Immunization Registries, HL7, and HIPAA

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This document is intended to discuss only the transaction regulations required by the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA), P.L. 104-191, which was enacted August 21, 1996. It does not address privacy, identifiers, security, or other HIPAA issues. The intent is to provide registry staff with a sense of context of the HIPAA standard transactions, and to provide sources for registries to study these issues further. For a general overview, review www.hhs.gov/news/press/2002pres/hipaa.html and scroll down to the topic, Electronic Transaction Standards.

Immunization registry staff members have followed with interest activities related to HIPAA implementation. The primary question on the minds of registry staff members, besides the privacy and security implications, has been the extent to which the electronic data transaction requirements would affect immunization record exchange using industry standards. As a rule, most immunization registries do not plan to transmit administrative and financial data as outlined in HIPAA's transaction section, because they are not engaged in business practices that require filing claims for healthcare payments from insurance companies. The HIPAA legislation says at Section 1172(a) that the standards apply to health plans, health care clearinghouses, and health care providers who transmit any health information in electronic form in connection with a transaction referred to in section 1173(a)(1) (emphasis added). These are the transactions discussed below. More detailed definitions of the covered entities and other HIPAA terms are available in the final transaction rule, available in the August 27, 2000, Federal Register (page 50366).

The specific requirements under HIPAA have become known over time, as the legal process for issuing implementing regulations has unfolded. The HIPAA language at Section 1173(a)(1) described the transactions listed in 1173(a)(2) in general terms as financial and administrative. None of the transactions selected as standards for processing claims were newly formed to meet HIPAA standards—all were in use at the time the legislation was passed. In giving the background of the standards for electronic transactions in the final rule, the August 27, 2000, Federal Register described (page 50312) the barrier to efficient electronic data interchange caused by the approximately 400 different formats for electronic health claims being used in the U.S. due to lack of standardization. It was this lack of standardization for commonly used claims transactions that led to the need for legislation.

Another section relevant to immunization registries that to this point has received less public notice than the final transaction sections is HIPAA's directive at Subtitle F, Section 263, which amended Section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and made changes to the membership of the National Committee on Vital and Health Statistics (NCVHS). This section also called on NCVHS to "study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information" and to report recommendations and legislative proposals for such standards and electronic exchange.

The NCVHS has collected information and held hearings from December 2000 through February 2002 on the issues of patient medical information. In a letter dated February 27, 2002, the NCVHS provided its recommendations for the first set of message format standards for patient medical record information. The letter recommends that the U.S. Department of Health and Human Service (DHHS) recognize Health Level Seven (HL7) versions 2.2, 2.3, 2.4 and later v2.x's as current standards for patient medical record information. It clarified that "vendors and users of these versions will not be asked to migrate to newer versions until the more advanced version (referring to HL7 Version 3.0) is fully implementable with the supporting implementation guides and conformance tests." Immunization registries that have worked toward record exchange capability using HL7 Version 2.3 and later will note that their work falls within the recommended standard for patient medical data exchange. Additional information about HL7 is available at http://www.hl7.org.

The HIPAA legislation itself is available at http://aspe.hhs.gov/admnsimp/pl104191.htm. Section 1173(a)(2) of the Act lists the nine transactions to be standardized. Figure 1 of this report displays the typical roles of each transaction in the electronic transmission of healthcare claims to insurance companies, called payers in the legislation. Following the legal process to promulgate implementing

regulations for HIPAA, a Notice of Proposed Rule-Making (NPRM) that included standards for electronic transactions was published in the Federal Register on May 7, 1998. (Search http://www.gpo.gov to find a copy.) On page 25287, the NPRM stated, "We will propose a claims attachment standard in a separate document as the statute gives the Secretary an additional year to designate this standard. The attachment standards are likely to be drafted so that health care providers using Health Level 7 (HL7) for their in-house clinical systems would be able to send HL7 clinical data to health plans. Anyone wishing to use the HL7 may want to consider a translator that supports the administrative transactions proposed in this proposed rule and the HL7." It also gave notice of the need to establish a method to maintain the data content for standard health care transactions. The final rule, which included standards for eight of the electronic transactions and the code sets to be used in them, was published on August 17, 2000. It also included on page 50344 the announcement that Designated Standard Maintenance Organizations (DSMOs) were being named for the maintenance of the standards in a separate part of that Federal Register. A PDF version of the final rule from the Federal Register is available at http://aspe.hhs.gov/admnsimp/final/exfinal.pdf. A copy of the separate notice of the DSMOs from the August 17, 2000, Federal Register can be found at http://aspe.hhs.gov/admnsimp/final/dsmofr.pdf. The notice names Health Level Seven as one of the six organizations comprising the DSMOs.

