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Collaborative Comments on the Office of the National Coordinator's Interim Final Rule on the Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

This paper represents a collective view that was deeply informed by the many and diverse collaborators of Markle Connecting for Health.

The Interim Final Rule (IFR) on health information technology (IT) standards[1] marks a positive step forward in the nation's efforts to improve health care by putting modern IT tools at the fingertips of medical professionals and consumers alike.

We applaud the US Department of Health and Human Services for drafting an initial set of standards that, in general, support the goals of "Meaningful Use" of health IT and allow for sufficient flexibility in a heterogeneous marketplace. This was a very challenging and novel undertaking, and the result is an important contribution to the potential of information technology to improve the quality and efficiency of health care.

The comments below, supported by the undersigned, propose modest but important modifications to the Interim Final Rule drafted by the Office of the National Coordinator for Health Information Technology (ONC).

The Right General Direction

The IFR sets a strong foundation for the Meaningful Use of health IT.

The adopted standards align with many of our prior collective recommendations, which outline an approach that encourages broad participation, encourages innovation, and protects patient privacy, including:

- The IFR focuses on "good enough" standards and assumes greater specification over time, and signals that implementation experience should be a key driver of greater specificity.
- The IFR enables a wide array of participants by allowing lighter-weight options and standards in key areas.
- The IFR appropriately separates standards for content and standards for transmission.

[1] "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule." 75 Federal Register 8 (13 January 2010), pp. 2014–2047.

- The IFR leverages the Internet for secure transport of information.
- The IFR requires only the "minimum necessary" standards and certification criteria to support Meaningful Use.

Suggested Modifications

Recommendation 1 — Use well tested standards that can be implemented in the near term for reporting quality measures.

ISSUE: The process for demonstrating Meaningful Use must be feasible by a wide array of providers and leverage well tested standards that can be implemented in the near term. The IFR's selection of the Centers for Medicare & Medicaid Services (CMS) Physician Quality Reporting Initiative (PQRI) 2008 Registry Extensible Markup Language (XML) specification meets these criteria, and is well suited for reporting summary quality results for Meaningful Use. The IFR also requests comments on the potential use of the Quality Reporting Document Architecture (QRDA).

RECOMMENDATION:

1. Maintain the adoption of the PQRI registry XML specification in Stage 1.
2. Based on current experience, we suggest QRDA not be adopted for quality reporting in Stage 1.

RATIONALE: As one of the most visible components of Meaningful Use, the process providers will use to report quality results will strongly impact participation, and can position the program itself as a high value part of a general care improvement program, rather than just a necessary administrative add-on for validating payment.

Early success in this area will be a critical factor in initial and ongoing participation by providers, and can be driven by adopting mechanisms and standards that are easy to implement and in use across diverse health care and technology settings.

The PQRI registry XML standard adopted by the IFR is a promising template that can be expanded upon and improved for direct reporting from electronic systems. CMS is already accepting electronic summary data from PQRI registries employing this standard, and it is well tested by many vendors.

In comparison, QRDA is not widely used or well tested, and therefore does not meet the criteria to make it a required standard at this juncture. Although QRDA is more versatile

than the PQRI registry XML standard, that versatility adds some complexity and it is not clear that the versatility is necessary to meet the Stage 1 requirements.

Theoretically, one of the advantages of QRDA is that it can be used to report patient-level data for quality metrics. However, while patient-level data will be of great value to individual providers for care and process improvements, it is not needed for CMS to evaluate provider performance in a program of this nature, size, and complexity. CMS should require only summary data to measure quality. The approach used by the new "popHealth" prototype launched by ONC provides such a model for using summary quality data to help providers improve care[2]. As stated by Vish Sankaran, Program Director for Federal Health Architecture at ONC, the "transmission of summary quality data is simpler, less data intensive and more scalable, and represents an alternative to traditional methods of data transmission".[3]

QRDA can also be used to report calculated population summary quality measures, but in this context it may be more complex than what is needed for the job at hand. For example, QRDA requires the capability to *generate* the HL7 Clinical Document Architecture (CDA) template, which goes beyond the current requirement to enable users to *display* CDA-based patient summary records in human readable format and could increase the technical work needed in some cases for implementation and participation. The IFR allows the CCR as an alternative to CCD for the exchange of patient summary records in Stage 1 to accommodate industry readiness in this area.

Recommendation 2 — Add guidance for the implementation of lab standards by specifying a core set of Logical Observation Identifiers Names and Codes (LOINC).

