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September 23, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
Washington, DC 20201

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
Department of Health and Human Services
Washington, DC 20201

Dear Secretary Sebelius and Dr. Mostashari:

On behalf of HIMSS, we are pleased to submit written comments to the Department of Health and Human Services and the Office of the National Coordinator for Health IT regarding the Advanced Notice of Proposed Rulemaking published in the *Federal Register* on July 29th, entitled, “Metadata Standards To Support Nationwide Electronic Health Information Exchange” [RIN 0991–AB78 July 29, 2011].

HIMSS is a cause-based, not-for-profit organization exclusively focused on providing global leadership for the optimal use of information technology (IT) and management systems for the betterment of healthcare. Founded over 50 years ago, HIMSS and its related organizations are headquartered in Chicago with additional offices in the United States, Europe and Asia. HIMSS represents more than 40,000 individual members, of which more than two-thirds work in healthcare provider, governmental and not-for-profit organizations. HIMSS also includes over 540 corporate members and more than 150 not-for-profit organizations that share our mission of transforming healthcare through the effective use of information technology and management systems. HIMSS frames and leads healthcare practices and public policy through its content expertise, professional development, research initiatives, and media vehicles designed to promote information and management systems' contributions to improving the quality, safety, access, and cost-effectiveness of patient care.

HIMSS applauds the continued development of interoperability standards to advance the secure exchange of health information. HIMSS has recognized the need to promote interoperability before the passage of the HITECH Act, and has actively contributed to the development and demonstration of the latest advancements in health information standards and interoperability. As you may know, the HIMSS Interoperability Showcase™ is one of the most heavily trafficked

37 areas at the HIMSS Annual Conference and Exhibition that annually draws over 28,000
38 healthcare leaders. Over 5,000 attendees visited the Showcase at HIMSS11. Additionally,
39 HIMSS – in partnership with the Radiological Society of North America (RSNA) – has led the
40 efforts of the “Integrating the Healthcare Enterprise” (IHE) initiatives in the USA and
41 participation in Europe since 1998, and composed of over 400+ healthcare-related organizations
42 world-wide. For the past seven years, HIMSS also served as the Secretary for ISO TC/215
43 Health Informatics and the U.S. Technical Advisory Group, contributing to substantial growth of
44 ISO/TC215 participation and scope and the seating of a U.S. chair. It is with this perspective that
45 we offer our commitment and dedicated resources to working with ONC to advance the adoption
46 of Metadata standards.

47 HIMSS appreciates the effort by ONC to incorporate public comments into the concept for the
48 ANPRM, including [HIMSS and other public comments](#) on the PCAST Report. One area of the
49 ANPRM we believe needs additional consideration is the ONC decision to adopt HL7 CDA R2
50 document header as the metadata specification rather than the IHE XDS Metadata specification.
51 The XDS Metadata specification is derived from the HL7 CDA, but currently exists with the
52 extensions that the ANPRM and the Power Team have identified as necessary in the CDA
53 header. It is also important to note that the XDS Metadata specification also supports any
54 document type, such as PDF, doc/docx, etc. allowing it to encompass non-CDA delineated data,
55 both structured and unstructured. Finally, as discussed in the recent [white paper developed by](#)
56 [the Electronic Health Records Association \(EHRA\)](#), the IHE-developed XDS metadata model
57 applies to the different architectures for Health Information Exchange, including the NwHIN-
58 Exchange and in the Direct Project.

59 In addition, HIMSS is concerned that the intent of the ANPRM to determine the core metadata
60 needed to support health information exchange through the definition and capture of metadata
61 that describes the document is being blurred as the ANPRM spends a considerable amount of
62 time defining metadata for patient-specific health information. HIMSS encourages ONC to keep
63 the requirements for metadata information exclusively focused on the information that is
64 necessary to identify the document in order to maximize the likelihood it can be exchanged and
65 read by external organizations. In following this narrowly defined approach, the metadata
66 should be sufficient to link document content to the patient.

