

To: The Implementation Workgroup of the HIT Standards Committee

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October 24, 2009

I appreciate the opportunity to share the experience the Consumer unit of RelayHealth, a division of McKesson Corporation, has had in the area of implementing health information exchange and electronic health records using the standards discussed in the current set of recommendations by the HIT Standards Committee. Given the panel format, I have prepared both a testimony section and a longer section providing detailed background information relevant to the standards in question.

Testimony

I would like to thank the Implementation Workgroup of the HIT Standards Committee for inviting me to participate in this panel session.

RelayHealth operates a Software-as-a-Service platform that provides both physician applications targeting a wide variety of practice sizes, and health information exchange services connecting hospitals, reference laboratories, and ancillary providers to community physicians and the patients they serve. We currently provide modular EHR functionality, and connectivity services covering laboratory and radiology results, referrals, discharge summary and other clinical documents, electronic prescribing, and orders, based on current day standards, primarily HL7 2.x, NCPDP SCRIPT, ANSI x12, and web services.

As a single-instance, multi-tenant SaaS EHR and HIE platform, we have a unique perspective on health information technology. In this context, I would like to walk through some areas of concern from our perspective in the current recommendations of the HIT Standards Committee. We believe the current recommendations are enterprise heavy and will drive significant additional development, deployment and implementation costs. We believe the core needs could be addressed with a simpler regulatory framework. Finally, we believe that much work needs to be done on terminology standards.

Many of the currently recommended standards (e.g., ATNA, SAML, XACML, etc.) are solving “enterprise” problems, and are not cleanly applicable either to a SaaS platform or to small practices. While implementation of these profiles may benefit some large health system enterprises, the considerable costs for compliance will be shared broadly across the health care community, including the small physician practices that are the most cost conscious, and have neither the need nor the support staff to administer or maintain enterprise features. These practices want to solve core connectivity pain points, and these are problems we can solve with current standards.

Our large enterprise health system customers have not asked us for these enterprise features either. They are asking us to help them connect and facilitate transactions across their communities, and to

provide better continuity of care. Most of these problems we can solve currently, with standards in wide use in health information technology. The business problem new standards could most help with is sharing medications, allergies, and problem lists across the community. Here, we believe the critical problem is about standardization of terminology, more than standardization of document formats or transport protocols.

Given the cost of compliance, we believe that CMS should be quite judicious in mandating standards as part of the certification process. In past regulatory action, such as in the areas of eligibility, claims, and electronic prescribing, CMS has implemented standards to facilitate transactions with the federal government. By contrast, many of the recommendations of the HIT Standards Committee are focused on transactions within a healthcare enterprise, or between private parties, and it is not clear what regulatory interest CMS has in mandating and enforcing these standards.

In areas where there is no direct transaction with the federal government, and where there are legitimately multiple valid approaches, we believe that CMS should regulate at the policy level, as opposed to mandating specific standards conformance. For example, in areas such as auditing, security, authentication, authorization, consenting, encryption, and the like, we believe CMS should regulate and certify according to conformance to policies, procedures and principles, as opposed to conformance to detailed specifications.

This approach can also apply to data formats, where we are concerned about the costs to be incurred through over-specification driving non-value-adding work. For example, as part of our results connectivity services, we map from the HL7 2.x version supported by the clinical laboratory, provide results in our own results management application, and remap to the specific HL7 2.x message format supported by community EHRs. Requiring all systems to upgrade to strict conformance to 2.5.1 would slightly facilitate this work, but not to the degree that it would cover the costs to develop and upgrade all of the relevant systems. A degree of regulatory flexibility (for instance requiring Certified EHRs to accept 2.5.1 but not requiring 2.5.1 for establishing meaningful use) would allow us to build on what currently works and is well supported across multiple systems.

One area where ONC, NIST, NLM, and other regulatory bodies can greatly assist in the fulfillment of the legislative aims of ARRA is that of terminology. In our experience, there is an urgent and desperate need to create workable, validated, well documented, well maintained, and usable subsets of the applicable terminology standards. In the current state, navigating clinical terminology requires a significant investment in clinical informatics expertise. We believe that terminology, to a much greater extent than messaging formats, is the single most critical barrier to meaningful health information exchange. If we are to hit a 2013 implementation date, we believe these workable subsets need to be in place, tested and validated, and well documented by mid-2011.

