February 16, 2010

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology

U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Blumenthal:

The members of the HIT Policy Committee Certification Adoption Workgroup (Workgroup) have developed several recommendations to communicate to the Centers for Medicare & Medicaid Services (CMS) in response to its Notice of Proposed Rule Making (NPRM) regarding CMS's incentive program for the Meaningful Use of electronic health records (EHRs) and the Office of the National Coordinator for Health Information Technology's (ONC) Interim Final Rule (IFR) on Standards, Certification Criteria, and Implementation Specifications related to Certified EHR technology. In the discussion below, we outline these recommendations and explain why we believe that these changes to the NPRM and IFR will result in more effective achievement of HHS' objectives with this incentive program for eligible professionals (EPs) and hospitals.

The Workgroup's recommendations were presented to the HIT Policy Committee on February 17, and they were approved by that committee, without any objections.

ADOPTION CERTIFICATION BROAD WORKGROUP CHARGE

Our workgroup makes recommendations to the HIT Policy Committee on issues related to the adoption of certified electronic health records, that support meaningful use, including issues related to certification, health information extension centers and workforce training.

GENERAL COMMENT

We were pleased that ONC accepted most of our workgroup's certification recommendations that were made in August. We were particularly pleased that certification criteria focused on Meaningful Use. ONC appears to have accepted our recommendation to use certification to leverage progress on privacy, security, and interoperability.

RECOMMENDATIONS:

Recommendation 1: Method and Specificity of Calculating and Reporting Metrics

According to the NPRM, in order to qualify for incentive payments and prove that Meaningful Use has been achieved, an EP must self-attest to data on at least 16 issues, which are:

1. CPOE Usage Percentage
2. Percentage of relevant prescriptions transmitted electronically with e-prescribing
3. Percentage of unique patients with electronic up to date problem list
4. Percentage of unique patients with active medication list maintained
5. Percentage of all unique patients with an active allergy list
6. Percentage of all unique patients with recorded demographics
7. Percentage of all unique patients with vitals recorded and charted
8. Percentage of patients 13 years and older with smoking status recorded in EHR
9. Percentage of EHR records with structured laboratory data
10 Percentage of all unique patients sent reminders
11. Percentage of patients whose eligibility status is electronically checked.
12. Percentage of claims submitted electronically.
13. Percentage of patients provided with electronic copies of medical records.
14. Percentage of patients with timely access to health information
15. Percentage of office visits in which clinical summaries are provided
16. Percentage of relevant encounters with med reconciliation.

A similar set of metrics exists for Hospitals. Although, nearly every EHR has the capability to track metrics and generate reports as the NPRM requests, several of the requested data elements needed for Metric reporting are not gathered within functionality included in Stage 1 of Meaningful Use.

Our Workgroup is not focusing on the value or importance of these metrics. Instead, we looked at the administrative effort to calculate these metrics, and we looked at whether there was ambiguity. In general, we found:

a. Even though self-attestation is involved, physicians want to accurately calculate these metrics. In particular, they want to be able to pass any audit that might occur.
b. The amount of effort involved with hand-counting various documents is significant and could be a barrier to applications for incentive payments.
c. Special concern was expressed about the amount of manual work for small physician groups with minimal administrative support.
d. Large hospital organizations also expressed concern about the amount of manual labor involved.
e. There is confusion about the definitions of many of the items.

***Recommendation 1.*0: Greater detail needs to be provided about how to calculate the reporting metrics for items involving the percentage of electronic usage versus manual usage.**

In particular, for each metric, for both EPs and Hospitals, that requires comparisons with manual (non-electronic) transactions, we request that the final rule include text, or, alternatively, that CMS provide guidance for the purpose of answering the following questions :

a. Are rough estimates accepted or is the metric expected to be precisely and accurately calculated?
b. Is manual review and counting of records expected, and if so, over what time period?
c. Can a statistical process be used? For example, is it acceptable to review all encounters for a single week to extrapolate percentages?

Recommendation 1.1: **The IFR should include certification criteria for a section called "Reporting Metrics", which would automatically calculate all metrics that are required to be reported. Reporting metrics should be aligned with the data requires of Meaningful Use.**

For example, the IFR should include certification criteria that automatically calculate the smoking status metric (percentage of patients over the age of 13 for whom smoking status is recorded). Such reports could also be beneficial in aiding EPs and Hospitals in monitoring their progress with adoption.

Recommendation 1.2: **The reporting process for Stage 2 of Meaningful Use should not require manual review of records or subjective judgments.**

All required metrics for Stage 2 should be automatically produced by the EHR. As a result, for Stage 2, certification criteria should be created to automatically produce the appropriate reports.

