



# Standards Insight

## An Analysis of Health Information Standards Development Initiatives

April 2002

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### Overview

The *Standards Insight* is provided to the HIMSS membership as a business strategy analysis of healthcare information technology (HCIT) interoperability initiatives. We noted in our December 2001 issue the relative shift of power from standards developers to standards implementers as we focus on Health Insurance Portability and Accountability Act (HIPAA) compliance. We are in a period of implementation -- not strategy, fixing problems -- not setting directions, waiting for rules -- not establishing new priorities. In this issue, we will review the new Privacy Notice of Proposed Rule Making (NPRM) and the one-year extension for the standard transactions but within a larger context of project management. We will also report on key WEDI-SNIP activities as they try to move from theory to practice, while attempting to limit the details widely examined by other HIPAA experts.

Although we remain necessarily tied to the implementation issues, we also raise the issue of leadership and direction setting within and among interoperability standards initiatives. The current HIPAA experience with mandated health insurance standards does not point to a model that can be extended to the clinical domain. However it is the clinical domain where real leverage exists for interoperability standards and where strategic directions need to be set. Voluntary consensus-based standards remain the model in the US. Yet setting the agenda, funding, and coordination remain unsettled issues. We will look at the central role of the American National Standards Institute Healthcare Information Standards Board (ANSI HISB) and the National Committee on Vital and Health Statistics (NCVHS) as well as other players. We will provide a preview and set the stage for addressing the Web and healthcare standards in our next issue.

## **HIPAA**

As we all know, HIPAA Administrative Simplification regulations<sup>1</sup> are of two types: the privacy and security rules and the standard transactions and their supporting rules. HHS introduced new components to both in the last month. First, there was the Notice of Proposed Rule Making (NPRM) that reduced the administrative compliance burden of the privacy rule. Second, there was the model request for extension that implemented the Administrative Simplification Compliance Act. Despite these steps forward, there is growing industry frustration over the rules that are not yet released.

### ***The Privacy NPRM***

Privacy will now be the first of the HIPAA rules with which the covered entities must comply by April 14, 2003. The NPRM, if it is finalized essentially as is by October, significantly reduces the administrative burdens on healthcare providers and should have positive impact on HCIT vendors. The NPRM retains most of the core provisions of the original final rules, such as patients' rights to confidentiality, accountability, and review of their records. The NPRM changes include and go beyond previous guidance and NCVHS recommendations from last fall.

Healthcare providers will not have to obtain written consent to use protected health information (PHI) for treatment, payment, and healthcare operations. This not only does away with the administrative tasks but with a whole set of unintended consequences dealing with first patient contact, e.g., obtaining a prescription or scheduling an encounter, and with the issues of record-keeping and withdrawing consent. The covered entity will still have to provide the patient with their information practices and either obtain an acknowledgement or record of the attempt made. From an IT perspective, this is probably a system break-even, tracking acknowledgements rather than consents, although any change at this point may be viewed as a setback.

There is also relief in terms of business associate agreements. First, existing contracts do not need compliant business associate agreements in place until April 2004. Second, the NPRM's model language may reduce the likelihood of covered entities each coming up with different contracts and terms. The latter is exceptionally important to HCIT vendors that may have otherwise faced the possibility of contractually complying with different policies and procedures based on each covered entity's legal aggressiveness and interpretation of these agreements.

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<sup>1</sup> We will continue to use HIPAA as short hand for its Administrative Simplification Section.

Use of de-identified data may be easier, although there is need for a contractual agreement concerning use of the “de-identified” data that was not included in the original privacy rule. This may be of value to benchmarking applications and services.

On the other hand, “minimum necessary,” the privacy rule of greatest impact on HCIT, was not changed in the NPRM. “Minimum necessary” drives system security requirements. Role-based access controls are required, and applications will have to support limiting access to patients and functions by user and role. It appears that most vendors and covered entities will rely on a combination of high-level user access controls and audits to implement “minimum necessary” policies. The general exemption for treatment has little importance to overall system design and implementation, which still must provide granular access controls and audits.