67 Finally, in an effort to address the additional issues outlined in the ANPRM, HIMSS offers
68 specific comments on the following questions in the ANPRM:

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72 **ONC Question: Are there additional metadata elements within the patient identity**
73 **category that we should consider including? If so, why and what purpose would the**
74 **additional element(s) serve? Should any of the elements listed above be removed? If so,**
75 **why?**

76 HIMSS suggests that the intent of the ANPRM is to define the core metadata necessary to
77 identify a document. The core metadata elements should be narrowly defined.

78
79 HIMSS suggests that the requirements provided for the recommended standard set of patient
80 identity metadata elements do not address the nature of the data and its collection. All too
81 frequently, systems dictate how data can be entered rather than how they should be entered to
82 ensure data integrity. As these are critical data elements for identification of individuals, there
83 should be careful consideration of the issues that play a confounding role in the integrity of those
84 elements. As presented in the [HIMSS White Paper on Patient Identity Integrity](#), there is a large
85 supporting wrapper around the data that must be addressed in order to achieve the goal of
86 identity integrity in record matching. The best metadata in the world is useless if it is not
87 utilized or implemented properly. Data integrity depends on the understanding of the
88 technology, executive level support of business processes with performance standards for data
89 accuracy and quality through funding and staffing, training and administration of intake and
90 scheduling areas, as well as clinical staff accessing and updating individual records. The
91 supporting infrastructure is critical to the success of the data integrity.

92 **ONC Question: In cases where individuals lack address information, would it be**
93 **appropriate to require that the current health care institution’s address be used?**

94 HIMSS does not consider it appropriate to use an institution address because of the lack of value
95 add this would provide to the record at the expense of staff hours used to collect and process the
96 information. We suggest that perhaps a default option for address unknown is better than using
97 an institutional address which could actually create misinformation in the case where a patient
98 was in the database under the real address and different name construct.

99
100 **ONC Question: How difficult would it be today to include a “display name” metadata**
101 **element? Should a different approach be considered to accommodate the differences**
102 **among cultural naming conventions?**

103

104 HIMSS suggests display name is an attribute of the Patient Identity Domain, not an attribute of
105 the data object or document to which the metadata is associated. It should not be considered a
106 required metadata value.

107

108 **ONC Question: We are also considering whether to propose as a second extension, beyond**
109 **the HL7 CDA R2, the use of a uniform resource identifier (URI) to act as a namespace for**
110 **the patient identifier metadata as opposed to the use of an object identifier (OID) as**
111 **specified in HL7 CDA R2.**

112 HIMSS suggests that there needs to be some flexible mechanism to express a wide variety of
113 patient identifiers. It is clear that restricting such identifiers to only OIDs is not acceptable.
114 Whether or not URIs represent the appropriate solution to this is also debatable. Rather, a set of
115 pre-defined XML metadata tags (e.g. driver's license, medical record number, insurance number)
116 would seem to be a more flexible solution that could be extended over time as the need for
117 additional classes of identifier are recognized. However, these raise substantial privacy concerns
118 when provided as external to the document in metadata.

119 **ONC Question: Are there additional metadata elements within the provenance category**
120 **that we should consider including? If so, why and what purpose would the additional**
121 **element(s) serve? Should any of the elements listed above be removed? If so, why?**

122
123 HIMSS suggests that provenance in this simple use case likely does not need much more
124 information than recommended in the ANPRM. However, if a data aggregator such as an HIE
125 organization is producing a (HITSP) C32 Summary Document based on current information
126 available in the organization, provenance must be much more explicitly defined to represent
127 original data sources.

128
129 **ONC Question: With respect to the provenance metadata elements for time stamp, actor,**
130 **and actor's affiliation, would it be more appropriate to require that those elements be**
131 **expressed in XML syntax instead of relying on their inclusion in a digital certificate? For**
132 **example, time stamp could express when the document to which the metadata pertain was**
133 **created as opposed to when the content was digitally signed. Because this approach would**
134 **decouple the provenance metadata from a specific security architecture, would its**
135 **advantages outweigh those of digital certificates?**

136 HIMSS agrees that representation of provenance would best be decoupled from the X.509
137 security architecture and represented as simple XML elements. This will be needed in creation of
138 composite clinical summary documents where data must be aggregated from multiple sources.
139 The digital signature itself could be included as a representational element with the associated
140 hash as an XML identifier.

