Regenstrief Institute
Better Care. Better Health.

Attention: National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards

Re: Hearing on HIPAA and ACA Administrative Simplification: Attachment Standard

Hubert Humphrey Building
200 Independence Avenue, SW – Room 705-A
Washington, DC 20024

February 12, 2016

Good afternoon. My name is Daniel Vreeman, and I am a Research Scientist at the Regenstrief Institute, Inc and Associate Research Professor at the Indiana University School of Medicine. The Regenstrief Institute is a distinguished medical research organization dedicated to improving the quality and effectiveness of health care. The Institute is the home of internationally recognized centers of excellence in biomedical informatics, aging, and health services research. At Regenstrief, I lead our work in data standards, including the development of LOINC®.

I'm very grateful to the Subcommittee for the opportunity to share comments on the proposed Attachment Standard, in particular as it relates to LOINC, a proposed code set.

Let me begin with just a brief overview of LOINC that focuses on the factors NCVHS is using to evaluate standards and code sets.

As many of you know, LOINC is a universal code system for identifying laboratory and clinical observations that facilitates exchange and pooling of results for clinical care, research, outcomes management, and many other purposes. LOINC is a rich catalog (encyclopedia) of measurements, including laboratory tests, clinical measures like vital signs and anthropomorphic measures, standardized survey instruments, and more. LOINC also creates codes for collections of observations such as laboratory panels, forms, and clinical documents like progress notes, discharge summaries, and radiology

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

procedures. Today, LOINC contains more than more than 78,000 terms, and we are adding about 4,000 new terms per year based on requests from the global user community.

LOINC's universal observation identifiers are an essential ingredient for combining health data from many sources. To promote widespread adoption, LOINC is distributed at no cost worldwide under a user-friendly license. With 42,000+ users from 172 countries, it has become ubiquitous in healthcare. LOINC is an official national standard in about 30 countries, including the U.S. where it has been adopted in many federal efforts, including the meaningful use program. There are tens of millions of patients around the world today with billions of discrete electronic health data elements coded with LOINC.

Since it's inception LOINC has been built as an open standard, and Regenstrief is committed to working with others who have similar goals of building seamless networks of health systems and data that live up to the promise of optimal health for all. We also want to avoid duplicative effort in standards development. We have official collaborations with other standards development organizations that create other vocabulary standards, including the International Health Terminology Standards Organisation that develops SNOMED CT and the Radiological Society of North America that develops RadLex. We also have agreements with standards development organizations that create syntactical and exchange standards, such as HL7 and IEEE.

I specifically want to highlight that Regenstrief has a close, long-standing collaboration with HL7 since the early days. It was by design that LOINC codes fit perfectly as the vocabulary standard for observation identifiers in HL7 messages and FHIR resources, and as document type codes in HL7 CDA documents. In this close working relationship, our collaboration with the Attachments Work Group has been productive and mutually beneficial. In fact, enhancements to LOINC and the RELMA mapping program related to their use for claims attachments were made before 1999 and continue today.

Thus, in our view, the proposed use of HL7 standards and LOINC as the standard code set in claims attachments is a natural and logical approach.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

In the following, I will address the specific questions posed to the Panelists for the Proposed Standard for Attachments.

How were the proposed standard and code sets developed? (Please provide timeline and industry input in the development; process for vetting, etc.)

Has there been an industry-wide representation of stakeholders that have agreed with the Proposed Standard and code sets?

What lessons learned from previously adopted standards have been applied to the proposed standard and code sets?

LOINC was initiated in 1994 by Clem McDonald, an investigator at the Regenstrief Institute. Regenstrief organized the LOINC committee to develop a common terminology for laboratory and clinical observations because there was a growing trend to send clinical data electronically from laboratories and other data producers to hospitals, physician's offices, and payers who use the data for clinical care and management purposes.