There has been some political pushback on eliminating the consent requirement and on some changes to marketing restrictions. Because a provider could withhold non-emergent treatment from anyone not signing the consent form for treatment, payment, and operations, there was not much practical leverage for the patient compared to receiving timely notice of information practices. In either case, a patient who does not consent to the uses of his or her protected health information would have to go to another provider. Our sense is that very few covered entities would negotiate or agree formally to an individual patient’s request for special handling of their PHI.<sup>2</sup>

The marketing issues involve expansion of permitted uses of PHI under treatment and healthcare operations, which could include recommending treatment options outside the direct encounter environment, while requiring a signed authorization for any other “marketing” or fundraising use of PHI. Neither of these issues appear to be politically important enough for Congress to intervene. In fact since there remains strong opposition to HIPAA from powerful lobbies, Congress is unlikely to want to reopen any of HIPAA.

At this point, it is more important that we get stability in the privacy rule rather than additional changes or we will likely see the unraveling of the entire construct.

We should note some of the unintended consequences of regulating PHI privacy rights. The rules become both the floor and ceiling for protecting PHI. Any physician or hospital that felt that their patient relationship was improved by obtaining signed patient consents to use PHI certainly is free to do it. Instead we are now waiting to hear how the Office of Civil Rights will enforce the rules. We have generally moved past concerns about clinicians not being able to share patient information. But in general, providers and plans will become unfriendlier in their patient/consumer relations as less PHI can be shared and less authority to make PHI-related decisions can be delegated. Moreover, few industry groups or member cooperatives, such as state medical societies, want to interpret the rules or draft model policies and procedures for other parties or members, fearing the liabilities of misinterpretation.

### ***Transactions and the Extension***

It became clear last year to the industry and CMS that we would not be able to make the October 2002 deadline for implementing the standard transactions and codes. Thus there was widespread support for the Administrative Simplification Compliance Act (ASCA) and its one-year extension. The ASCA permits all covered entities (except the small health plans which already had an extra year to comply) to apply to HHS for a one-year extension, setting a new compliance date of October 2003. To obtain the extension, each covered entity must submit a compliance plan to HHS by the original October 16, 2002 date. However, the “plan” is rudimentary (available at [www.cms.hhs.gov/hipaa](http://www.cms.hhs.gov/hipaa)) and not subject to review. The alternative to the extension is to comply with the existing transactions and code rules by October 2002. The addenda that fix well-known problems, such as inappropriate use of National Council for Prescription Drug Programs

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<sup>2</sup> While virtually all providers would attempt within reason to accommodate special requests informally, the HIPAA rules subject such agreements to the full force of the HIPAA rules if accepted. No CE would accept this legal liability; even the idea that such “contracts” could be negotiated at the admissions desk would send risk managers through the roof.

(NCPDP) drug codes, have not been published as an NPRM yet and will not be the rules effective on the original date. A covered entity intending to meet the original compliance date would have to use the NCPDP codes even though most, except retail pharmacies, now use J codes and would have to convert back to them eventually. Thus to be in compliance on the original date and the on the second date established by the addendum, a covered entity would implement drug codes twice. Of course one Chief Executive (CE)'s election to be compliant by the original date makes no difference if one's trading partners have elected the extension. With no known downside, all covered entities are expected to seek the extension.

### **WEDI-SNIP**

Implementing standard HIPAA transactions is a complex project, subject to the same problems that beset all major projects, and there are still many issues to address. We are converting all healthcare billing to a common electronic transaction format. However, this standard format does not change business practices. The many different types of providers must submit different data for different services. Hospitals, nursing homes, dentists, ambulance services, ambulatory surgical centers, and physician practices do not provide the same care or submit the same billing data.<sup>3</sup> WEDI-SNIP reported that the "standard" 837 claims transaction requires 89 different data sets for institutional bills and 33 for professional bills. Most health plans are reported to be developing "companion documents" to explicitly describe how to conduct these standard transactions with them. Some items, such as communications, security, and financial requirements, are necessary bi-lateral details<sup>4</sup>. Other items concerning optionality and situational requirements get very close to compromising "standard" formats.