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145 **ONC Question: What experience, if any, do stakeholders have regarding policy pointers? If**
146 **implemented, in what form and for what purpose have policy pointers been used (for**
147 **instance, to point to state, regional, or organizational policies, or to capture in a central**
148 **location a patient’s preferences regarding the sharing of their health information)? Could**
149 **helpful concepts be drawn from the Health Information Technology Standards Panel**
150 **(HITSP) Transaction Package 30 (TP30) “Manage Consent Directives?”**

151 Current industry experience suggests that policy pointer metadata is not mature enough in
152 concept to be proposed as a solution at this time. The presence of this pointer could have an
153 unintended consequence of incorrect sharing decisions being made because of unrecorded
154 changes in preference, or a mistaken understanding of a more recent preference statement at a

155 This concept should be monitored and evaluated as it matures in the industry for identification of
156 future experience and case studies of success.

157 **ONC Question: Is a policy pointer metadata element a concept that is mature enough to**
158 **include as part of the metadata standards we are considering? More specifically, we**
159 **request comment on issues related to the persistence of URLs that would point to privacy**
160 **policies (i.e., what if the URL changes over time) and the implication of changes in privacy**
161 **policies over time (i.e., how would new policy available at the URL apply to data that was**
162 **transmitted at an earlier date under an older policy that was available at the same URL)?**

163 As we indicated in the previous question, current industry experience suggests that policy pointer
164 metadata is not mature enough in concept to be proposed as a solution at this time. The presence
165 of this pointer could have an unintended consequence of incorrect sharing decisions being made
166 because of unrecorded changes in preference, or a mistaken understanding of a more recent
167 preference statement at a different location overriding the preference stated at this pointer. This
168 concept should be monitored and reevaluated for future success.

169 **ONC Question: Assuming that a policy pointer metadata element pointed to one or more**
170 **privacy policies, what standards would need to be in place for these policies to be**
171 **computable?**

172 HIMSS suggests the standards requirements would depend on federal and state statute and
173 regulation that are utilized in development of an organization’s privacy policies, procedures and
174 overall Governance model.

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179 **ONC Question: What kind of starter value set would be most useful for a sensitivity**
180 **metadata element to indicate? How should those values be referenced? Should the value set**
181 **be small and general, or larger and specific, or some other combination? Does a widely**
182 **used/commonly agreed to value set already exist for sensitivity that we should considering**
183 **using?**

184 HIMSS suggests a single meta-value that indicates that sensitive data is present which would be
185 based on state rules and interpreted by institution rules. Beyond that meta-value, the HL7
186 ConfidentialityByAccessKind code set could be used to further refine the access decision for
187 more sophisticated analysis, but the patient should be allowed to allow or deny access simply
188 based on the sensitivity meta-tag.

189 **ONC Question: The HIT Standards Committee concluded that it was not viable to include**
190 **the policy applicable to each TDE because policy changes over time. Is this the appropriate**
191 **approach? Are there circumstances in which it would be appropriate to include privacy**
192 **preferences or policy with each data tagged element? If so, under what circumstances?**
193 **What is the appropriate way to indicate that exchanged information may not be re-**
194 **disclosed without obtaining additional patient permission? Are there existing standards to**
195 **communicate this limitation?**

196 HIMSS concurs with the HIT Standards Committee's conclusion that it is not viable to include
197 the policy applicable to each TDE due to the long-term time and resources required to maintain
198 the currency of the information. HIMSS suggests that regardless of the fact that the record has
199 PHI sourced externally the root issue appears to be the facility sharing the data without
200 appropriate consent from the patient. The facility's policies, procedures, and governance
201 structure should support the appropriate exchange and sharing of PHI information without
202 having to tag it to each TDE.