At the time, and still today, most laboratories and clinical services use HL7 to send their results electronically from their reporting systems to their care systems. However, the tests in these messages are identified by means of their internal, idiosyncratic code values. As a result, receiving care system cannot fully "understand" and properly file the results they receive unless they either adopt the producer's test codes (which is impossible if they receive results from multiple sources), or invest in the work to map each result producer's code system to their internal code system.

While curated by Regenstrief, LOINC development is spurred by large global community. New LOINC terms are added to the database based on the requests of end users. Figure 1 displays the growth in LOINC codes over time. In the last four years, we have processed submissions from more than 195 different organizations from 19 countries. The current version of LOINC contains 78,959 terms, and we are currently adding about 1,800 new terms in each twice yearly release (June and December).

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

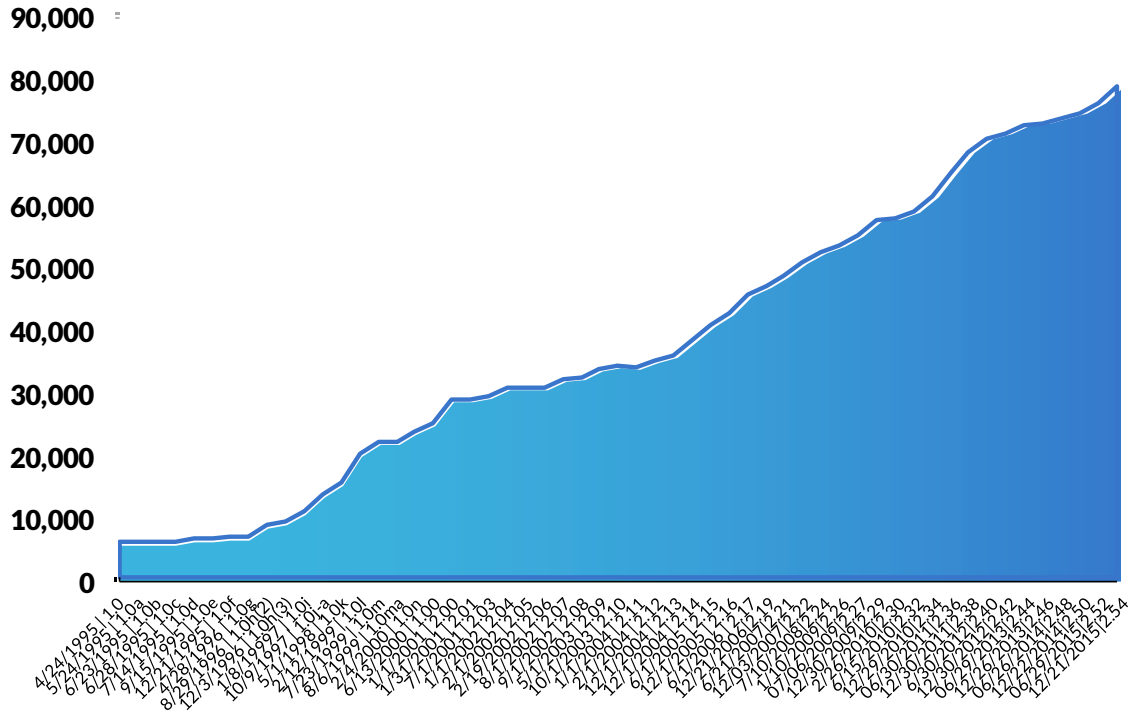

Figure 1. Growth in number of LOINC codes over time by release

In the context of proposed claims attachments standards, LOINC's use has had extensive stakeholder input over the years. All of the earliest drafts of the HL7 attachment specifications (circa 1999) through today have used and recommended LOINC codes for specifying the clinical content being requested and returned. The balloting cycles and standards development process within HL7 have structured opportunities for stakeholder input. The claims attachment notice of proposed rulemaking (NPRM) published on September 23, 2005 proposed the adoption of LOINC for these purposes, and HHS received comments on this approach, including those from NVCHS. NCVHS held hearings in November 2011 where there was support for the HL7 CDA (with LOINC inside) approach, as summarized in the March 2012 letter from NCVHS. In February 2013, NCVHS held a second hearing on attachments with summary recommendations provided to HHS in a June 2013 letter that recommended LOINC as the attachment type code set.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

What testing (including pilots) of the proposed standard and code sets have been done?