The final regulations announcing the selected standards for the following eight transactions were published in the August 17, 2000, Federal Register:

Enrollment and disenrollment in a health plan	(X12N 834)
Eligibility for a health plan	(X12N 270)
Health care payment and remittance advice	(X12N 835)
Health plan premium payments	(X12N 820)
First report of injury	(X12N 148)
Health claim status	(X12N 276/277)
Referral certification and authorization	(X12N 278)
Health claims or equivalent encounter information	(X12N 837, ADA for Dental, and NCPDP for Pharmacy

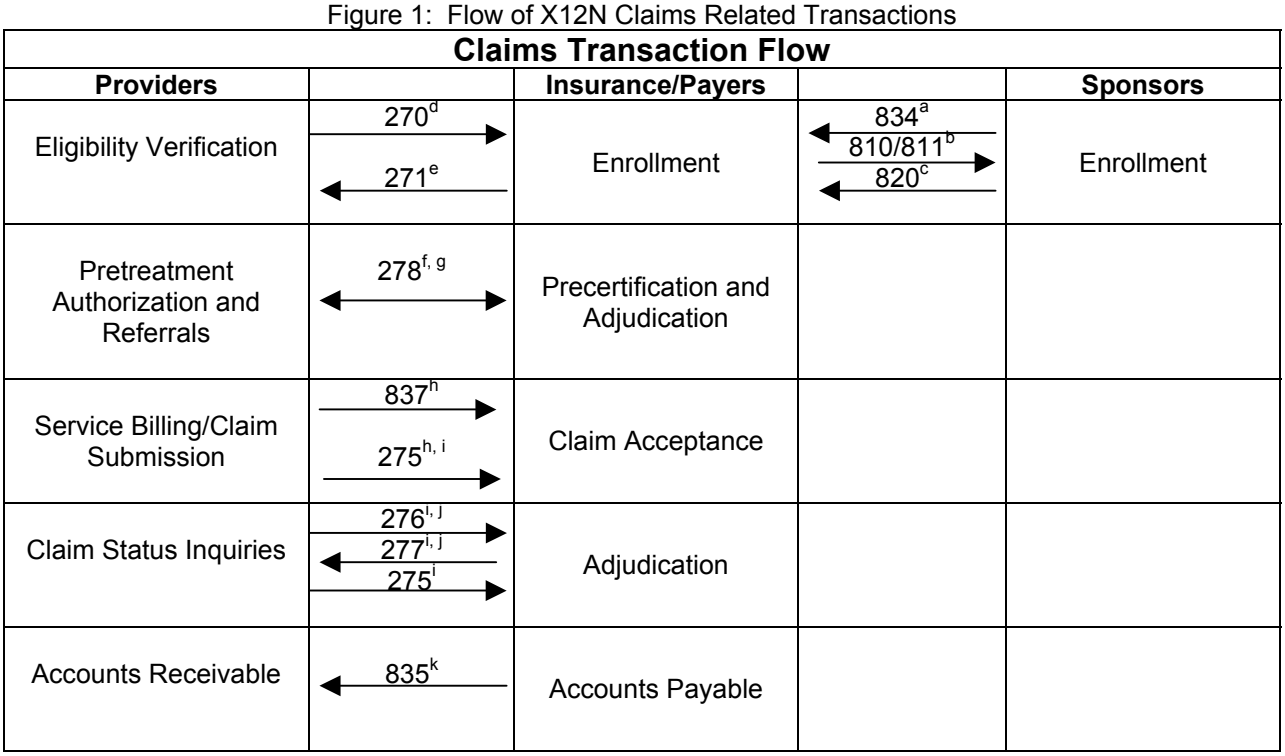
Additional information about the X12 Standards Development Organization is at http://www.X12.org, and additional information on each of these transactions is available at http://www.wpc-edi.com/HIPAA. Other helpful information can be found at http://www.wedi.org/public/articles. Figure 1 shows the information flow of these transactions and the administrative and financial processes they implement.

