

Patient Command, Inc.
McLean, Virginia

May 6, 2009

Hon. Kathleen Sebelius
Secretary of the Department of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Interoperability Standards for Qualified Electronic Health Records Under the
HITECH Act – Proposal for Rulemaking

Dear Madam Secretary:

On behalf of Patient Command, Inc., we write to propose, for inclusion in notice and comment rulemaking under Title XIII of The American Recovery and Reinvestment Act of 2009, Pub. L. 111-5 (the “HITECH Act” or the “Act”), an initial interoperability standard to begin enabling the routine exchange of electronic health records. The standard we suggest is designed to satisfy the Act’s criteria for a “Qualified Electronic Health Record.” If adopted, it would be realistic and achievable in the short term. It would accelerate the exchange of medical record information, even though it is technologically modest.

As background, Patient Command, Inc. is developing a personal health record (PHR) system.

Introduction

The HITECH Act sets ambitious deadlines for achieving an as-yet-undefined level of interoperability of electronic medical records. Meanwhile, however, technical incompatibilities among record formats, a large base of vital but non-interoperable legacy health industry computer systems, the absence of data standards, and a persistent lack of any clear path toward standards development remain substantial obstacles.

Overcoming these barriers in a short time, as Congress and the President seek via the Act, is a daunting task, because efforts to settle on a consistent approach to electronic medical record interoperability remain in turmoil. It is possible that a practical path to interoperability may continue to elude policy makers and industry veterans alike.

A rapidly implementable initial standard for interoperability of Qualified EHRs will unlock the Act’s promise only if it can be based on using existing technology to reach realistically achievable, useful, goals. Conversely, promoting technologically

ambitious but infeasible standards, such as those explored by many in healthcare during the past several years, will block progress under the Act.

Meanwhile, industry groups are offering proposals for regulations to implement “meaningful use” standards under the Act; but scant attention is paid to defining the foundational regulatory standard for “Qualified Electronic Health Record.” We focus on the initial practical definition of interoperability because “Qualified EHR” is the key concept underlying constructs in the Act such as “meaningful use” by professionals and hospitals of “certified EHR technology.” It is the prerequisite for progress under the HITECH Act.

Proposal for Rulemaking

We ask that you issue a notice of proposed rulemaking to offer the following interoperability standard for comment, in accordance with the Administrative Procedure Act. The rulemaking in question is mandated in new Section 3004(b)(1) of the Public Health Service Act (the “PHS Act,” 42 U.S.C. 201 et seq., as amended by Section 13101 of the HITECH Act) . It sets a deadline of December 31, 2009 for adopting an “initial set of standards, implementation specifications, and certification criteria,” which may be issued on an interim final basis.

The areas for which the standards are required are listed in Section 3002(b)(2)(B) of the PHS Act. They include security, privacy, a nationwide technology infrastructure for the electronic use and accurate exchange of health information, and use of a certified EHR for each person in the United States by 2014.

Our proposed standard contemplates requiring that any system, in order to be a Qualified EHR for purposes of the Act, must be able to output medical record narrative according to an XML (eXtensible Markup Language) schema maintained by NIST and based on current standards development work. The system would also be required to receive input using that XML schema. It would also require the capacity to output and input images using the DICOM (Digital Imaging and Communications in Medicine) standard.

Relatively speaking, this two-part standard is straightforward and amenable to rapid refinement and adoption through notice and comment rulemaking. It then can be implemented in the healthcare industry affordably and relatively quickly. Later, this standard may be supplemented to deal with messaging standards using XDS (Cross-Enterprise Document Sharing), as we will discuss below.

This is a statement of the initial standard we suggest for rulemaking:

As an initial standard for interoperability, a “Qualified Electronic Health Record” shall meet the requirements of 42 U.S.C. § 3000(13)(b) if it is capable of producing electronic output, and receiving electronic input, as follows:

(1) For narrative, output and input formatted in Extensible Markup Language (XML) according to an XML schema that shall be –

A. Based on the Continuity of Care Document (CCD) developed cooperatively by Health Level Seven (HL7) and ASTM International (ASTM), and that in turn is consistent with HL7's Clinical Document Architecture (CDA), and

B. Maintained and updated by the National Institute of Standards and Technology (NIST) in consultation with HL7, ASTM, and such other entities as NIST shall from time to time deem appropriate.