Which stakeholder entities were included in the testing (pilots included)?

Was the sample size for the pilot/testing statistically significant?

What were the outcomes of the testing (pilots included)?

Regenstrief has not directly conducted or been involved in the testing of LOINC codes for use in attachments, though we are aware of efforts by others including Humana, Availity, NGS Anthem, Mayo, etc.

Though not a direct test of its use for attachments, healthcare organizations have been using the C-CDA + LOINC approach for data exchange under the meaningful use program.

Does the proposed standard comply with and support existing standards used in other transactions and programs (for example, Meaningful Use)?

The 2015 Edition meaningful use criterion require C-CDA Release 2.1 (which specifies using LOINC codes for identifying document types). The 2014 Edition adopted C-CDA Release 1.1. In these adoptions, use of the "unstructured" document template is forbidden for purposes of fulfilling the MU criterion.

Many other federal programs use CDA-based implementation guides with document level LOINC codes. A few examples include CMS's use of the QRDA standard for exchange of electronic clinical quality measure data, CDC's National Healthcare Safety Network Healthcare Associated Infection Reporting, CDC's Public Health Case Reports.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

In addition to the use of the proposed standards and code sets in health care claims transaction (Claim Attachments), what other transactions can the standard support (for example, eligibility, prior authorization, post-paid claim audits).

LOINC codes can be used in any healthcare transaction or exchange that needs to identify a test, measurement, observation, or collection thereof (including documents, panels, forms, data sets, etc) with a universal code. Although LOINC has a robust set of codes (including many kinds of clinical documents), new use cases may require that additional codes be added to LOINC. LOINC has an open submissions policy for handling such requests.

Do the proposed standard and code sets support the intended business function/ intended use?

Does it provide a complete set of information needed to achieve the purpose of the transaction?

Does the standard achieve the transaction in the fastest, simplest, and cost –effective manner?

We believe that C-CDA plus the upcoming HL7 Attachment Supplement Specification: Exchange Implementation Guide Release 1 (and its referenced standards such as ASC X12N), together with the adoption of LOINC codes, does fully support the intended business functions and uses. It provides the ability to send both structured and unstructured clinical data. It also has the flexibility to evolve to accommodate new attachment types by adding new LOINC codes flagged as "unstructured" without changing anything about the syntax/structure of the exchange.

We ultimately believe that C-CDA Release 2.0 is a better long-term standard than C-CDA Release 2.1. Why? C-CDA 2.0 fixed many of the vocabulary coding problems in C-CDA Release 1.1 that required providers to use SNOMED CT codes for some observables when all of the other national initiatives (HITSC, CMS quality measures, Federal Health Architecture etc) adopted LOINC codes. So, for many purposes they might be recording

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

wound measurements with LOINC, but for sending that result in C-CDA they had to convert it to something else. It was a mistake that never should have happened.

Yet, the "lack of backwards compatibility" (i.e. correcting the error) led to the creation of C-CDA 2.1, where the approach was have implementers send both codes for places where Release 2.0 had a LOINC code and Release 1.1 inadvertently had a SNOMED CT code. For many value sets this means that the implementers would have to do the mapping between LOINC and SNOMED themselves, because the templates were not specific enough to allow a 1:1 correspondence. This is no trivial matter, and it seems that this approach would be even more problematic and challenging than just making a one time switch to the more widely adopted (and consistent with federal advisory guidance) codes from LOINC.