To discourage the industry from using the extension to further delay implementation plans, the ASCA also requires all covered entities to begin testing transactions by April 16, 2003, six months prior to compliance go-live. Testing and certification for the transactions have themselves become a new HIPAA industry. Bi-lateral testing of all covered entities and their partners, with or without clearinghouses, would be an impossible undertaking. Moreover, it could become a gridlock of mutual debugging.

WEDI-SNIP ([www.wedi.org](http://www.wedi.org)) has revised the sequencing timeline for covered entities and their software vendors that would allow development and testing schedules to align. The 837 claims transaction was first in line and still represents the only standard transaction that has been widely tried. The sequencing originally targeted the October 16, 2002 date. With the extension, and the assumption that all covered entities would use it, WEDI-SNIP has developed a new sequencing plan, which now takes into account that external testing must begin by April 2003. Claims (837), remittance advice (835), eligibility related transactions (270/271), and pharmacy claims are seen as having high payback and thus are at the top of the list for earliest testing. However, there are other complex and less frequently used transactions that are only now being evaluated. Health plans are deciding how to use the 834 transaction (enrollment/disenrollment) not only with employers but coordinating coverage between plans. The 278 transaction (request for authorizations and referrals) is an interesting case study. It had been and still remains the last transaction in the sequencing queue – set to begin external testing in April 2003. There has been some consideration given to moving it up due to its complexity and because it has not previously been an automated process. It is more likely at the end because it will be an easy candidate for further delay.

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<sup>3</sup> In fact the "standard" billing transaction for the same surgery can be different depending on whether it was performed in a practice office (professional billing) or ambulatory surgery center (institutional billing).

<sup>4</sup> ebXML, which will be discussed in the next issue, represents an approach to automating these business agreements.

Sequencing has been a very valuable tool for evaluating industry progress. Like the quarterly HIPAA surveys performed by HIMSS and Phoenix Health Systems, it has provided a sense of what has yet to be done and how much time is remaining. Sequencing gaps led WEDI to understand that the industry could not meet the original deadline. We were not on track to implement and test the later transactions and were bogged down in resolving problems with the 837. While the SNIP sequencing has not necessarily been adopted by vendors for their product remediation plans or by covered entities for their implementations, it will continue to show us where we are and how much time we have to complete the remaining transactions.

## **Outlook**

Viewed as an IT project, HIPAA is in trouble. It is late and over budget<sup>5</sup> and subject to creeping requirements.<sup>6</sup> There are many skeptical users (i.e., covered entities) waiting to see all the final rules before implementing them. If one used the Privacy NPRM as an example, what amount of wasted effort and rework did those who rushed to implement consent forms incur? Only by using the ASCA extension (often referred to as “slipping the date” in the HCIT world) do covered entities avoid mandatory rework. Although one can proceed to implement the standard transactions without the addenda, claims attachments, provider, health plan and employer identification numbers, and without final security requirements, each represents risk and bad project management. At the least, one should be assured that work done now is modular and will not be changed by new rules.

WEDI has sent a strong letter to HHS making the case that the remaining regulations must be published in a timely fashion if it expects continued industry efforts. There have been signals back from HHS concerning inadequate funding by Congress.

## ***The Chicken and Egg***

We are now at that point in an IT project when there is little of the original vision that has not been tarnished by the details of implementation. In fact, with the change in administration and in national priorities, there is a diminishing number of those who were present at the vision's instantiation. It is noteworthy to see how CMS appears to view the HIPAA problem. CMS has raised concerns that there are still many small organizations and executives at large organizations that are not on board with HIPAA requirements and have not committed the necessary resources to implementation. They see this as an outreach problem. They and WEDI are cooperating on HIPAA awareness training and regional programs. One could as easily imagine that executives at large organizations and principals at small organizations are most concerned about bottom lines and in fact are delaying funding until they know the final requirements.

