

ReadMe File for the HL7 ASIG May 2007 "HIPAA" Ballot

Note: The Attachments Special Interest Group (ASIG) had originally planned to conduct two separate ballots in this cycle. The other one, for a new Periodontal Attachment, is postponed until the next cycle. We point this out here, in case you were looking only for that other ballot.

In this ReadMe file, we seek to describe at a high level what you see in the ballot package of the attachment specifications, and add a little background on where we are in the process. **This file is only a guide, for educational purposes.** The rest of the ballot package should stand on its own, and you should comment on those things we did not adequately explain in the ballot material. **Note:** this ReadMe file may be presented multiple times in the package; the Word/PDF version of the file has much better formatting than the text version.

Sections in this document

- Ballot package contents
- Scope of this ballot
- Major changes for the May 2007 ballot
- ASIG and Ballot History
- Major changes for the January 2007 ballot
- Background on specific new concepts

Ballot Package Contents

The ballot package contains the following narrative specifications in PDF format.

File name

Ballot May07 CDAR2AIS0000R030 Implementation Guide
Ballot May07 CDAR2AIS0001R030 Ambulance Service Attachment
Ballot May07 CDAR2AIS0003R030 Rehabilitation Services Attachment (Word and PDF)
Ballot May07 CDAR2AIS0004R030 Clinical Reports Attachment
Ballot May07 CDAR2AIS0005R030 Laboratory Results Attachment
Ballot May07 CDAR2AIS0006R030 Medications Attachment
Ballot May07 CDAR2AIS0999R030 LOINC Modifier Codes
Acronyms list

(The old specification for Emergency Department, AIS #0002, was withdrawn in late 2006.)

As time permits, we will also make available the CDA (XML) example files, and a revised XML stylesheet that may be used to render a CDA document instance. **Only the narrative specifications are being balloted** - the other materials (e.g., acronyms list and all the XML files) are supplemental. Some of these supplemental files may not be in the ballot package; however, we will post them to the ASIG webpage and announce their availability on the ASIG list service.

For your reference, we retained the full set of May 2004 materials, including various example files, on the main ASIG webpage at: <http://www.hl7.org/asig#publications>. At that spot on the webpage, there are also links to the HIPAA NPRM and other related materials. The updated materials from the January 2007 ballot, comments, and dispositions of the comments, are available on the HL7 Ballot Desktop (i.e., where this May 2007 package was found).

Scope of this Ballot

The majority of this material has already successfully passed through several rounds of balloting within HL7, and is not within scope of this current ballot. In January 2007 these were balloted for the first time after the conversion to using the CDA Release 2 as the base standard. The scope of this ballot is limited to comments received from the January ballot and those content change comments received from the NPRM comment period. Track changes have been left on to clarify the changes that are in scope of this ballot.

- Did we correctly interpret the ballot comments?
- Did we correctly interpret a requestor's need for a new LOINC code in the specifications?
- Did we inadvertently change the cardinality of an item?
- Are the explanations we provide in new paragraphs correct?
- Do we use "shall", "should", and "may" in accordance with the Implementation Guide? (See: Section 3.1, Definitions)
- Are new paragraphs in an appropriate sequence relative to the rest of the material?
- Are all inter-section and inter-document references still correct?
- Did we make any typographical or other errors?

We welcome additional comments, about anything; however, please understand that during the reconciliation of your comments, the committee may determine that your suggestions be part of future work, rather than in the current set of specifications.

For more high-level details, see the section below, *Major Changes for the January 2007 Ballot*.

Major Changes for the May 2007 Ballot

This current ballot includes two kinds of changes since the last time we conducted a ballot:

- Changes in reaction to comments on the January 2007 ballot, and
- Changes in reaction to comments on the NPRM, which we had not fully decided upon prior to the January ballot.

For process-related details leading to the changes, see the section below, *ASIG and Ballot History*. The major changes to each of the specifications are summarized next.

Note: The ballot documents have change tracking on (i.e., change bars, strike-outs, etc.). A set of the same documents without the change tracking is available here: <http://www.hl7.org/Special/committees/claims/docs.cfm>. The document package is titled:

ASIG-May-2007-Ballot-Package-No-Track-Changes.zip.