But, alas, the ONC has adopted C-CDA Release 2.1 in the 2015 Edition meaningful use criterion. At the level of the Document type codes, which is the main focus of the attachment standards, these code system problems do not exist. (All the document type codes come from LOINC). The complexity of dealing with both code systems, when you really only needed one, occurs at the level of interpreting entries within the document. This would not effect the request and exchange of specific kinds of attachments (documents).

Therefore, despite some reservation, we think that use of the C-CDA release 2.1 standard for attachments is probably still the best course because it leverages the same underlying clinical document standards required in meaningful use. However, it is not as straightforward a path to success as it could have been.

If the business need arises, a new standard document template could be created (either as part of C-CDA or a separate CDA implementation guide) to accommodate additional structured attachments.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

What is the potential impact of the standard to various health care entities (providers, payers, etc.) on the daily workflow/transaction process; administrative costs, required capabilities and agility to implement the operating rules changes?

Does the proposed standard provide efficiency improvement opportunities for administrative and/or clinical processes in health care?

Has the potential for decrease in cost and improved efficiency been demonstrated by using the proposed standard?

Overall, the impact of the proposed standards and code sets will have the effect of massively improving the efficiencies of claims processing. It will eliminate the manual-labor intensive paper-centric processing currently happening. To the extent that attachments are sent as structured data, it will enable more automated processing.

There is, of course, an up-front cost to the downstream efficiencies. Payers will have to build the technical infrastructure to support this exchange, and for many, the C-CDA and LOINC standards will be new. (Although we know many payers are familiar with LOINC for aggregating lab data, the document level codes are likely unfamiliar). The vendors of provider EHR systems may have to integrate with practice management system functions in order to package the clinical payload with the X12 message.

Does the proposed standard and code sets support changes in technology and health care models?

Does it support different forms of performing the transactions they relate to?

Does it support the new, emerging alternative payment models?

At the code-set level, LOINC is completely technology and health care delivery/payment model agnostic. It enables the "collect once, reuse many" goal we aspire to.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

The HL7 standards, as the name indicates, fit in the seventh layer of the OSI model. This means, that they can be used with a variety of technologies that operate at the other layers, including the network layer, transport layer, session layer, etc.

We do not have enough experience to know whether the entire suite of standards will support all possible alternative payment models. The clinical payload (C-CDA with LOINC inside) is certainly useful for ACOs, etc.

How will the proposed standard provide consistency or limit the degree of variability to achieve optimal intended results?

Overall, the proposed standards provide additional consistency for both syntax (structure of the information) and semantics (a shared understanding of meaning).

The HL7 C-CDA standard provides a consistent structure for clinical documents, but has few required data elements. By supporting both structure and unstructured attachments, the proposed standards provide a consistent format for the exchange wrapper while allowing flexibility in the organization, format, and content inside the document.

The document templates in HL7 CDP1 are designed for use when the provider needs to exchange more clinical information than is required by the C-CDA R2 document-level templates and/or must indicate why information for specific section-level or entry-level templates is not included.

How will the proposed standard and code sets demonstrate or ensure ease in adoption and use?

A technological change of this magnitude and scale is never "easy". This is not to say that it is not worth it. Regenstrief does not have capacity or a plan to demonstrate "ease of use" in this context. Like the other SDOs, the extent to which we promote "implementation ease" is largely a function of the design of the standard, which is driven by end users. In addition, we have developed and distribute at no cost both the code set itself, as well as a set of tools and resources to help users implement them. With each LOINC release we publish a desktop mapping program called RELMA that has features for browsing LOINC and mapping local codes to LOINC codes. Inside RELMA is a special section for

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

navigating the attachments content in LOINC. In addition, we make available an online LOINC search application (http://search.loinc.org) for browsing the latest LOINC release. We also have a special section on the LOINC website (http://loinc.org/attachments) describing how LOINC is used in the context of the other proposed standards and how to find attachment content in LOINC.