(2) For images, output and input formatted under the DICOM (Digital Imaging and Communications in Medicine) standard as that standard is maintained and updated by the DICOM Standards Committee or its successor(s).

Whether, where, or the extent to which, the XML schema NIST maintains should specify CCD Level 2 (generally recognizing, but not encoding, CCD subsets) or Level 3 (requiring all CCD information to be encoded precisely as structured data) should be open to comment in the rulemaking. We suggest proposing that, to begin, the NIST-maintained schema generally incorporate CCD Level 2, because the standard we propose is designed for rapid implementation. Therefore, the level of exchange it will facilitate may to some be less than theoretically optimal. It will, however, be useful because it will immediately permit the exchange of copies of medical record narrative through a variety of familiar, inexpensive ways, including electronic mail and the exchange of discs and similar media.

The exchange we contemplate depends on humans, rather than machines, to read and interpret the information. It is not the “semantic” interoperability that may be possible when CCD is largely implemented in Level 3. However, even a substantial, partial implementation of semantic interoperability, via CCD Level 3 or any other means, is many years away. (Semantic interoperability is the ability of two or more computer systems to exchange information and have the meaning of that information accurately and automatically interpreted for use by the receiving systems.) The reason is that coding each subset of data in CCD Level 3 (or any other alternate system) is itself a major technology standards project. Each of these projects requires substantial industry consultation and time. In total, it is a lengthy process that must be undertaken carefully, and will continue indefinitely, in order to incorporate progress in medical practice and science.

In the interim, the benefits of the approach we suggest are transformative:

- First, the output of medical record narrative in XML that is standardized for the United States will permit clinicians routinely to exchange and interpret medical records from a wide variety of sources – all Qualified EHRs. Of course, these sources will grow rapidly because of the impact of the Act on professionals and hospitals who seek the incentives that attend “meaningful use” of certified HR technology.
- Second, patients, on request under HIPAA (45 CFR §164.524(c)(2)), will be able to receive standardized electronic copies of their medical information for use in personal health records (PHRs). The availability of medical record narrative in standard XML form means that consumers’ input into, and output from, their PHRs is vastly simplified. This will encourage consumers to adopt PHRs, and make it easier for clinicians to use PHR outputs. Among other things, the digital text, once input, is searchable by computer. This goes a long way toward reducing the data quality problems reported in PHRs that, for example, attempt to auto-populate PHRs using claims data from health insurance companies. The claims data of course has gaps and other inherent inaccuracies that make its use for populating PHRs foreseeably, and unacceptably, dangerous. (See, for example, Boston Globe, Editorial, “Diagnosis Inaccuracy,” April 24, 2009, available at http://www.boston.com/bostonglobe/editorial_opinion/editorials/articles/2009/04/24/diagnosis_inaccuracy/).
- Third, use of the Continuity of Care Document (CCD), an XML instantiation of HL7’s Clinical Document Architecture (CDA), offers the foundation for eventual routine, inexpensive exchange of electronic medical record information between clinicians and researchers. The CDA is based on an information model that uses successive levels of data abstraction. Clinical information can be abstracted and then accurately translated (via a reverse of the abstraction process) into formats used in research. The effort involved to set up these abstraction and translation systems is enormous, and we do not intend to minimize it. The transformative point, however, is that using the CDA information model makes possible eventually bridging the now-vast gap between the information practices of the clinicians and researchers. (The CDA is already used in many research settings, such as the National Cancer Institute’s Bio-Informatics Grid, CaBIG.) We are looking at the long-term system engineering opportunities for medical record information in the digital age. In that framework, providing affordable, easy use of clinical data in the laboratory, and vice versa, is essential.

Statutory Compliance

Some critics may argue that this proposal is too rudimentary to satisfy the statutory standard for a Qualified EHR, or that it offers too little an improvement. To anticipate these objections, it is essential to review this proposal in light of the statute.

The definition of “Qualified Electronic Health Record” is in Section 13101 of the HITECH Act as it amends The Public Health Service Act (42 U.S.C. et seq.) by adding Section 3000(13) to the PHS Act. It is:

The term ‘qualified electronic health record’ means an electronic record of health-related information on [*sic*] 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 [*sic*] other sources.