General changes

- For handy reference, we include a new document that lists the **acronyms** and abbreviations that are not easy to find in the specifications. We expect to add to this list periodically and ensure the most recent list is available on the www.HL7.org/asig web page. Note that this is for reference only, and while comments are welcome, it is not part of the normative ballot material.
- Since our set of use cases is broader than what HIPAA mentions, wherever possible, we have clarified the wording to be more specific, or more general, when mentioning the use cases for the specifications. For example, in addition to claims, the language may now include mention of prior authorization. You will typically see this where the X12 transaction sets (277, 275, 278) are referenced. HIPAA does not mandate attachments within the context of a 278.
- To be more consistent in how we reference X12 (i.e., ASC X12 instead of X12N or ASC X12N); and to reduce any further confusion, we intentionally use the term ASC X12 and we say "implementation guides" instead of "TR3s".

Implementation Guide changes

- Section has been re-structured to highlight the various uses of this implementation guide and the attachments concept as well as clarify the business usages and flow.
- The section on MIME has been changed to better represent our expectations with MIME packaging of non-XML body parts.
- Section 2.5.1 has been expanded to list all the CDA Header requirements (both required and optional).
- Section 3.6 and 3.7 have been expanded to include all the Entry classes and all data types currently being used in attachments.
- The reference table of UCUM units in Section 5 is shortened to contain only the units of measure which are most likely to be used in attachments, and additional text is added to instruct implementers where to find the full UCUM specification in the event we overlooked any that are needed. Several units have been added to the reference list, for example, for miles and pounds.

Ambulance changes

Note: Many changes resulted from the NPRM comments and outreach process, including:

- Added elements and codes related to air, and water, transport
- Added elements regarding times and distances
- Changed or added elements related to addresses, including GPS coordinates
- Added elements which describe when/why more than one patient is transported
- Added elements to identify the person who receives the patient
- Added elements to describe extra attendants
- Added elements to describe rationale behind other answers

Rehabilitation changes

Warning: Due to the number of changes in this document, some users have been experiencing issues when printing the document or when switching from one layout view to another. At this time, we are unsure what is causing this problem. For this reason, we include two copies in the package; the Word version has tracked changes and opens in the normal view, and the PDF is the entire "clean" document with all changes accepted. (The problem with Word prevented making a PDF which shows the tracked changes.)

Note: Many changes resulted from the NPRM comments and outreach process, including:

- Most of the Rehab disciplines had exactly the same set of changes made, although the Alcohol/Substance and Psych Rehab had a few more specific changes, e.g., adding the Global Assessment of Functioning (GAF) scale.
 - Removed several instances of duplicate or unneeded elements, e.g., the previously added "date range of treatment" now replaces the "date range described by plan".
 - Added a new discipline, with 20+ questions, for Pulmonary Therapy Rehab
 - Split assessment component into multiple answer parts to ensure that all the appropriate data is being coaptured.
 - Added elements to describe Referral Information for several Rehab disciplines
 - Separated "level of function" question/answers from "past history" questions.
 - Added Individual Education Plan questions to PT, OT, and Speech to accommodate questions around school based or lack of school based services.
 - Added questions for the Actual Plan of Care Start Date, Treatment Encounter Note and other relevant questions and answers.
 - The Outreach group discussed the possibility of having a common content area for all the components/answer parts that are duplicate across all disciplines and then separate areas only for those disciplines with unique requirements. This was declined by the outreach group due to the need to ask specific questions relating to specific disciplines.
- Clinical Reports changes

Laboratory Results changes

- Minor editorial changes
- Added footnote to the Observation Interpretation table to clarify that < and > symbols must be represented by the < and > values due to the XML conflicts.

Medications changes

- Added Body Weight component and answer parts as a result of an NPRM comment.

Clinical Reports

- Minor editorial changes as well as clean-up of some cardinality issues.

LOINC Modifier Codes changes

- We now have a document number for this document: CDAR2AIS0999R030
- The line-level LOINC (19016-5) is removed, since the new X12 v5010 implementation guides handle the line-level use case natively.

Example files and other supplemental changes

- The example files may not be ready in time for the open of the May 2007 ballot period in mid-March; however, as soon as possible, we will upload the new examples to the "Documents/Presentations" section of the www.hl7.org/asig website and send a note to the ASIG list service. **Example files are not normative** content for ballot purposes.
- For your reference, the examples from January are now uploaded to the above page, with filename: **HL7-ASIG-January2007-Examples.zip**. Included is the small fix to the style sheet, to include rendering of the Attachment Control Number (ACN).

ASIG and Ballot History

Most of the material included in this current ballot package was successfully balloted in the past, and at various times published as "final" in anticipation of a proposed rule (NPRM) under the "Administrative Simplification" section of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The changes in the current package are in response to the public comments received in response to that NPRM, which was published in September 2005 and included the "May 2004" version of ASIG final specifications.

