Comments from ISDS on proposed rule for meaningful use
Medicare and Medicaid Programs; Electronic Health Record Incentive Program
42 CFR Parts 412, 413, 422, and 495
CMS-0033-P
RIN 0938-AP78

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Introduction
The mission of the International Society for Disease Surveillance (ISDS) is to improve population health by advancing the field of disease surveillance. In support of this mission, the Society provides an educational and scientific forum where epidemiologists, informaticists, public health practitioners, health care providers, statisticians, and others can work together to explore and address population health monitoring across institutional and professional boundaries.

ISDS is currently working in partnership with State and Local public health departments, the Centers for Disease Control (CDC), and other stakeholders including the Public Health Informatics Institute (PHII), the Council of State and Territorial Epidemiologists (CSTE), and the National Association of County and City Health Officials (NACCHO) to improve surveillance for influenza-like illness. This initiative leverages the Distribute syndromic surveillance project (ISDSdistribute.org), developed and piloted by ISDS, to enhance and support Emergency Department (ED) surveillance by making aggregate level data available to experts in public health. Distribute complements existing surveillance methods by providing a more comprehensive and detailed situational awareness of geographic and age-specific patterns of influenza-like illness.

Structure of comments
ISDS makes comments from the perspective of public health professionals who develop, operate, evaluate, or utilize syndromic surveillance data on a daily basis.

Society members and Distribute project epidemiologists and technical staff were surveyed regarding the proposed measures for meaningful use of electronic health record (EHR) technology, particularly those measures that will affect the quality of automated public health surveillance using electronically-available clinical and laboratory data. Survey results inform the following comments made by the ISDS Board. Comments are organized in two sections: 1) General; 2) specific to section found in the 42 CFR Parts 412, 413, 422, and 495, RIN 0938-AP78.
General Comments

- ISDS applauds improving population and public health as a policy priority for the Medicare and Medicaid EHR Incentive Programs. There is widespread support among ISDS members for EHR technology standards that enhance the ability of public health authorities to monitor community and population health.

- ISDS applauds the presence of measures that concretely demonstrate data transmission to public health agencies. Furthermore, ISDS strongly supports the specific consideration given to syndromic surveillance within these measures.

- Although beyond the scope of this proposed rule, ISDS emphasizes that without a concomittant investment to develop the information and workforce capabilities of public health agencies, the ambitious goals of this program to enhance population and public health are unlikely to be fully realized.

- ISDS applauds the effort to ensure interoperability among electronic immunization, syndromic, and laboratory patient records, because it is crucial for realizing the future potential of these data for improved public health surveillance.

Specific Comments

II. Provisions of the Proposed Regulations

d. Stage 1 Criteria for Meaningful Use; (2) Health IT Functionality Measures

Eligible Hospital Objective: Capability to provide electronic submission of reportable lab results to public health agencies and actual submission where it can be received.

Eligible Hospital Measure: 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 eligible hospital submits such information have the capacity to receive the information electronically). The capability to send reportable lab results is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we propose that eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. More stringent requirements may be established for hospitals under the Medicaid program in States where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any modification or addition to CMS in accordance with the discussion in II.A.2.c, of this proposed rule.
• We agree that the infrastructure for exchanging reportable lab results electronically with public health authorities is generally not in place. However, the absence of such infrastructure in a specific jurisdiction should not excuse EPs and providers from the requirement that they demonstrate their capacity to submit information electronically to public health.

• Testing the capability of EP’s and Hospitals to transmit these data to public health agencies is necessary, but not sufficient, to demonstrate the meaningful use of EHR for public health surveillance. If the public health agency in a jurisdiction is not able to participate in testing, ISDS recommends that testing and verification be done by an independent entity under the authority of public health.

• In future stages, ISDS looks forward to measures that demonstrate an ability to routinely exchange EHR data between public health agencies and EP’s and Hospitals.