203

204 **ONC Question: With respect to the first use case identified by the HIT Policy Committee**
205 **for when metadata should be assigned (i.e., a patient obtaining their summary care record**
206 **from a health care provider), how difficult would it be for EHR technology developers to**
207 **include this capability in EHR technology according to the standards discussed above in**
208 **order to support meaningful use Stage 2?**

209 Depending on the specific metadata approach ultimately chosen by ONC, we believe that there
210 could be substantial implications for providers and EHR vendors in terms of adding support for
211 specific metadata elements, especially regarding privacy and, to some degree, provenance. We
212 therefore urge that ONC and CMS look at staging in adoption across Stages 2 and 3 of
213 meaningful use in terms of addition of metadata certification requirements, reflecting the final
214 approach taken and data in provider and vendor readiness and standards maturity. The major
215 issues include whether an appropriately refined approach could be included in the Stage 2
216 certification NPRM, the extent to which vendors and providers would have confidence that they



217 could and should pursue development based on the proposed rule rather than the Stage 2 Final
218 Rules, and the nature of the changes in data models, workflows, and other aspects of EHR
219 technology and provider usage that would be needed. We defer to the EHRA comments for
220 additional information on the impact this would have on vendors' product development and
221 deployment within their client base.

222 **ONC Question: Assuming we were to require that EHR technology be capable of meeting**
223 **the first use case identified by the HIT Policy Committee, how much more difficult would it**
224 **be to design EHR technology to assign metadata in other electronic exchange scenarios in**
225 **order to support meaningful use Stage 2? Please identify any difficulties and the specific**
226 **electronic exchange scenario(s).**

227 As indicated in the above question, HIMSS suggests that the EHR technology developers would
228 need to have the requirements for incorporation into their software applications and enough time
229 allowed for them to deploy the updated version of the software to their client base. We defer to
230 the EHRA comments for additional information on the impact this would have on vendors'
231 product development and deployment within their client base.

232
233 **ONC Question: How would the extension of metadata standards to other forms of**
234 **electronic health information exchange affect ongoing messaging and transactions? Are**
235 **there other potential uses cases (e.g., exchanging information for treatment by a health care**
236 **provider, for research, or public health) for metadata that we should be considering?**
237 **Would the set of metadata currently under consideration support these different use cases**
238 **or would we need to consider other metadata elements?**

239 Overall, HIMSS suggests that as an industry, we are just beginning to understand the impacts of
240 these type of proposals have on our implementation and use of HIT and software applications.
241 HIMSS recommends leveraging and working with existing initiatives focused on data standards,
242 interoperability, and the exchange of data in order to facilitate the efficiency of the ANPRM.
243 Examples include the Query Health Initiative of the S&I framework, IHE, LOINC, CDISC and
244 related HL7 standard initiatives.

245
246 **ONC Question: Are there other metadata categories besides the three (patient identity,**
247 **provenance, and privacy) we considered above that should be included? If so, please**
248 **identify the metadata elements that would be within the category or categories, your**
249 **rationale for including them, and the syntax that should be used to represent the metadata**
250 **element(s).**

251 HIMSS suggests the government consider including a standardized way of sharing the
252 authorization levels supported across facilities. For example, roles related to licensed
253 professionals and non-licensed professionals and other role based access controls. This may be
254 useful in relation to privacy preference configuration.

255



256 **ONC Question: In addition to the metadata standards and data elements we are**
257 **considering, what other implementation factors or contexts should be considered as we**
258 **think about implementation specifications for these metadata standards?**

259 HIMSS suggests that as the processes for exchanging clinical data and other patient related
260 documents across facilities continue to expand, we can anticipate that additional requirements
261 will emerge. In the future, we may easily see the need for a standard approach for representing
262 expert rules for execution within the system boundary if the implementation model is to be able
263 to support processing of rules at the local node, while exchanging information across facilities.
264