To summarize, our key points are as follows:

- 1) CMS should facilitate building on the successful work with existing standards, such as HL7 2.x while we extend support for additional transactions

- 2) Many of the current recommendations are built around large-scale enterprise needs, and do not have clean applicability to SaaS platforms or to smaller physician practices
- 3) These recommendations will add significant costs to the creation, maintenance, deployment and support of health information technology
- 4) CMS should generally regulate at the policy level, and reserve specific standards regulation solely to those standards strictly necessary for facilitating transactions with the federal government
- 5) Well-validated, documented and maintained terminology subsets that work “out of the box” are an urgent and critical need.

Because of the time limits of my testimony, I have prepared a longer document with additional detail on these topics. Again, I would like to thank the Implementation Workgroup for inviting me to share our experience in this area, and we appreciate the consideration.

Background Material

The following material provides additional detail on our experience and concerns related to the current recommendations of the HIT Standards Committee:

- 1) **HL7 2.5.1:** It should be noted that the predominant set of laboratory, radiology, transcription, and EMR systems on the market support HL7 2.x messaging (for example, 2.3, 2.4) but may not enable strict 2.5.1 conformance. Despite this lack of strict conformance, many millions of clinical transactions flow between systems every day. For example, RelayHealth transmits millions of laboratory records, discharge summaries, radiology reports, and the like. While our base template is HL7 2.5.1, we may accept and send to edge systems using HL7 2.x. Such transmission meets the clear intent of the meaningful use criteria. Requiring all of the component systems to upgrade vendor support to natively transmit 2.5.1, or to require physician practices or hospitals to use and deploy integrations engines to manually remap these transactions to 2.5.1 would add significant costs to the health care industry, and would not add to enabling support for meaningful use.
- 2) **Summary Records, Clinical Reports, Encounter Messages, Radiology Messages, Allergies and Clinical Notes Content Exchange:** With regard to the 2011 exemption for “Unstructured documents with HL7 CDA header such as PDF or free text or images of documents with HL7 CDA header in certain cases such as history & physical or consultation notes, or, local or proprietary exchange such as other HL7 v2 implementations in certain cases such as radiology messages”, it is unclear what is being exempted in these cases. For example, would a discharge summary formatted textually using an HL7 2.x MDM message count as a structured or unstructured document according to the intent of the HIT Standards Committee? Would transfer of such a document qualify for Meaningful Use? We would also note that industry experience in sending unstructured documents with CDA headers is currently slim, whereas we, and industry in general, have broad experience using HL7 MDM messages to serve this purpose. HL7 MDM is broadly supported by current EHR systems and currently transmitted by most clinical transcription and textual reporting systems. Allowing text document transmission but requiring CDA as the transmission format may add, rather than reduce the costs of compliance. We recommend building on the broad scale support for HL7 2.x MDM messages by allowing continued transmission of textual documents in this format as a pragmatic and workable solution in this area.
- 3) **SNOMED-CT:** This is a large clinical vocabulary that serves multiple health care stakeholders with comprehensive terminology. Because of the size of SNOMED-CT, naïve use of it for describing ambulatory problem lists creates application workflows that are unwieldy, and have significant usability and clinical problems. As alternatives, there are both the CORE and KP/VA subsets; these need to be unified, tested, and maintained, and augmented with fully validated ICD-9-CM and ICD-10-CM crosswalks for billing purposes. In addition, comprehensive implementation documentation is needed.
- 4) **UNII:** We note that there is an overlap between this recommendation and the recommendation for RxNorm (in that ingredients are codified in RxNorm at the IN level) for medication vocabulary. For simplicity of implementation, we would prefer a single standard