To some extent, all covered entities already have some level of privacy and security in place and can conduct transactions with each other, inefficient as they may be. However, neither large nor small organizations have an interest in ongoing process changes, revising training programs, technical reworks, and multiple implementations. There are few executives that would fund an open-ended IT implementation with incomplete requirements. HHS and CMS would do more to ensure covered entity commitment and funding if they themselves produced all of their deliverables, the remaining rules for security, identifiers, transaction fixes, and claims attachments.

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<sup>5</sup> Over budget can be assumed by the year's delay that continues costs without any benefits. One might argue that CMS has no budget from Congress and the rest of the industry is withholding as much spending as possible until “everything” is final. In this sense HIPAA is more like an unbudgeted project.

<sup>6</sup> While we are beyond the debate extending the privacy and security rules to all forms of PHI, this decision has confounded implementing the standard electronic transactions.

Whenever a project gets in trouble, one looks to the leadership. In the case of HIPAA, it is the federal government. We have had a change in management -- a new administration not so ready to apply regulations. Moreover, project management responsibility is split. Privacy and security are in OCR and the Secretary's office; the transactions and other insurance standards are under CMS. Like some, but not all, troubled projects, HIPAA implementation is under funded -- by Congress in this case. Like many long-term projects, the need to freeze requirements and implementations in time is overrun by changing technology and new problem sets. Thus we see finger-pointing within the standards industrial complex.

### **Leadership in Standards Initiatives**

Leadership, the ability to see important opportunities and problems, to set priorities, and to marshal the resources to get results, is critical in any domain and for any successful endeavor. Healthcare interoperability standards are a segment of the HCIT industry, which in turn supports the healthcare industry. HCIT and its standards are enablers of healthcare delivery. Thus the opportunities and problems, priorities, and resources that give purpose to the various standards initiatives are all external to the standards initiatives themselves. Interoperability standards are technical solutions to healthcare industry problems. Standards initiatives are often several steps removed from those that set healthcare priorities and control HCIT resources. This creates a challenging leadership problem – we have solutions but not necessarily the right problems and priorities and therefore, the necessary funding.<sup>7</sup>

Whatever the intent of HIPAA (e.g., to mandate the use of already existing standards), it has clearly shown that government leadership in the form of federal regulation is not more effective or timely in setting priorities, getting funding, and implementing standards than voluntary acceptance by the market. The premise that the government can effectively mandate “existing” standards to accelerate their acceptance is largely disproved by the HIPAA experience.

### **Coordination of Standards**

Interoperability standards in the United States are the products of an open, consensus-based process staffed by volunteers. Thus leadership has evolved into creating consensus and cooperation among those that participate. In turn, participation is based on sponsors' self-interest and shared view of the problem-solution set. We have previously described the overlapping turf and competitive positioning among the accredited standards development organizations (SDOs) and ad hoc projects. The leadership problem among such standards initiatives is one degree more difficult: how to ensure necessary interoperability between different standards by obtaining voluntary coordination of the voluntary standards bodies. The ANSI HISB is the designated forum for such coordination in the United States.

### **ANSI HISB**

The mission of ANSI HISB ([www.ansi.org/rooms/room\\_41/](http://www.ansi.org/rooms/room_41/)) is to provide an environment that facilitates, coordinates, and harmonizes national and international healthcare informatics standards. As such, it attempts to represent the interests of users, consumers, vendors, consultants, and government.<sup>8</sup>

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<sup>7</sup> Funding remains one of the most acute problems for voluntary standards development initiatives. There are two self-limiting financial principles in standards – they must be free and open.

<sup>8</sup> ANSI accredits SDOs in the United States, ensuring an open, voluntary consensus process, and represents the US position in ISO and other international and regional standards organizations. It has a leading policy and coordination role with participation by both public and private organizations.