Defining the Qualified EHR as we propose meets all these capacity criteria at an initial level. We demonstrate this by analyzing the proposal at its most rudimentary, where standardized XML narrative output is transferred from one doctor to another, no matter the clinical setting. The second doctor can generate narrative in electronic or print format to review.

(i) Almost by definition, having the patient’s previous medical record data in standardized CCD output will support clinical decision making. The extent of support will vary depending on factors such as relevance of the earlier data to the patient’s current condition, the thoroughness of earlier care and accuracy of its documentation in the earlier record, and the treating physician’s confidence in the security of the narrative as conveyed.

(ii) Similarly, the availability of XML-formatted narrative will help capture earlier physician orders and promote the accuracy of new orders. It will also promote standardizing physician order entry systems according to CCD standards as they develop. This in turn will lead to standardizing physician training in and use of computerized order entry systems, making order entry faster, easier, and likely more accurate across clinical settings.

(iii) The availability of medical record data in CCD format will hasten the exchange of patients’ records among caregivers and allow them to search data for a wide variety of purposes, from enhancing the quality of care for a patient at a given moment to studying data on quality of care across patient populations.

(iv) The availability of Qualified EHRs that produce standardized narrative in electronic form will by itself hasten both the exchange of information and its integration with XML-standardized record data from other caregivers.

Moreover, in the longer term, as we describe above, it will enable exchange of data between clinical and research environments because the Continuity of Care Document format is based on HL7's Clinical Document Architecture.

We note that the HITECH Act contemplates starting with initial standards to meet an early deadline, with further standards development to follow. See, for example, new Section 3004 of the PHR Act. The Secretary and the National Coordinator for Health Information Technology are given specific authority for an evolutionary approach to standards. Therefore, the initial standards selection process we suggest complies with the statutory scheme.

Consideration of Alternatives to the CCD and CDA

We suggest that you also issue notice and seek comment on whether HHS should adopt – critics might say “anoint” – the Continuity of Care Document, and the Clinical Document Architecture that underlies it, as foundation standards for interoperability of the Qualified EHR. Critics of using the CDA as a foundation for interoperability standards are likely to argue that the CDA is too abstract and arcane to be usefully implemented. They may point to Version 3 of the CCD, an advanced structured data standard for implementing the CDA for clinical records, as proof that any CDA-based standard is unnecessarily complex. They may advocate a simpler foundational standard. These well known criticisms of the CCD and CDA should be aired thoroughly at this critical juncture.

In light of these criticisms, it also is fair to ask, before a rulemaking notice issues, why the CCD and CDA form a core element of the initial standards we propose. We offer three principal reasons:

- Enabling the exchange of standardized medical record narrative would be an enormous advance over the state of the art. The fastest way path to this goal is to use the proven capacity of XML, which is used throughout government and industry, is well developed, and well understood. XML is the product of intense, sustained, successful systems development – proven technology available and affordable immediately. The CCD uses XML technology
- The CCD itself is the most highly developed consensus standard available to the Department to meet the goals of the HITECH Act. Were you for some reason to seek another standard, you would have little choice but to retrace the years of industry consultation and technology development that have led to the CCD. The ontological issues are profound, and industry groups have grappled with them for decades. The CCD has evolved as a result. No other standard is comparable for robustness, effective use of existing technology, or consensus support among the many groups and factions in U.S. healthcare information technology. Why retrace the path that industry has forged painfully over so many years?

- The CCD and CDA are complex because the data they must cover are complex. Stated another way, the CCD and CDA have evolved because their designers recognize that only powerful systems are capable of representing the vast, complex scope of data accurately, in the required detail, to support the wide range of uses that clinical practice and research demand.

Nevertheless, an open rulemaking process should examine adoption of the CCD and CDA, and use of XML, for reasons of satisfying the Administrative Procedure Act, satisfying all elements of the healthcare industry about the fairness of the inquiry, and satisfying government that it is pursuing the most effective course.

In addition, some commentators may assert that basing Qualified EHR standards on the CCD is too great a step even to be offered for comment. They may assert that it is beyond the capacity of legacy system vendors and operators to modify their systems to output medical record narratives using an XML schema, and particularly one based on the CCD. They will argue that the CCD, the CDA, and the CDA's Reference Information Model are too abstract and complicated to instantiate in useful form for keeping and interchanging medical record data.