Recommendation 2.0: Leveraging Certification to achieve Interoperability

In our Workgroup's previous recommendations to the Committee, we suggested that in order to achieve greater interoperability, greater specificity in exchange standards was needed. In some areas, we would have preferred to see greater specificity. In addition, while the IFR needs to have certification criteria for all functionality described in the NPRM, it is also possible for the IFR to describe certification criteria for interoperability functions that are not included in the NPRM for Meaningful Use. Based upon these general comments, we have the following additional recommendations related to Interoperability:

Recommendation 2.0: **For laboratory transactions, ONC adopt the implementation specifications (guide) for HL7 2.5.1 which has been approved by the HIT Standards Committee. For this implementation specification (guide), we further recommend that the implementation specification be adopted as a "minimum" standard, which would indicate that compliance with any future revisions also meet the regulations.**

In our certification investigations, we learned that existing standards have too much variability. Vendors have differing interpretations of these standards, and, as a result, interoperability suffers. An implementation specification contains very specific details

about exchange standards. Adoption of a single implementation specification for laboratory results will significantly improve laboratory interoperability, which is needed.

The IFR contains the following statement "We [ONC] will consider adopting implementation specifications, though, for any or all adopted standards provided that there is convincing evidence submitted in public comment of the specifications' maturity and widespread usage." We suggest that the need for "convincing evidence" or for "widespread usage" needs to be balanced against the urgency for improving interoperability of laboratory test results.. Indeed, ONC leadership is especially needed because there is an absence of widespread usage of needed laboratory exchange specifications. While we understand ONC's desire for maturity in implementation standards, we believe that "maturity" is a subjective standard. For evidence of "maturity", we recommend that ONC rely on the recommendations of the Standards Committee. By designating this implementation specification as a "minimum" with a percentage sign, a Vendor who utilizes any future revision of the implementation specification will also conform to the regulations .

The certification (and testing) of vendors' implementation of HL7 2.5.1 will be improved by the adoption of an implementation specification, because there will be a specific specification to test against.

Recommendation 2.1: **Require hospitals to use HL7 2.5.1 when transmitting laboratory data to providers.**

The IFR specifies the use of HL7 2.5.1 when lab results are submitted to Public Health Agencies. Since all certified EHRs will be required to have this interface, we recommend that, for Hospitals, HL7 2.5.1 also be used and certified for an additional purpose, the submission of lab results to other providers. It is important to note that most physician groups obtain their lab results from community hospitals rather than independent laboratories. By using this interface for this additional purpose, a significant forward step will be made in interoperability of laboratory data. Because this interface specification is already required, the addition of this purpose will have minimal cost implications. By adopting the HL7 2.51 Implementation Specification (Guide), hospitals will also be required to use LOINC for the most common test results. The HL7 2.5.1 Implementation Specification (Guide) contains a list of the most frequently used LOINC codes..

Recommendation 2.2**: Establish certification criteria requiring the use of HL7 2.5.1 for receipt of laboratory data.**

There are no certification criteria for receiving laboratory data by EPs or by Hospitals. We view this issue as a major omission, since automated receipt is required to achieve Meaningful Use for EPs. In the absence of this certification criteria, it will be possible for physicians to purchase computer systems that are not able to achieve meaningful use, because they won't be able to electronically receive laboratory results.. We recommend that certification criteria be established for Hospitals and EPs for the use of HL7 2.5.1 for receipt of laboratory data.

Recommendation 2.3: **Explain reasons when more than one standard is described**

There are several areas where two or more standards are adopted. Similarly, there are several areas where, for Stage 2, two or more vocabularies are specified. For each function with more than one standard, whenever possible, we recommend the adoption of a single standard for exchange. After reviewing the four areas listed below, we believe that ONC probably acted correctly in specifying more than one alternative, however. As a result, whenever more than one alternative is specified, we request that ONC explain the reasons that more than one was specified and also explain the circumstances under which a particular specification should be used. This recommendation refers to:

a. Submission to Public Health Agencies for Surveillance or Reporting (Table 2a, Row 7).
b. Submission to Immunization Registries (Table 2a, Row 8).
c. Problem List use of ICD 9 or SNOMED-CT (Table 2a, Row 1).
d. Use of Vocabularies LOINC, UCUM, and SNOMED-CT for laboratory reporting (Table2a, Row 6-Stage 2).

The Workgroup respectfully submits the recommendations contained in this letter, which we believe would strengthen the criteria and respond to many of the issues and concerns which were made known to the committee. We remain available and willing to assist ONC and the Department in any way we can.

Sincerely yours,

/Paul Egerman/

Paul Egerman
Co-Chair Certification Adoption Workgroup

Sincerely yours,

/Marc Probst/

Marc Probst
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