

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.

1 The Interim Final Rule (IFR) on health information technology (IT) standards¹ marks a
2 positive step forward in the nation's efforts to improve health care by putting modern IT
3 tools at the fingertips of medical professionals and consumers alike.

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

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

12 The Right General Direction

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

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

- 18 • The IFR focuses on "good enough" standards and assumes greater specification
19 over time, and signals that implementation experience should be a key driver of
20 greater specificity.
- 21 • The IFR enables a wide array of participants by allowing lighter-weight options
22 and standards in key areas.
- 23 • The IFR appropriately separates standards for content and standards for
24 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.

- 25 • The IFR leverages the Internet for secure transport of information.
- 26 • The IFR requires only the “minimum necessary” standards and certification
- 27 criteria to support Meaningful Use.

28 **Suggested Modifications**

29 **Recommendation 1** **Use well tested standards that can be**
30 **implemented in the near term for reporting**
31 **quality measures.**

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

39 **RECOMMENDATION:**

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

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

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

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

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

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

58 Theoretically, one of the advantages of QRDA is that it can be used to report patient-
59 level data for quality metrics. However, while patient-level data will be of great value to
60 individual providers for care and process improvements, it is not needed for CMS to
61 evaluate provider performance in a program of this nature, size, and complexity. CMS
62 should require only summary data to measure quality. The approach used by the new
63 “popHealth” prototype launched by ONC provides such a model for using summary
64 quality data to help providers improve care². As stated by Vish Sankaran, Program
65 Director for Federal Health Architecture at ONC, the “transmission of summary quality
66 data is simpler, less data intensive and more scalable, and represents an alternative to
67 traditional methods of data transmission”.³

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

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

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

84 **RECOMMENDATION:**

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

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>

87 codes that represent the vast majority of lab orders and results. For example, the
88 LOINC Common Lab Orders Value Set identifies roughly 300 tests that cover 98
89 percent of the LOINC codes used for lab orders.⁴ Similarly, one study identified
90 784 codes (19 percent of all codes used in a representative sample) that account
91 for 99 percent of the volume of lab results.⁵ This would obviate the need for
92 providers and labs to implement the more than 50,000 codes specified by LOINC
93 and still enable them to derive the benefits.

94 2. Recommend the adoption of LOINC for lab *orders* in stage 2 of Meaningful Use.
95

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

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

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

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

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.

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

122 **Recommendation 3** **Add a download capability to qualified health**
123 **IT to facilitate the goals of patient**
124 **engagement.**

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

128 **RECOMMENDATION:**

- 129 1. Clarify that enabling providers to offer patients a download capability is sufficient
130 to meet the certification criteria for delivering electronic copies of health
131 information,⁷ timely electronic access to records,⁸ and clinical summaries⁹ (from
132 eligible providers) and discharge instructions¹⁰ (from hospitals).

133
134 This download function should enable a user to:

- 135 • Provide access to the patients of an eligible provider or hospital from a
136 secure online site (e.g., patient portal or PHR).
- 137 • Make available priority information such as:
- 138 ▪ lists of problems, medications, allergies, immunizations,
139 procedures
- 140 ▪ laboratory and diagnostic test results
- 141 • Provide patients with a downloadable copy of their clinical information in:
142 (1) human readable format, and (2) in accordance with the standards
143 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)

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

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

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

155 Qualified EHR is an electronic record of health-related information on an
156 individual that:
157

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

160 (B) has the capacity:

- 161 (i) to provide clinical decision support;
162 (ii) to support physician order entry;
163 (iii) to capture and query information relevant to health care quality;
164 and
165 (iv) to exchange electronic health information with, and integrate such
166 information from other sources;
167 **(v) to provide a patient with an electronic copy of their**
168 **health information.**
169

170 In general, the IFR implicitly supports the basic idea of a download capability, but we
171 recommend that both the Notice of Proposed Rulemaking (NPRM) on Meaningful Use¹¹
172 and the IFR explicitly identify that option for Stage 1 compliance for providers and make
173 it a requirement for qualified or certified health IT. By recommending that this
174 capability be made an allowable option to satisfy the Stage 1 patient engagement
175 requirements, we do not suggest that it be the only such option. If an EHR is being used
176 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.

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

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

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

202 **Recommendation 4** **Limit the use of “illustrative” standards**
203 **examples.**

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

206 **RECOMMENDATION:**

- 207 • 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/phiti/reports/overview.html>

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

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

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

- 221 1. Keep it simple.
- 222 2. Think big, but start small.
- 223 3. Don’t let “perfect” be the enemy of “good enough”.
- 224 4. Keep the implementation cost as low as possible.
- 225 5. Do not try to create a one-size-fits-all standard.
- 226 6. Separate content and transmission standards.
- 227 7. Create publicly available vocabularies & code sets.
- 228 8. Leverage the Web for transport (“health Internet”).
- 229 9. Position quality measures so they motivate standards adoption.
- 230 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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