Registry implementers have expressed a particular interest in the claims attachments and the method they would provide for including patient medical data in the standard HIPAA administrative and financial transactions. The final rule for the ninth transaction, Health Claims Attachment, has not been issued as of February 2002. However, a cooperative effort of both the X12 and HL7 organizations has proceeded to draft parts of a final notice that would name the X12N 275 as one part of the attachment standard transaction and HL7 as another part. The draft NPRM documents that result from the HL7 efforts are available for review at http://www.hl7.org. At the HL7 homepage, under Committees, link to Special Interest Groups, then to Attachments. Click on Publications, then HL7 Implementation Guide. The Guide, entitled "Additional Information Message Implementation Guide" describes the proposed attachment message. This Guide is supplemented by subject-specific booklets describing the six clinical focus areas of work to date: Ambulance, Clinical Reports, Emergency Department, Laboratory Results, Medications, and Rehabilitation Services. These six are being proposed as the first set of standard attachments, but additional messages will be developed to provide information on other common services. The limited number of focus areas in the initial proposal could lead one to conclude that the information covered is more limited in scope than it is. A review of the booklets, however, will reveal the great amount of clinical data that has been standardized in the standard HL7 message for the proposed standard X12N 275 HIPAA attachments transaction. For example, the single HL7 Clinical Reports Attachment includes specifications for EKG studies, OB ultrasound studies, hospital discharge summaries, operative notes, MRI studies, mammogram screening studies, nuclear medicine bone scan studies, CT studies, and others. The clinical information is structured through the use of Logical Observation Identifier Names and Codes (LOINC® codes). Information about the LOINC® consortium and codes, as well as the free LOINC search engine Relma™, is available at http://www.regenstrief.org/loinc.

The X12N part of the message specifies the 275, “Additional Information To Support a Health Care Claim or Encounter Transaction Set” (the 275) as the transaction standard for attachments. It is informally called the “Claims Attachment.” This message is designed for use in healthcare when two (or more) trading partners need to exchange information concerning a healthcare claim or encounter that is not contained in the standard 837 “Health Care Claims Transaction Set” (the 837). A healthcare provider could use the 275 to respond to a request from a healthcare insurance company/payer for additional information about a particular claim or encounter submitted previously by the provider using an 837. The payer requests additional information so that it can adjudicate the claim or better understand the nature of the encounter in order to meet various business needs (e.g., assessing quality of care; satisfying reporting requirements).

The 275 is designed to be flexible enough to provide almost any health care-related information needed to explain a claim or to describe an encounter and uses the X12 Binary, or BIN, segment to carry this information. The transaction begins with a few lines comprising a header and ends with a very short trailer, and the combination of these is frequently referred to as “an X12 envelope.” As the name implies, the BIN segment is undefined in the X12 standard and can contain many kinds of information. The HIPAA Claims Attachments proposal is that the content of the BIN segment be an HL7 message to convey specific health-related information that can be processed unambiguously by computers.
The HL7 message that would carry clinical information in the BIN segment is the HL7 Unsolicited Transmission of an Observation or Result message (ORU, Event R01), HL7 Version 2.4. (Note that HL7 Version 2.x standards are backwardly compatible with earlier versions.) The ORU is a commonly used message and one that is included in the HL7 Communications Tool being developed under a grant to the National Immunization Program. One future use of the ORU message for registries will be to automate VAERS reporting from existing systems using HL7. An example of an entire X12 275 message containing the HL7 message is given on page 2 of the draft Guide on the HL7 website. The proposed transaction may be visualized as shown in Figure 2 as an enveloped HL7 message inside the envelope of an X12 transaction.

Figure 1: Flow of X12N Claims Related Transactions



a. Sponsor, possibly an employer, enrolls a new insured with an insurance company/payer. The sponsor does this electronically by sending an 834 transaction set to the payer.
b. Insurance company/payer accepts the new insured as a client and sends an invoice to sponsor. The payer does this electronically by sending an 810/811 invoice transaction set (not named in the HIPAA legislation) to the sponsor.
c. Sponsor sends payment electronically using an 820 transaction set to the insurance company/payer. Insured is now enrolled with a policy.
d. Insured goes to his medical care provider and identifies his insurance company/payer. The provider sends an inquiry to verify eligibility. The provider does this electronically by sending a 270 transaction set to the insurance company/payer.
e. The insurance company/payer responds with a verification of eligibility. The insurance company/payer does this electronically by sending a 271 transaction set to the provider.
f. If the care provider recommends a medical procedure, the insured may need to have a referral for this treatment. The provider and insurance company/payer communicate these electronically using a 278 transaction set.
g. The insurance company/payer issues the precertification for treatment electronically by sending a 278 transaction set to the provider.
h. After treatment, a bill for service is sent from the provider to the insurance company/payer electronically by sending an 837 transaction set. The provider may anticipate that the insurance company/payer may need additional information and supply it in the form of a 275 attachment transaction set with the original bill.
i. The insurance company/payer may determine that it needs additional information from the patient's medical record to adjudicate the claim and requests it electronically using a 277 transaction set. The provider responds to this request by providing the information (using an HL7 message) in a 275 transaction set.
j. During the processing period, inquiries about the claim status may be sent via a 276, and the adjudication response is returned electronically via a 277 transaction set.
k. The insurance company/payer then sends payment to the provider via the 835 transaction set.

Figure 2: Graphic of HL7 message inside the X12 275 Transaction

*Sample message from Additional Information Message Implementation Guide, HL7 Version 2.4 Standard, Release 1.0, NPRM Draft, December 11, 2001.