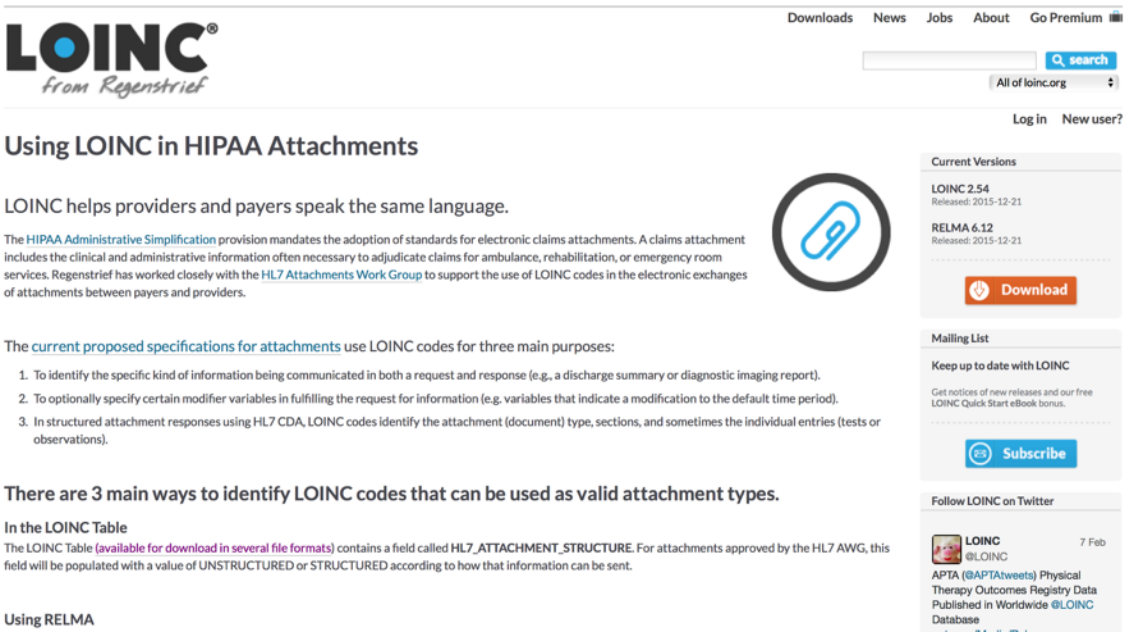

Figure 2. Attachments page on loinc.org

Will system changes be required by the industry to implement the proposed standard and code sets?

Yes. There is, of course, an up-front cost to the downstream efficiencies. Payers will have to build the technical infrastructure to support this exchange, and for many, the C-CDA and LOINC standards will be new. (Although we know many payers are familiar with LOINC for aggregating lab data, the document level codes are likely unfamiliar). The vendors of provider EHR systems may have to integrate with practice management system functions in order to package the clinical payload with X12 message.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

What amount of time is needed for the industry to implement the proposed standard?

We suggest that a period of three year from the date of final rule until implementation is required. Within this timeframe, some time is needed to develop the software capabilities (vendors), and additional time needed for actual implementation. This might work out to be something like Year 1 for product development (vendors) to support the transactions. Year 2 for starting to implement the exchange of the attachment standards. Implementation will also require analysis and redesign of business workflows. Using HL7+LOINC will be relatively new for payers. Providers have experience with theses standards, but not on administrative side.

Has HL7, ASC X12 & LOINC developed strategies to measure the impact of adopting the proposed standard on the industry?

Regenstrief has not developed a strategy for measuring the impact of adopting LOINC in this context. We know that ONC is interested in partnering with SDOs in this regard, as reflected in the cooperative agreement announced in 2015 and discussed among members of the SCO about this as well. Some of the general sentiments were that the work of the SDOs to create standards is driven by their members (users). Historically they have not focused on measuring uptake. To accomplish this aim, the SDOs would have to work collaboratively with others. For example, to sample data on instances of usage, survey the industry, etc. Given the funding model for LOINC, Regenstrief would need additional resources to pursue such an effort.