ISSUE: The IFR sets a forward-looking path toward the adoption of LOINC for standardizing laboratory data in order to fully support Stage 2 of Meaningful Use. However, guidance will be necessary for providers and labs to implement and transition to LOINC.

RECOMMENDATION:

1. Offer guidance in the form of a "starter set" of LOINC codes to help labs and providers use the standard. A starter set should include a unique set of LOINC

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[2] See http://projectpophealth.org/ (accessed March 12, 2010).

[3] Mosquera, M. "ONC unveils 'popHealth' for EHR-based quality reporting." Government Health IT 2006, February 2010. http://govhealthit.com/newsitem.aspx?nid=73203

codes that represent the vast majority of lab orders and results. For example, the LOINC Common Lab Orders Value Set identifies roughly 300 tests that cover 98 percent of the LOINC codes used for lab orders.[4] Similarly, one study identified 784 codes (19 percent of all codes used in a representative sample) that account for 99 percent of the volume of lab results.[5] This would obviate the need for providers and labs to implement the more than 50,000 codes specified by LOINC and still enable them to derive the benefits.

2. Recommend the adoption of LOINC for lab *orders* in stage 2 of Meaningful Use.

RATIONALE: Adopting starter sets for LOINC will provide a manageable first step for labs attempting to use the standard. The large number of LOINC codes is often overwhelming to new implementers. There is also great variability in implementation because different codes can be used to represent the same lab order or result. These difficulties can greatly impact providers who work with multiple labs, each of which may have slightly different implementations of LOINC.

A recent survey found that providers are already facing difficulties managing their lab data. For example, only 41 percent of physicians are satisfied with how they manage test results. Another survey found that providers spend an average of 74 minutes per clinical day managing lab results.[6]

While ONC can help providers develop strategies for managing structured lab results through the extension centers, labs will also need guidance to successfully adopt and use LOINC. Identifying a starter set is a concrete step ONC can take to guide implementations, similar to successful efforts with other standards such as RxNorm for National Drug Codes (NDC). These efforts should ensure that the LOINC codes necessary for reporting quality measures in the Meaningful Use incentive program are included in the starter set.

Finally, ONC can play a strong role in facilitating the use of LOINC for lab *orders* for future stages of Meaningful Use, since the current requirements apply only to results. Currently, providers contend with the varying standards used by the many different labs with which they work. This is not only time consuming, it is also challenging for

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[4] Developed by National Library of Medicine and Regenstrief Institute and Reviewed by American Clinical Laboratory Association (ACLA). Common Lab Orders – Version 1.0., January 14, 2010. http://loinc.org/usage/orders/common-lab-orders-value-set.

[5] Vreeman, DJ; Finnell, JT; Overhage, JM. "A Rationale for Parsimonious Laboratory Term Mapping by Frequency." Proceedings of the AMIA Symposium. 2007;771-775.

[6] Poon, EG; Gandhi, TK; Sequist, TD; et al. "I wish I had seen this test result earlier!": Dissatisfaction with test result management systems in primary care. Arch Intern Med 2004;164:2223e8.

providers to consistently track and manage outstanding orders and results. Identifying a path towards standardization of lab orders will also encourage standard connectivity between providers and labs. ONC can foster this development by identifying the use of LOINC for lab orders, and a corresponding "starter set", as a clear goal for Stage 2 of Meaningful Use.

Recommendation 3 — Add a download capability to qualified health IT to facilitate the goals of patient engagement.

ISSUE: Fulfilling the core expectation that the individual should get copies of personal health information in a useful electronic format should be possible without creating burden.

RECOMMENDATION:

1. Clarify that enabling providers to offer patients a download capability is sufficient to meet the certification criteria for delivering electronic copies of health information,[7] timely electronic access to records,[8] and clinical summaries[9] (from eligible providers) and discharge instructions[10] (from hospitals).

   This download function should enable a user to:

   - Provide access to the patients of an eligible provider or hospital from a secure online site (e.g., patient portal or PHR).
   - Make available priority information such as:
     - lists of problems, medications, allergies, immunizations, procedures
     - laboratory and diagnostic test results
   - Provide patients with a downloadable copy of their clinical information in: (1) human readable format, and (2) in accordance with the standards specified in §170.205(a) for a Patient Summary Record.

[7] §170.304(f), §170.306(d)

[8] §170.304(g)

[9] §170.304(h)

[10] §170.306(d)

- Offer a preferred alternative to compact disc or USB drive (except for images) because of security and interoperability concerns related to portable storage devices.

The technical requirements should include automation of counts of basic utilization (e.g., number of clinical summaries and hospital discharge instructions delivered, number of patients who log in, number of electronic downloads requested and delivered.)