The full history of the ballots and major events, at a high level is as follows. Note that some of the dates may be off by a month or two because of the way HL7 ballot cycles have been nicknamed over the years. The ballot dates shown here depict the month where most of the open comment period occurred. After the close of the ballot period, the comments are reconciled at the working group meeting (WGM), which typically occurs a week or two later.

- **HIPAA** Law signed in 8/1996, including a provision that a Claims Attachments rule be promulgated in 1999.
- HL7 Claims Attachments special interest group - **CASIG** formed in 8/1997. Usage of SGML (predecessor of XML) was suggested at that time, but the direction chosen was to use only consensus-based (e.g., ANSI) standards. And so, the CASIG worked on the draft proposals using LOINC and HL7 version 2.3 OBX messages. The message would be transported inside the X12 275 BIN segment, in fulfillment of a request in the X12 277 transaction set. Note: "Claims" was dropped from the committee name a few years later, when there was greater realization that the specifications and methodology can be used for purposes other than claims. By the end of 2000, the committee formerly known as CASIG became **ASIG**.
- **Ballot** (12/1998) of various documents expressing the concepts using a defined set of LOINC codes and descriptions, HL7 v2 ORU/OBX constructs, an X12 275 response envelope, and the X12 277 request for information.
- **Ballot** (6/2001) of various changes to the previous material, now using HL7 v2.4 messaging constructs.

- **Ballot** (8/2003) The Implementation Guide and the six "booklets" were upgraded from using the HL7 v2.4 messaging construct, to using the Clinical Document Architecture Release 1.0 (CDA R1), which had become an ANSI standard in 2000.
- **Ballot** (12/2003) of several substantive changes that were suggested during the reconciliation of the 8/2003 ballot.
- **Publish** (5/2004) of the combined results of the 8/2003 and 12/2003 ballots, with expectation of a 9/2004 proposed rule.
- HHS published (9/2005) the HIPAA Claims Attachments **NPRM**, citing the May 2004 final published documents (and corresponding X12 277 and X12 275 implementation guides). A 60-day public comment period extended to 120 days, ending in 1/2006.
- HHS forwarded (3/2006) roughly 1000 HL7-specific comments to HL7 (a similar process occurred for X12 comments in that organization). HL7 ASIG and other interested parties met face-to-face in March and May 2006, with multiple interim conference calls to address the comments, with a secondary review by a smaller sign-off team during the summer. A few comments were discussed during the September 2006 WGM, and a separate "outreach" project was initiated to address the Emergency Department specifications. Most of the document rework (for the January 2007 ballot) occurred from August through November, with discussion/review during the September WGM and subsequent ASIG conference calls.
- **Ballot** (January 2007) to address the changes suggested in comments to the NPRM. These are described in the section below, *Major Changes for the January 2007 Ballot*. All changes trace back to NPRM comments.
- **Ballot** (May 2007) addresses further changes that were discussed during the reconciliation of the comments to the January 2007 ballot, and additional NPRM comment resolutions stemming from the Outreach efforts for the Ambulance and Rehab attachments. All changes trace back to NPRM comments.

Also note that coincident with the above, the ASIG conducted the following ballots – these materials are **not** part of the initial proposal for HIPAA Claims Attachments. Some may be cited by future rulemaking under HIPAA or other legislation; however the point in mentioning them is that during the ballot process for these documents, various suggestions for improvement occurred which we incorporated into the changes in the set of HIPAA documents. Indeed, during 2007, we expect to re-visit all of these materials and re-ballot them using the CDA R2-based implementation guide which is part of the current (May 2007) ballot.

- **Ballots** (4/2005 and 8/2005) of a specification for Children's Preventive Health Services (CPHS) attachments
- **Ballot** (8/2005) of a generic specification for Patient Information Unspecified Content (PIUC) attachments.
- **Ballot** (April 2006) of a specification for Drug Prior Authorization (DrugPA) attachments. Reconciliation of the ballot comments was completed in 9/2006, and there is intention to re-ballot this in April 2007, depending upon availability of information regarding ePrescribing pilots that occurred during 2006.
- **Ballot** (August? 2007) of a new attachment for periodontal services based upon the content in American Dental Association (ADA) specification No. 1047. We had planned to ballot this in May 2007, but the ASIG material was not quite ready in time.

Major Changes for the January 2007 Ballot

The January 2007 Ballot material is located on the HL7 ballot website. www.hl7.org. The Reconciliation Package has also been uploaded (this contains all the comments received on the January ballot, and the line-by-line committee decisions regarding the comments). This can be found at the same ballot website.