Its membership is self-selected, eclectic and of two levels: voting and observer. It includes broad user organizations such as the American Medical Association and American Dental Association, but not the American Hospital Association or HIMSS. Key standards development organizations are members including HL7, ASC X12N, ASTM, and NCPDP. Many government agencies are members including CMS, Centers for Disease Control and Prevention, National Center for Vital and Health Statistics (NCVHS), Agency for Healthcare Research and Quality, Food and Drug Administration (FDA), and the Veteran's Administration (VA). There are also a number of individual health organizations such as Mayo Clinic and Kaiser Permanente as well as HCIT vendors such as Per-Se Technologies and McKesson. The full list is on the Web site.

The ANSI HISB does not create standards nor can it use the ANSI's accreditation process to coerce the SDOs into any particular course of action. It really is the voluntary participation of all that gives it leverage. The government agencies, in particular, use this forum to signal their directions and interests. ANSI HISB, through common members, also is attempting to more formally influence the US TAG, which represents the United States in healthcare informatics at ISO.<sup>9</sup>

The ANSI HISB is seeking to reestablish its influence among the SDOs and the industry in general. To accomplish this, it is seeking to provide leadership-- not just coordination -- to national standards initiatives. Since participation is voluntary, HISB must provide value. It has just completed a strategic plan that demonstrated its leadership role. It wants to provide vision and priorities to the rest of the standards community by producing guiding principles for:

- ~~///~~ Common reference information model
- ~~///~~ Common vocabulary or reference terminology model
- ~~///~~ Common method for information messaging
- ~~///~~ Common trust framework
- ~~///~~ Common approach to coordination, conflict resolution, legal issues, and business arrangements

These are essentially technical objectives and deliverables that facilitate interoperability standards. They will require a significant amount of effort among the leaders in standards development to accomplish. But they may not reflect the business needs, priorities, and spending plans of the healthcare industry. Thus ANSI HISB is an important technical leader within standards development, but it does not appear, based on its strategic directions, to be a liaison between the healthcare industry and the standards initiatives. This disconnects solutions from business priorities and funding.

### **NCVHS**

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<sup>9</sup> The US TAG to ISO Technical Committee 215 represents the United States in international healthcare informatics standards organizations. Its secretariat is ASTM International, not ANSI. ASTM also has its own healthcare informatics standards development organization, Committee E31 on Healthcare Informatics. This sets up the potential for political tensions and turf concerns between ANSI HISB and the US TAG, between E31 and another ANSI accredited clinical informatics SDO, HL7.

We have discussed the NCVHS and its activities in past issues of the *Standards Insight*. NCVHS serves as an advisory board to the Secretary of HHS and indirectly to Congress. It has a very broad portfolio although much of its focus is on the national healthcare infrastructure. Thus it has recently held hearings attempting to coordinate Federal activities, such as the Drug Enforcement Agency (DEA) and the Centers for Disease Control and Prevention (CDC)'s National Electronic Disease Surveillance System (NEDSS). NCVHS serves many government masters, not the least being public health research needs, but it is not a source of funding. Besides providing recommendations to the Secretary on Administrative Simplification rules, the HIPAA legislation charged NCVHS with recommending standards to facilitate personal medical records. In this regard, NCVHS has sent the Secretary a recommendation that HHS promote voluntary "standards" for the PMRI including use of HL7, DICOM and NCPDP. ([www.ncvhs.hhs.gov](http://www.ncvhs.hhs.gov)) While this is clear recognition of political, technical, and market place reality, it is not clear what such recommendations add to the voluntary process already in place. Obviously if CMS mandated use of personal medical records, based on specific standards, as a requirement for payment, there would be a major impact on standardization. However, experience with the languishing HIPAA claims attachments shows the difficulty of merging clinical and financial standards.

Like ANSI HISB, NCVHS seeks consensus positions but from a government perspective. Its membership is not open, but appointed, and does not necessarily reflect different interests. It is exceptionally valuable in its staff role of HCIT coordination within HHS and with the private sector. But it is not a leadership forum able to set priorities and allocate funds across the healthcare industry.