- Revise the definition of "Qualified EHR" (§170.102) to include the capability to provide patients with an electronic copy of their health information. A revised definition could be written as follows (revised text in bold):

  Qualified EHR is an electronic record of health-related information on an individual that:

  (A) Includes patient demographic and clinical health information, such as medical history and problem lists; and

  (B) has the capacity:
  (i) to provide clinical decision support;
  (ii) to support physician order entry;
  (iii) to capture and query information relevant to health care quality; and
  (iv) to exchange electronic health information with, and integrate such information from other sources**;**
  (v) to provide a patient with an electronic copy of their health information.

In general, the IFR implicitly supports the basic idea of a download capability, but we recommend that both the Notice of Proposed Rulemaking (NPRM) on Meaningful Use[11] and the IFR explicitly identify that option for Stage 1 compliance for providers and make it a requirement for qualified or certified health IT. By recommending that this capability be made an allowable option to satisfy the Stage 1 patient engagement requirements, we do not suggest that it be the only such option. If an EHR is being used to meet the requirements in the NPRM, (e.g., it has a functioning patient portal that

[11] Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed rule. 75 Federal Register 8 (January 13, 2010), pp. 1844–2011.

displays the information but no download option), that should not prevent the provider from using it to achieve Stage 1 Meaningful Use in the patient engagement category.

We recommend that the download capability be added to the criteria for qualified health IT. Thus, it should be *an allowable option for providers* in Stage 1, but be *required as a criterion for deeming health IT qualified*. Similarly, we recommend that human readability be a requirement for data formats when providers and hospitals deliver electronic information to patients during Stage 1 of Meaningful Use, and that the certification criteria should require EHRs to be able to deliver the information to patients in accordance with the standards specified in §170.205 (a) for a Patient Summary Record.

RATIONALE: If Stage 1 patient engagement requirements can be met with a download capability, this can reduce burden for providers and vendors and would allow for early progress. Supporting and implementing a full patient portal may not be a practical endeavor for many providers, particularly those in small-practice settings. Not every vendor and provider is suited or capable to support patient portals, develop high value applications for patients to use, and deal with the implementation and adoption challenges. In fact, it is not feasible for every holder of a patient's data to also act as the purveyor of patient-facing portals or applications. This may be untenable for patients and providers alike. Rather, we recommend that HHS support the individual's ability to download their information and make it possible for them to choose the applications or services that can compile and make use of copies of health information from multiple providers and sources. This basic approach to consumer engagement is described in the architecture and recommended practices for such services (Consumer Access Services) in the Markle Connecting for Health Common Framework for Networked Personal Health Information.[12]

Recommendation 4 — Limit the use of "illustrative" standards examples.

ISSUE : The IFR lists illustrative examples for adopted privacy and security standards. However, these examples can easily be misinterpreted as requirements.

RECOMMENDATION:

- Clarify that the examples provided in the IFR are illustrative and not required.

[12] Markle Connecting for Health. Common Framework for Networked Personal Health Information, Overview and Principles. 2008. http://www.connectingforhealth.org/phti/reports/overview.html

- Limit the use of illustrative examples to those that are broadly implemented and provide a clear vision in keeping with future direction of the IFR.

RATIONALE: The illustrative examples listed in the discussion section of the IFR can easily be mistaken as requirements. This is not only confusing, but can run counter to the IFR's intent to allow for innovation and broad participation in these areas by NOT adopting a specific standard.

Misinterpretation is especially undesirable for standards that signal a future direction beyond the scope of the criteria. As a static document, the IFR should be used to cite examples of standards when they will provide valuable guidance over time in keeping with the vision set forth by the Meaningful Use Incentive Program. A framework for specifying and maintaining a broader list of example technology standards has clear value, but should be identified through other mechanisms that have greater flexibility, and be guided by the principles adopted by the Health IT Standards Committee:[13]

1. Keep it simple.
2. Think big, but start small.
3. Don't let "perfect" be the enemy of "good enough".
4. Keep the implementation cost as low as possible.
5. Do not try to create a one-size-fits-all standard.
6. Separate content and transmission standards.
7. Create publicly available vocabularies & code sets.
8. Leverage the Web for transport ("health Internet").
9. Position quality measures so they motivate standards adoption.
10. Support implementers

[13] The Office of the National Coordinator for Health IT, Health IT Standards Committee Implementation Work Group. Review of the Adoption Experience Hearing. November 19, 2009. http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_11673_909257_0_0_18/ChopraImplementationWGUpdate.ppt

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