submission phase can be deemed as having met the performance standard at that point in time. Where states require ELR submission as part of their state-specific meaningful use criteria, hospitals can attest to SHA data review, and CMS compliance review verification (and state Medicaid verification) can be conducted as confirmation by consultation with the SHA public health unit.

7. **We recommend that SHA data review be an acceptable method to verify actual submission of syndromic surveillance data.** Many states have established expectations for syndromic surveillance in terms of data completeness, accuracy and timeliness. State health agency data review is the preferred method for performance testing of actual submission. Operational syndromic surveillance systems can evaluate performance through the use of automated systems that monitor data feeds for completeness (number of messages received daily versus historical values) and accuracy (inclusion of all necessary data fields). As noted above, the HITSP Biosurveillance Interoperability Specification is available. Where states require syndromic surveillance data submission as part of their state-specific meaningful use criteria, EPs and hospitals can attest to SHA data review, and CMS compliance review verification (and state Medicaid verification) can be conducted as confirmation by consultation with the SHA public health unit.

8. **We recommend hospital laboratory capability to send to PH using standardized vocabularies in ELR**

A. **We recommend inclusion of rule language which requires use of LOINC codes in ELR messages sent to public health.** Although hospital EHRs are required to be capable of receiving/using LOINC, hospital labs are not required to send messages to public health using the standardized LOINC vocabulary. Because use of local codes for identifying laboratory test names significantly impacts successful exchange of ELR from healthcare providers to SHAs, we believe that labs should use LOINC codes (in the most recent version) for the small subset of tests that comprise reportable laboratory results.

B. **We recommend inclusion of rule language which requires use of SNOMED CT codes in ELR messages sent to public health.** Although hospital EHRs are required to

be capable of using either ICD-9-CM or SNOMED CT diagnosis codes in the problem list, SNOMED codes are included only as a Stage 2 Candidate Standard for ELR HIE. Because use of local codes for identifying laboratory test results significantly impacts successful exchange of ELR from healthcare providers to SHAs, we believe that labs should use SNOMED CT codes (in the most recent version) for the small subset of tests that comprise reportable laboratory results.

9. We recommend that additional information be included regarding the details of Stage 2.

Because of the short anticipated gap between the issuance of Stage 2 criteria and its implementation, we would like to see more detail in the current rule language. In Stage 1, the draft rules were released about ten months before implementation is expected to start. If implementation of Stage 2 can start in October 2012, and if draft rules will not be issued until early 2012, the gap is challengingly short for public health agency HIE capability development. In particular, it would be desirable to see mention of expectations regarding cancer registry (such as pathology lab ELR); an expectation of required use of HL7 2.5.1 for Immunization Registries; expectations regarding electronic birth registration systems; and, expectations for public health case reporting.

10. External-cause-of-injury codes, which provide information about the injury circumstances associated with injury-related emergency department visits and hospitalizations, should be essential data elements of the Electronic Health Record proposed by CMS and should be included in the Meaningful Use Criteria. External-cause-of-injury-coded data from emergency department visits and hospitalizations are critical for use by public health professionals to (1) monitor trends in leading causes of nonfatal injuries and (2) develop and evaluate injury prevention efforts at the national, state, and local levels. This recommendation is in direct reference to Meaningful Use Criteria given in Table 2, p 1867, which aims at Improving quality, safety, efficiency, and reducing health disparities; Report information for quality improvement and public reporting; Hospitals. For example, external-cause-of-injury codes are used to monitor our nation's health in the Healthy People 2010 objectives and are used in Patient Safety Indicators promulgated by the Agency for Healthcare Research and Quality. External-cause-of-injury codes are also useful for injury-related quality of care assessment (e.g., risk of falls among older persons) in the emergency care, hospital, assisted living/nursing care, and home health care settings. Fall prevention (e.g., reducing fall-related hip fractures) is one of the priority areas for quality and patient safety initiatives relevant to Present-On-Admission (POA) codes required for billing by CMS. External-cause-of-injury codes can also be useful for other quality initiatives associated with injury-related claims (e.g., motor vehicle crash-related injuries) that could help CMS make payment decisions. When the principal or secondary diagnosis of an emergency department visit or a hospitalization is an injury (i.e., an ICD-9-CM or ICD-10-CM injury-related diagnosis code), the external causes of injury (i.e., the codes for the mechanism/intent of injury [fall, motor vehicle traffic, fire/burn, cut/pierce, assault, self-harm] and place of occurrence [home, street/highway, residential institution] using ICD-9-CM or ICD-10-CM external-cause-of-injury codes) should be coded. Improving external-cause-of-injury coding in state morbidity data systems is a national priority as addressed by

two Healthy People 2020 objectives – an extension of two HP2010 objectives. The HP2020 objectives are:

- IVP HP2020 33. Increase the number of States and the District of Columbia with statewide emergency department data systems that routinely collect external-cause-of-injury codes for 90 percent or more of injury-related visits, and
- IVP HP2020 34. Increase the number of States and the District of Columbia with statewide hospital discharge data systems that routinely collect external-cause-of-injury codes for 90 percent or more of injury-related discharges.

Actions aimed at improving external-cause-of-injury coding in state-based emergency department and hospital discharge data systems for use in injury prevention activities and quality of care assessment have been recently recommended by federal, state and non-governmental health organizations⁹ in response to recommended strategies.¹⁰

Conclusion

CSTE appreciates the opportunity to comment and wants to emphasize that the public health and population-wide benefits to be expected from the implementation of electronic health records complement the benefits to be expected at the clinical care level. Improved patient care and improved awareness of and response to significant health events in the community are mutually supportive and can both be moved forward through adoption and implementation of meaningful use standards in the ways that we recommend in this letter. We would like to emphasize our enthusiastic support of the original reason for the ARRA-HITECH Act – to improve individual and population health as well as control costs.

Sincerely,



Patrick J. McConnon, MPH
Executive Director

⁹ National Center for Injury Prevention & Control. *Recommended Actions to Improve External-Cause-of-Injury Coding in State-Based Hospital Discharge and Emergency Department Data Systems*. Atlanta (GA): US Department of Health & Human Services, Centers for Disease Control & Prevention; December 2009.
http://www.cdc.gov/injury/data/ecode_report.html.

¹⁰ Annett JL, Fingerhut LA, Gallagher SS, Grossman DC, Hedegaard H, Johnson RL, Kohn M, Pickett D, Thomas KE, Trent RB; Centers for Disease Control & Prevention (CDC). Strategies to improve external cause-of-injury coding in state-based hospital discharge and emergency department data systems: recommendations of the CDC Workgroup for Improvement of External Cause-of-Injury Coding. *MMWR Recomm Rep*. 2008 Mar 28;57(RR-1):1-15.
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5701a1.htm>.