All of the changes in this ballot are based upon the comments received by HHS during the NPRM public comment period, including many comments that we (HL7) submitted. All NPRM comments related to HL7 were discussed during the face-to-face meetings of the full ASIG (and other interested participants) in March and May 2006, and multiple conference calls between March and May, followed by subsequent review and sign-off by a smaller group during the summer.

Note: We dropped one document entirely. **AIS #0002, *Emergency Department Attachment***, has been removed due to substantial comments to the NPRM and the results of additional outreach activity coordinated under contract to HL7 in 2006. In general, the content of the document no longer reflects how emergency care is provided, and it would take considerable time to bring the material up-to-date for CDV (computer decision variant) usage. Instead, the HDV (human decision variant) within the *Clinical Reports Attachment* (AIS #0004) may be used for emergency care services.

While we appreciate comments on all of the material, for this ballot we are focused on these substantive changes that occurred since the last successful ballot in 2003 (final published in May 2004, and cited in the September 2005 NPRM).

- Our base standard is now CDA Release 2.0 (CDA R2). The former specifications (May 2004) were based upon CDA Release 1.0. This is not a trivial change. Additional information is given in the New Concepts section below.

Note that our approach with CDA R2 is similar to that of CDA R1, in that the specifications are modeled for the business analyst and real-world programmers; and not the super-modeling experts).
- In a few cases, we added new LOINC codes so that additional information may be requested or sent, and in some cases the cardinality (repeatability and/or optionality) of individual elements has changed. These changes are highlighted in each document.
- The LOINC Modifiers document is included in the ballot package because we added one additional time range modifier.

In addition, we made quite a few changes to the documents that we consider more editorial in nature, and not substantive from a standards creation point of view. Certainly, comments on these things are welcome (we may have made mistakes).

- We learned a few things within our own (ASIG) committee, from other HL7 committees, and from various outside sources (especially from pilot implementations) since first creating the CDA R1-based Implementation Guide for attachments. This broader knowledge is reflected throughout, in many editorial changes to the specifications. We seek to be consistent with other CDA implementations, while retaining all of the business purpose content (i.e., all the LOINC codes) as described by the May 2004 specifications.
- Several sections of the Implementation Guide are moved to a more logical reading order, and greater explanation of the more complex topics is now presented. For example, we tried to better explain how the MIME Standard is used, and we display more XML code fragments to further explain new elements in the CDA R2 Standard.

- We use many more XPath statements imbedded throughout the documents to explain exactly (to the programmer) where concepts or values would be encoded into the CDA document. We began doing this in the previous (May 2004) specifications; however, it is now used much more robustly in an effort to make the specifications more useful to the technical audience, while trying not to confuse the non-technical audience.
- We removed the long XML examples from each AIS document. The examples are not normative material, and their presence in the (MS Word) documents introduced editing challenges. Instead, the examples are – or soon will be – available as separate XML files. Additional comments and vertical white space is added to the XML files to aid their human readability.
- New paragraphs are added to the beginning of each AIS document to describe the business purpose at a high level. Previously, we incorrectly assumed that readers knew the background and purpose of the specifications.
- Business uses other than HIPAA claims – while this has been the intention for some time, we attempt to explicitly clarify where the specifications may be extended for non-HIPAA use, and added information regarding usage in with the X12 278 transaction set.
- We added more information, including a new column "Entry Type" to the LOINC value tables throughout the AIS specifications. We hope for this to be valuable to programmers creating the CDV attachment. This new column is explained in the Implementation Guide.

Background on Specific New Concepts

CDA Release 2.0 (CDA R2)

By far, the most significant changes to the AIS documents are due to upgrading the underlying standard upon which our attachments implementation is built. Our prior work was based upon CDA Release 1.0 (CDA R1); in this ballot, we are based upon CDA Release 2.0 (CDA R2).

The following, from the April 2005 CDA R2 Standard, section *B.4 Changes from CDA Release 1*, helps set the stage for understanding the kinds of changes to the standard:

"CDA, Release One became an ANSI-approved HL7 Standard in November 2000, representing the first specification derived from the HL7 Reference Information Model (RIM). Since then, the RIM has matured, as has the methodology used to derive RIM-based specifications. In addition, early adopters are posing new use cases for incorporation.

"The basic model of CDA, Release Two is essentially unchanged. A CDA document has a header and a body. The body contains nested sections. These sections can be coded using standard vocabularies, and can contain "entries". CDA, Release One entries included such things as character data, hyperlinks, and multimedia.