Clearly, we do not agree with this line of criticism, but we think it sensible to anticipate it, include it in the rulemaking notice, and encourage comment about it. The long search for interoperability standards sees swings to extremes. They alternate between utopian visions that are beyond current technology and dark fears that real interoperability would demand technical uniformity beyond feasibility. Now, with the Act's first deadlines upon us, is the time to chart a course that avoids both traps.

A Possible Supplement to the Rulemaking Proposal: XDS

The proposed initial standard for interoperability of a Qualified EHR is powerful because it uses existing and practicable technology in a simplified framework to reach a useful, achievable objective quickly. All the same, one additional set of standards, for the computer communications that will carry the XML content, may accelerate progress towards reaching an initial nationwide level of interoperability. That standard is Cross-Enterprise Document Sharing, or XDS.

To quote an industry publication:

The *Cross-Enterprise Document Sharing* IHE Integration Profile facilitates the registration, distribution and access across health enterprises of patient electronic health records. Cross-Enterprise Document Sharing (XDS) is focused on providing a standards-based specification for managing the sharing of documents between any healthcare enterprise, ranging from a private physician office to a clinic to an acute care in-patient facility.

IHE International, IHE Infrastructure Technical Framework, Vol.1 (Dec. 12, 2008), at 64 (available at http://www.ihe.net/Technical_Framework/upload/IHE_ITI_TF_5-0_Vol1_FT_2008-12-12.pdf).

For purposes of our rulemaking proposal, adoption of a nationwide XDS “Affinity Domain” should be considered because it could make CCD messaging using XML far easier. Considerations running the other way include worries that defining an initial nationwide Affinity Domain for this purpose really is unnecessary for exchange of CCD narrative among providers; would take too long; and would distract from the task, already sufficiently complicated, of arriving at a CCD-based XML schema for NIST to promulgate and maintain. For these reasons among others, it might be preferable to defer consideration of a nationwide XDS Affinity Domain for this purpose to a second phase of standard setting that would take place after December 31, 2009.

We believe your consideration of these questions would benefit from comments obtained via rulemaking. Many healthcare information technology industry associations and system vendors might support developing an XDS Affinity Domain for initial standards purposes, and might suggest doing so earlier rather than later.

The Importance of Enabling PHRs

The President’s goal of an electronic medical record for everyone in the United States by 2014 may best be reached by integrating records around each patient. That is done most efficiently through personal health records (PHRs) where the data is owned, compiled, and controlled by the patients.

This systems architecture is more efficient than ad hoc efforts to assemble medical records, but that is in some ways the least of its virtues. The PHR gives patients a way to understand their health, and to manage their health, healthcare, and interactions with caregivers and insurers, in ways that are impossible without unfettered access to one’s compiled medical records.

The societal benefits of fostering easy-to-use, affordable PHRs are enormous. Consumers with access to and control of their own data will be healthier; their healthcare decisions will be better; and the total cost of their care, across society as a whole, will be lower. PHRs are essential to making the American public more resourceful managers of their health and more efficient consumers of healthcare. PHRs are a significant element in the drive to reduce U.S. healthcare costs, higher quality care, and better outcomes.

PHRs controlled by patients, as in a health record bank model, also offer better security and privacy simply because of the architecture of health banks. Further, they can ameliorate many of the data quality issues that attend other medical record system architectures.

Thus there is reason for the Department to promote the public’s adoption of PHRs using the health record bank architecture. The barrier to doing so is that, at present, patients have difficulty inputting copies of their medical records into PHRs. This makes PHRs too difficult for many patients to use. Adoption is far too slow.

The essential step is straightforward: Make it easier for patients to obtain copies of their medical records in standard electronic form so that the data can easily be input into their health record bank PHR accounts.

One of our purposes in suggesting this rulemaking is to facilitate that easy input process. If providers are encouraged under the HITECH Act to acquire medical record systems that produce a standardized XML output (and can receive a standardized XML input) based on the Continuity of Care Document (in any version), then consumers' input to their PHRs will be vastly simplified. It will help overcome a major barrier to PHR adoption. Then PHRs can become an affordable reality that will spread across the United States.