What is the envisioned product life cycle, i.e., how long will the proposed claim attachment standards meet industry needs and what is the frequency and size of maintenance updates to the standards and associated code sets?

This is a difficult question to answer. We suggest that they might meet industry needs for 7-10 years. There is enough flexibility in the standard (for example, adding new LOINC codes for unstructured attachments) to accommodate many kinds of new demands. But, the lifespan of the recommended standards suite does depend on on whether the SDO develops new versions of the implementation guides in the meantime.

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

Has HL7, ASC X12 & LOINC developed metrics to measure the effectiveness and value of adopting the proposed standard? What are they?

Regenstrief has not developed metrics to measure effectiveness and value of adoption. (See also response about measuring impact). Given the funding model for LOINC, Regenstrief would need additional resources to pursue such an effort.

Does the proposed standard incorporate privacy, security and confidentiality?

The standards do not specifically address these issues, but neither do they obstruct them. The HIPAA regulations cover these aspects, which can be applied to information exchange using the proposed standards. Ensuring privacy, security, and confidentiality is only partially a technological issue.

How will the attachment standard support interoperability and efficiencies in a health care system?

Implementing the attachment standard will enable much for efficient processing of claims by eliminating the paper mess we now have and reducing manual processing.

For payers, receiving structured, standardized electronic data will facilitate automatically adjudicate the claim because they have the data necessary in a computer-understandable format. Automatic adjudication will greatly reduce the administrative overhead necessary to process their transactions (i.e. claims, prior authorizations, etc). This is a massive improvement over the paper-based process we now have.

For providers, not only will automation reduce the manual, human intervention necessary, but automated adjudication will also improve turnaround time. Greater automation means greater predictability. They will be better equipped to provide the information supporting a healthcare transaction on the initial transmission. Standardized electronic transactions will enable shorter turnaround times for exchanging attachments both on initial submission and in response requests for additional information. Providers will rejoice at opportunity for a more efficient solution than the manual, paper driven process that exists today. If these data can be gathered and submitted electronically, senders will no longer have to retrieve and copy records and prepare paper (sometimes

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org

many pages of paper) attachments for the receiver. By adopting standards used in other contexts (e.g. CDA and LOINC), providers will be able to leverage to the infrastructure investments they've already made.

Can the proposed standard be enforced? How?

The proposed standards can be enforced through the conformance statements contained in the implementation guide. Certification requirements are one possible mechanism for enforcing the requirements. This approach has worked for the meaningful use program. The lessons learned (both successful and unsuccessful tactics) from that effort can be applied here. Partnering with the ONC for creating or modifying the requirements of Authorized Testing and Certification Bodies should certainly be explored.

Why should NCVHS recommend the adoption of the standard and code sets?

NCVHS should recommend standards and code sets for attachments because it is the right thing to do. The X12+C-CDA+LOINC combination is the best solution available, and there is evidence from early adopters that it can have real benefits. Adopting a uniform set of standards across the industry will have a significant impact on the efficiency of processing attachments. Limiting the initial implementation to health care claims attachments for which the C-CDA has defined a template (e.g., hospital discharge summary, operating notes, ambulance runs) is a reasonable, incremental path that builds on the existing infrastructure being created to support a truly learning healthcare system.

Closing Remarks

Once again, I thank you for the opportunity to share with NCVHS our thoughts on the attachment standards. We look forward to partnering with others in this effort and helping reduce the clerical burden on patients, health care providers, and health plans.

Sincerely,
Daniel J. Vreeman, PT, DPT, MSc
Associate Research Professor, Indiana University School of Medicine
Research Scientist, Regenstrief Institute, Inc

Regenstrief Institute, Inc.
1101 West Tenth Street
Indianapolis, Indiana 46202

tel 317.274.9000
www.regenstrief.org