### ***New players***

Coordination is not the same as leadership. It is really not technical leadership that is lacking within standards initiatives. We have many able leaders within the SDOs and other initiatives. The void exists at the interface between HCIT and healthcare. What are the problems and priorities that HCIT and its supporting standards should be addressing? We have discussed the issue of business IT alignment at the healthcare organization level in several past *Standards Insights*. It is a problem that also exists at the national level.

The Institutes of Medicine studies, highlighting the magnitude of the medical error problem, stating that the healthcare system is broken and recommending process improvements and information system investments, have greatly impacted the healthcare and HCIT agenda. But IOM has no standing to drive funding or to solve the problems.

In the previous issue we noted the impact of Leapfrog on the healthcare industry.<sup>10</sup> If its market pressure approach gains traction, its requirement that physicians use computerized order entry could do more to advance clinical information systems than any other factor to date. It has established itself as a leader by setting priorities and, potentially, driving the economics. It essentially leaves to the healthcare organizations how to solve the problems.

Such strategic directions are still filtered and implemented by the provider industry, which will question both the need and source of funding. Already the American Hospital Association and other hospital groups have sought to dismiss the Leapfrog requirements as unrealistic and unfair to most patients and hospitals. The AHA proposes alternative measures. More important to the HCIT industry, the AHA is calling for a national coalition to improve the quality and performance of the health system. Specifically it wants to bring together the "stakeholders - to develop standards based health care information systems".<sup>11</sup>

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<sup>10</sup> Leapfrog is a loose organization of large employers who are also large buyers of healthcare. They have criticized the quality (and costs) of the care their employees receive and propose to shift their business to providers that take specific steps to improve their processes and outcomes. They are supported by CMS and JCAHO.

<sup>11</sup> AHA News Now, April 8, 2002 announcing a meeting in Washington for June 25. ([www.ahanews.com](http://www.ahanews.com))

Of course it is unclear whom the AHA will ultimately represent. To the extent that it represents executive leadership of a third of the healthcare industry, it is in a position to set priorities. To the extent that it ignores other healthcare segments and jumps into technical interoperability solutions, the faster it becomes irrelevant and redundant. The HCIT industry and its standards bodies must be at the table since we can provide insight into technical feasibility, costs, and tradeoffs. We do not need more technical leadership, but more executive management that can set priorities and commit funds. Without both components, nothing happens.

It is very important to understand these dynamics. How one defines the interoperability problem will determine what gets done. If the problem is efficient reporting of disease symptoms from primary care to national analysis, one might define interoperability in one way. If the problem is getting someone's medical record from one side of the country or globe to another in the case of an emergency, one would define interoperability differently. If the problem is the efficient and effective operation of a health system, one certainly could define interoperability differently. HIPAA and Web technologies have focused us on enterprise-to-enterprise interoperability but most work processes and resources in healthcare are used within an enterprise. There are important dialogues that should occur between the leadership in healthcare and the HCIT industry and its standards developers. The HCIT industry is an important enabler of high quality, cost-effective healthcare but it cannot provide the executive leadership.

#### **Next issue**

In a future issue, we intend to examine the underlying Web technologies that are being used within healthcare interoperability standards. XML has become language of interoperability. Web technologies and frameworks are reshaping information systems, not just the Internet. These advances are working their way into HCIT. For example, HL7 embraced XML early on as its preferred implementation technology and as the technical base for its clinical document architecture. It has announced its endorsement of ebXML messaging services. However, the Web technologies are moving quickly and multiple "standards" are evolving. How we use them in healthcare goes back to the problems we are seeking to solve. We noted two issues ago that ASTM E31 was consolidating its subcommittees and rethinking its strategies as it faced declining influence and participation. Out of this review have come new ideas for using Web-based tools, the Semantic Web for Healthcare, and real-time managed care transactions. We will attempt to sort out these important issues of future directions in the next issue.

Please direct any questions, suggestions or comments regarding *Standards Insight* to Joyce Sensmeier (jsensmeier@himss.org) or its author, Ed Larsen (erlarsen@erlinc.com).