- based on RxNorm. We would also note that the terminology standards do not currently provide a way to express allergies to medication classes. We believe there is a strong role for NIST and ONC to collaborate on pilots to clarifying terminology standards in this area. (It may be that UNII is being promoted by the HIT Standards Committee for allergies to non-medication substances, such as food or latex allergies. It would be our preference, in general, to reduce the number of terminology systems required to a minimum. Many commercial drug databases include support for allergies to non-medication substances. To the extent possible, augmenting RxNorm and SNOMED-CT would be preferable to additional terminology systems, as each supported system requires specific development, maintenance and support.)
- 5) **Medication Prescriptions And Other Medication Content Exchange:** We would request that CMS standards in this area keep harmonized with what is happening with standard intermediaries, such as Surescripts, such that, as standards progress to solve real-world business problems. For example, if NDPCP creates a new revision of the SCRIPT standard, and Surescripts has a compelling business need to upgrade to a new standard version, it would be helpful if standardization were coordinated with the intermediary. We would note that Surescripts has historically made multiple changes to the currently supported version of NCPDP SCRIPT, and is currently in the process of moving from NCPDP SCRIPT Standard 10.1 to 10.6. For a time, CMS was standardized on an NCPDP SCRIPT Standard version not supported by any intermediary; such mismatches between certified standard and real-world support should be eliminated.
 - 6) **Clinical Laboratory Vocabulary:** We would note that the clinical laboratory industry's current support for the suggested standards is minimal, and in many cases, the standard vocabularies selected are not "out of the box" usable (for example, we need usable subsets of both LOINC and SNOMED-CT). Accordingly, current industry practice is based almost entirely on proprietary laboratory codes and units of measure. There are no incentives provided under ARRA to clinical laboratories to comply with the selected vocabulary sets, which could create issues if EHRs were required to support standards that were not available by real-world clinical laboratories. In this area, we believe that NLM, NIST and ONC should collaborate on pilots to clarify terminology, and should work with reference clinical laboratories to encourage support of standards.
 - 7) **RBAC, SAML, XACML, WS-Trust, XUA, PWP, etc. (2013 and 2015):** These are a complex set of specification defining a structured approach for enterprise and cross-enterprise authentication and authorization for specific health care resources. Most of these standards have more applicability in the enterprise space than in the ambulatory space, and are not well structured for authentication and authorization in a SaaS platform. It is not clear, in the context of meaningful use and HHS Certification the regulatory interest CMS has in requiring and enforcing compliance to these specifications. In our experience in the SaaS environment, there are no market drivers for adoption of these standards, and it is also our experience in the context of providing authentication and authorization to physicians, staff, and other health care, that these standards are not necessary to adequately and securely provide enterprise and cross-enterprise sign-in capability. We would also note that there are

competing standards in this area, including OpenID, and OAuth. We believe that mandating conformance to these standards would require a significant amount of development work, time, and expense in the systems we currently maintain and develop; we believe that when this cost is multiplied across both the many existing vendors, and potential entrants who wish to offer innovative technologies to the health care space, the unintended consequence of TP20 compliance will be a stifling of innovation and reduction in the resources applied to the core HITECH outcomes. We believe a better approach is for CMS to require strong authorization and authentication by certified EHRs without mandating conformance to a specific set of standards.

- 8) **ATNA (2011)**: This standard, which requires a specific formatting structure for audit logs, and the ability for a logging system to send log information to a remote logging server, addresses a key security logging issue for large scale health enterprises. It is, however, not the only sensible way to implement logging, has significantly more applicability to an enterprise context than to a small practice context, and has uncertain applicability to a SaaS context. As the standard primarily covers security monitoring within an enterprise, it is not clear the regulatory interest CMS would have in standardizing ATNA as a required part of a Certified EHR. Changing an existing logging mechanism over to ATNA will require significant development effort, time, and resources. We believe a better approach would be for CMS to require secure auditing and logging for a certified EHR without mandating a specific logging framework.
- 9) **CCD (2011), XDS.b, ebXML (2013)**: This standard requires a specific federated document-passing architecture, allowing for the strict separation of registry and repository, with a specific orchestration of messages for sharing C32 CCD formatted clinical documents among multiple systems. While we believe that the XDS.b transaction set, and the overall approach of sharing multiple documents may be an appropriate mechanism for solving a set of health information exchange problems, we do not believe it is the only appropriate mechanism. Except to the extent that is required to transact with CMS or the federal government itself (for example, with the NHIN or Health Internet, we believe that CMS should require the act of health information exchange (mobilization of specific health information data, including medications, allergies, problems, laboratory data, discharge summaries, radiology reports, and the like) without mandating the form that health information exchange should take. We believe this approach will lead to increased innovation in the health care information technology space.
- 10) **HITSP TP30 (2013, 2015)**: HITSP TP30 is a mechanism to share patient consent metadata among systems. It is not the only appropriate one, and most current health information exchange is currently conducted with alternative approaches to managing patient consent. TP30 should therefore be not mandatory for health information exchange except as narrowly required to specifically transact with the federal government. Again, we believe that a better approach would be for CMS to require the outcome and process of obtaining appropriate patient consents, without requiring specific enabling technology.

In these matters in general, we would recommend that CMS regulate at the policy level, without specifically regulating the specific security message formats or exchange formats, except as minimally required to facilitate transactions with the federal government. This would allow CMS to, for example, require mobilization of discrete data, with an exemption for textual reports for 2011, without forcing specific format standardization, and therefore significant cost to upgrade systems, to a set of message formats or exchange formats without broad current industry support. We believe that this approach will lead to the greatest possible degree of health care innovation and the fastest path to national achievement of the ARRA overall legislative objectives.