265 **ONC Question: Besides the HL7 CDA R2 header, are there other standards that we should**
266 **consider that can provide an equivalent level of syntax and specificity? If so, do these**
267 **alternative standards offer any benefits with regard to intellectual property and licensing**
268 **issues?**

269 HIMSS appreciates the effort by ONC to incorporate public comments into the concept for the
270 ANPRM, including [HIMSS and other public comments](#) on the PCAST Report. One area of the
271 ANPRM we believe needs additional consideration is the ONC decision to adopt HL7 CDA R2
272 document header as the metadata specification rather than the IHE XDS Metadata specification.
273 The XDS Metadata specification is derived from the HL7 CDA, but currently exists with the
274 extensions that the ANPRM and the Power Team have identified as necessary in the CDA
275 header. It is also important to note that the XDS Metadata specification also supports any
276 document type, such as PDF, doc/docx, etc. allowing it to encompass non-CDA delineated data,
277 both structured and unstructured. With regard to intellectual property and licensing issues, IHE
278 specifications are freely available in the public domain. Finally, as discussed in the recent [white](#)
279 [paper developed by the Electronic Health Records Association \(EHRA\)](#), the IHE-developed
280 XDS metadata model applies to the different architectures for Health Information Exchange,
281 including the NwHIN-Exchange and in the Direct Project.

282 **ONC Question: Presently, we are considering leveraging the HL7 CDA R2 header insofar**
283 **as the syntax requirement it expresses relate to a metadata element we are considering.**
284 **Should we consider including as a proposed requirement the additional structures to create**
285 **valid HL7 CDA R2 header??**

286
287 As stated above, HIMSS appreciates the effort by ONC to incorporate public comments into the
288 concept for the ANPRM, including [HIMSS and other public comments](#) on the PCAST Report .
289 One area of the ANPRM we believe needs additional consideration is the ONC decision to adopt
290 HL7 CDA R2 document header as the metadata specification rather than the IHE XDS Metadata
291 specification. The XDS Metadata specification is derived from the HL7 CDA, but currently
292 exists with the extensions that the ANPRM and the Power Team have identified as necessary in
293 the CDA header. It is also important to note that the XDS Metadata specification also supports



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295 data, both structured and unstructured. With regard to intellectual property and licensing issues,
296 IHE specifications are freely available in the public domain. Finally, as discussed in the recent
297 [white paper developed by the Electronic Health Records Association \(EHRA\)](#), the IHE-
298 developed XDS metadata model applies to the different architectures for Health Information
299 Exchange, including the NwHIN-Exchange and in the Direct Project.

300 **Additional Comments and Suggestions:**

301 **Errors:** HIMSS suggests that the eventual proposed rule include requirements for a discussion
302 of how to address errors that will occur with implementation of the proposed metadata set.

303
304 **Privacy & Identity Theft:** HIMSS suggests that the eventual proposed rule address the privacy
305 and identity theft implications of using this set of information elements as the primary
306 mechanism to identify the literally thousands of various medical information items needed to
307 manage healthcare for an individual over their lifetime.

308
309 **Patient as Consumer and Provider Engagement:** As the government and the healthcare
310 community move forward on the metadata initiative, HIMSS suggests that the patient as
311 consumer and the provider need to be at the center of the discussion. We need to find a balance
312 to avoid the unintended consequence of the metadata tagging process impacting an overburdened
313 provider, resulting in an adverse encounter for the consumer.

314
315 HIMSS looks forward to providing ONC additional information throughout the rulemaking
316 process. For more information on HIMSS activities in support of this effort, please contact
317 [Mr. James St. Clair](#), HIMSS Senior Director for Interoperability and Standards, [Ms. Lisa](#)
318 [Gallagher](#), HIMSS Senior Director for Privacy and Security, or [Mr. Thomas M. Leary](#), HIMSS
319 Senior Director of Federal Affairs.

320
321 Sincerely,

322 

323 H. Stephen Lieber, CAE
324 President and CEO

325 cc: Steven Posnack, MS, MHS, Director of Federal Policy, Office of the National Coordinator