XML Narrative and Existing Data Standards

Regulations prescribing that Qualified EHRs exchange medical record narrative under a standard XML schema can meet, imperfectly and on an interim basis, the need to use standards for specialized vocabularies and messaging instructions. These standards include, for example (and not as an exhaustive list), medical problem lists written using SNOMED-CT; medications described in RxNorm and Structured SIG; and laboratory results using LOINC for lab names, UCUM for units of measure, and SNOMED-CT for test ordering reasons.

The goal is to incorporate a variety of vocabularies and other auxiliary standards, all of which are undergoing constant development. This description sounds elaborate. The point is that professionals have the capacity now to read and make use of narrative in this form, if only we can get the narrative in their hands.

We believe this goal can be reached in the short term.

Open Source Code to Meet the Proposed Standard

The rulemaking notice we suggest should seek comment on whether, and the extent to which, open source code may be available to implement the initial interoperability standard suggested here for Qualified EHRs. The use of open source for this and similar purposes continues to be of interest in Congress. Its availability offers the potential both for rapid implementation and significant cost savings.

We believe that open source code for this purpose exists now, and that the developers of the code will respond in detail to an appropriate rulemaking notice.

The Proposed Standard and the Military Health System

The Military Health System seeks to develop a "Virtual Lifetime Record" for service members and veterans. The Virtual Lifetime Record should be compatible with Qualified EHRs in civilian healthcare, so the rulemaking proposal we suggest should include a request for comment about how to achieve that interoperability.

Integrating the country's evolving civilian and military electronic health record systems is essential. There is little policy debate on that score. We have already explained how the initial interoperability standard we suggest for Qualified EHRs would promote PHRs, and particularly PHRs using a health record bank architecture. Among other advantages, health record bank PHRs are scalable, in the same way that nationwide financial banks are scalable within an appropriate regulatory framework. This scalability offers an architectural path for consideration by the Military Health System. This concept is all the more compelling because of the potential availability of open source code to implement this architecture in both the civilian and military spheres. These possibilities should also be explored by requesting comment in the rulemaking notice.

Conclusion

As we stated earlier, many unrealistic proposals for computerized exchange of electronic health records advocate standards that not technically achievable in the near term. These proposals underestimate the difficulty of engineering existing medical record systems – with different operating systems, storage and communications protocols, and different data schemes – to interoperate. These many diverse, incompatible computer systems are found in hospitals and doctors' offices throughout the United States.

Some unrealistic proposals will be supported by powerful industry groups. They will be based on rosy assessments of the state of electronic medical record records, and will underplay the difficulties in re-engineering existing clinical information systems so that they can interoperate, even at a basic or primitive level. Experience of the last decade teaches away from optimism that, intractably, will not confront engineering reality.

Unless a realistic way emerges to initiate a transition toward information exchange among these diverse systems, we cannot achieve the President's 2014 goal of an electronic medical record for each person in the U.S. To fulfill the President's goal and the HITECH Act's mandate, policy makers and systems engineers must find a practical way in the near term for our large installed base of medical computers to exchange medical record data usefully.

In this letter we suggest just such a realistic path toward initial levels of exchange of medical record information. Our proposals are consistent with the definition of Qualified Electronic Health Record in new Section 3000 (13) of the PHS Act. They acknowledge the incompatibility of today's installed base of medical record computer systems. Our proposals also build on existing standards work. They are feasible for use in the installed base of legacy healthcare computer systems.

If clinical systems were required to output and receive standard XML narrative – narrative that any clinician could create, read, and search – that would be a major advance over the state of the art. It would also functionally integrate legacy healthcare

systems quickly and relatively inexpensively – and years before even the rudiments of more ambitious schemes (such as those for semantic interoperability) might begin to bear fruit. It would also enable the rapid, widespread introduction of personal health records, with benefits to individual consumers and to society.

Our proposals carry a cost, but it will be lower than other proposals, and will not waste money available under the HITECH Act. Our proposals are tailored realistically for adoption by the Act's deadline of December 31, 2009. Moreover, they can be implemented on the installed base of medical record computer systems shortly after the first set of standards is adopted.

Respectfully submitted,
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