"The main evolutionary steps in CDA, Release Two are that both header and body are fully RIM-derived, and there is a much richer assortment of entries to use within CDA sections. CDA, Release Two enables clinical content to be formally expressed to the extent that it is modeled in the RIM.

"CDA, Release Two takes advantage of HL7's growing expertise in creating model-based XML standards. Given the evolution of the RIM and the HL7 development methodology since November 2000, there are a number of changes between the new and the old CDA. "

Much more information about changes in the CDA Standard follows the above introduction. The CDA R2 Standard is available from the HL7 website, and is also on the CDs published by HL7 for "V3 Normative Edition 2005" and "V3 Normative Edition 2006".

Additionally, there are several CDA and related tutorials conducted during the HL7 Working Group Meetings and the HL7 Education Summits. See the top of the main www.hl7.org webpage for the upcoming meeting in January, and check the "Events" red button (lower on that webpage) for the events later in the year.

The most visible changes are described in the Implementation Guide, including:

- New or replacement Data Types (e.g., dates, times, quantities, etc.)
- Units of measure are now expressed in UCUM instead of ANS+ and ISO+
- Additional mandatory data elements in the CDA header and body
- Some provider-related data moved from CDA body to header

Value tables

The AIS specifications use several dozen HL7 value tables. These were constructed at a time when the primary HL7 standard was HL7 version 2.3 (then 2.3.1, and then 2.4). One example is table HL70136, which contains the values "Y" and "N" (to represent "Yes" and "No", respectively). When we revised the attachment specifications in 2003 to use CDA R1, we continued the practice of using these tables.

Now, with CDA R2, there are alternatives that are more native to the CDA and underlying HL7 v3 vocabularies. Some tables are kept just as they were, some are replaced completely with more current terminology, and others have minor changes (e.g., to remove the "don't know" or "unknown" flavors of null values that exist natively in the CDA R2 data types).

SNOMED-CT

Consistent with the above, about value tables, we discovered that a few of our tables were describing concepts that had near-total overlap with existing SNOMED codes. See the Ambulance specification, where two tables describe reasons for the trip. One or two smaller tables in other AIS specifications have a similar overlap. We expect that various licensing-related issues will be resolved prior to the end of the current NLM contract with the SNOMED folks.

The following two topics relate more to our balloting and publishing processes.

Placeholders for post-ballot LOINC code assignment

You may already be aware that LOINC codes, concepts, and other information in the LOINC encoding system from the Regenstrief Institute are copyrighted materials. A primary reason for this copyright is to protect the integrity of the coding system. Once a LOINC code is assigned, it always means the same thing. Old LOINC codes are never re-used to represent a different concept.

In various ballots of ASIG specifications, we found that we sometimes had to request changes of Regenstrief to our already granted requests, thus creating an extra maintenance burden for both ASIG editors and Regenstrief. Subsequently, we changed our ASIG process to instead use an artificial or "placeholder" code with a draft description of the concept, then ballot the material, and following the reconciliation of comments to the ballot, acquire from Regenstrief a legitimate LOINC code, which is included with the ASIG specification in time for final publishing.

A real LOINC code is all numeric with a dash and a check digit. A placeholder LOINC in the ASIG draft documents can be identified by the presence of non-numeric characters.

In the current ballot materials, we added a few new items that contain a draft description and a "placeholder" LOINC code. All of these additions were based upon specific NPRM comments, and the discussions during HL7's reconciliation of those comments.

Placeholders for OIDs used in examples

The HL7 v3 and CDA standards require OIDs to represent various concepts. Our CDA R1-based specifications introduced this topic in 2003.

Since then, we discovered that in a few cases there was ambiguous usage of the same OID for different purposes, and in at least one case, an unregistered OID was used. Some of these editing errors are now preventable by using "placeholder" OIDs under the HL7 OID Root reserved for examples – i.e., these example OIDs begin with 2.16.840.1.113883.19. These are **never** used in a real world implementation. We hope to reduce confusion among other committees using the example root by adding "2744", followed by whatever we think is appropriate within the context of the rest of our specification documentation. E.g., 2.16.840.1.113883.19.2744.1.3.

In Section 5 of each AIS document, we added a new sub-section that describes the placeholder OIDs used in the AIS.

We also registered the "2744" example branch in the HL7 OID Registry, so that anyone who stumbles upon any of these placeholder OIDs can then be referred to the ASIG committee. FYI, "2744" is a telephone pad's representation of "ASIG".

The HL7 OID Registry is accessible by a link on the main page at www.hl7.org. We expect that some additional instruction or documentation will be of value to attachment implementers, and envision this as a potential "whitepaper" in 2007.