**EP/Eligible Hospital Objective: Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.**

**EP/Eligible Hospital Measure: 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 an EP or eligible hospital submits such information have the capacity to receive the information electronically).**

The capability to send electronic data to immunization registries is included in the certification standards for certified EHR technology (to be defined by ONC in its upcoming interim final rule). Meaningful use seeks to ensure that those capabilities are utilized. However, this objective is reliant on the electronic exchange of information. We are cognizant that in most areas of the country, the infrastructure necessary to support such exchange is still being developed. Therefore, for the Stage 1 criteria of meaningful use we are proposing that EPs and eligible hospitals test their ability to send such information at least once prior to the end of the EHR reporting period. The testing could occur prior to the beginning of the EHR reporting period. EPs in a group setting using identical certified EHR technology would only need to conduct a single test, not one test per EP. More stringent requirements may be established for EPs and hospitals under the Medicaid program in States where this capability exists. This is just one example of a possible State proposed modification to meaningful use in the Medicaid EHR incentive program. States may propose any modification or addition to CMS in accordance with the discussion in II.A.2.c. of this proposed rule.

• We agree that the infrastructure for the electronic exchange of syndromic surveillance data per ONCHIT’s proposed certification standards is largely not in place.

• Testing the capability of EP’s and Hospitals to transmit these data to public health agencies is crucial to demonstrating meaningful use and ISDS is supportive of testing. If the public health agency in a jurisdiction is not able to participate in testing, ISDS recommends that testing and verification be done by an independent entity under the authority of public health.
§ 495.6 Meaningful use objectives and measures for EPs, eligible hospitals, and CAHs

(c) Stage 1 criteria for EPs and eligible hospitals or CAHs. An EP, eligible hospital or CAH must satisfy the following objectives and associated measures:

(16) (i) Objective. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.

- ISDS supports this objective. We note that existing systems either transmit individual-level records or daily batch files to public health agencies. The objective should clarify that both approaches are acceptable from a public health perspective.

- ISDS strongly recommends that syndromic surveillance data be defined. A useful definition, and one that will best support improved public health surveillance, will include a minimum set of variables for syndromic surveillance data.

(16)(ii) Measure. 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).

- ISDS supports a demonstration of an EHR technology’s ability to transmit electronic syndromic surveillance data. We note, however, that transmission of data on its own is necessary but not sufficient for meaningful use of EHR technology from a public health perspective. Informatics infrastructure and trained personnel are also essential.

- Syndromic surveillance is widely practiced by public health authorities at local and state levels of government. Among its members and the Distribute Community of Practice, ISDS finds excitement that increasing the availability of electronic health data for public health authorities has tremendous potential to enhance surveillance for syndromes as well as other health indicators.

- ISDS does not agree with the exception clause of this proposed measure. If the public health agency in a jurisdiction is not able to participate in testing, ISDS recommends that testing and verification be done by an independent entity under the authority of public health. Once a public health agency has infrastructure established, EP’s and hospitals should then be able to initiate routine transmission with minimal additional effort.

- In future stages, ISDS looks forward to measures that demonstrate an EHR technology’s ability to routinely exchange data between public health agencies and EP’s and Hospitals. Barriers to effective use of clinical data for surveillance may emerge only after repeated transmission of data in the context of usual practice. Accordingly, subsequent measures should examine the quality of transmission over an interval.
(d) Additional Stage 1 criteria for EPs. An EP must meet the following objectives and associated measures:

(6)(i) Objective. 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.

- ISDS is supports this objective.

(6)(ii) Measure. 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).

- ISDS does not agree with the exception clause of this proposed measure. ISDS agrees that it is unreasonable to expect tests of this capacity when public health agencies lack the appropriate infrastructure. In keeping with this position, it is important that EP’s and hospitals demonstrate this capability once the appropriate infrastructure is in place.

- In future stages, ISDS looks forward to measures that demonstrate an EHR technology’s ability to routinely exchange data between public health agencies and EP’s and Hospitals.