



# Standards Insight

## An Analysis of Health Information Standards Development Initiatives

December 20, 2001

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## **Introduction and Overview**

This is the first issue of the *Standards Insight* sponsored by HIMSS. However, the *Standards Insight* has been published by the Center of Healthcare Information Management (CHIM) since December 1999 for management at its member firms. Its purpose is to provide business analysis of interoperability standards initiatives. Interoperability is our shared environment within which the HCIT industry plans, develops, sells and implements its products and services. On January 1, 2002, CHIM merged back into HIMSS and so too the *Standards Insight* will now serve a broader base, including not only vendor and consulting management, but also their customer executives and management. We expect this to be a synergistic relationship that builds value for both sets of stakeholders.

### ***What's going on within the various standards initiatives and why does it matter?***

The standards development process in the United States is undergoing significant change as we move from a purely voluntary consensus-driven process to one of regulatory mandate. HIPAA is, of course, the model. The standard transactions and code rules set forth specific interoperability standards that must be used by all covered entities. Some find this an attractive model to apply to other domains, such as the electronic medical record (EMR), rather than waiting for marketplace acceptance. The National Center for Vital and Health Statistics (NCVHS), as mandated by the HIPAA legislation, is evaluating EMR standards that might be recommended to HHS as mandatory standards. We will continue this evaluation in the next issue of *Standards Insight*.

In this issue, we focus on another powerful phenomenon – the shift of power from standards developers to standards implementers. A corollary to shifting from voluntary to mandated standards is setting a date certain for compliance. Rather than normal adoption patterns, all must implement new standards in the same time frame. This transfers power and resources to those who implement and creates the opportunity for implementation consortia to coordinate, share, and direct efforts to solve common problems. This is in contrast to a 10-year adoption cycle for HL7 standards, which were generally implemented one application at a time by consultants, analysts, and vendors.

### **Implementation Initiatives: SNIP and IHE**

Two key implementation initiatives reviewed in this issue are WEDI-SNIP and Integrating the Healthcare Enterprise (IHE). The former moves us into HIPAA implementation. Most within the HCIT industry have moved beyond considerations about whether the HIPAA regulations are good or bad to how to implement them. IHE, which is sponsored by the Radiological Society of North America (RSNA) and the Healthcare Information and Management Systems Society (HIMSS), has developed a technical framework for implementing existing HL7 and DICOM standards, primarily within the radiology domain. Both WEDI-SNIP, whose strength is in the standard financial transactions, and IHE are examples of voluntary consortia of end users and vendors who take the interoperability standards from Standards Development Organizations (SDOs) and facilitate their implementation. Information systems and business processes are still not plug and play. As long as this is true, implementation will take on an increasingly important role and interfacing healthcare information systems will become more a workflow than a technical project. The alternative to such implementation consortia is one-of-a-kind system integration projects where each healthcare organization repeats the same tasks and mistakes. Of interest is that both SNIP and IHE are seeking to extend their reach more broadly into healthcare organizations.

### **Clinical Standards - ASTM**

Of course at the center of healthcare organizations are patient data and clinical systems. Whether one comes at this center as a backup for claims, as protected health information that must be secured, as source data for public health, as a means of improving care processes, or as the basic patient record of care, we are all converging on clinical information.

At present, HL7 dominates clinical data interoperability standards. It is not without problems, critics, and would-be competitors. Next month we will again review HL7. This month we will look at ASTM E31 Committee on Healthcare Informatics, another SDO in the clinical domain.

## **IT – Business Alignment**

We will also take a nominal look at one of the top issues of CIOs – IT- Business Alignment and see how this failed in the case of HIPAA And ask why isn't HIPAA seen as a clear opportunity to reduce costs and reengineer organizations.

## **Year in Review**

Finally, we conclude with a series of excerpts from the previous five issues of the *Standards Insight* to summarize the year in standards development initiatives.

## **HIPAA Note**

As we complete this issue, the Senate has adopted the House provisions for delaying the compliance date for using the Standard Transactions and Codes one year, to October 16, 2003. Presuming the expected signature by the President<sup>1</sup>, all covered parties will have an additional year to comply with Transactions and Codes, providing they submit a compliance plan to HHS by the original date, October 16, 2002. We believe this delay reflects the real ability of the provider and payor industry to comply (see WEDI SNIP discussion following).

This delay has no impact on the Privacy rules and their compliance date of April 14, 2003 nor on the yet-to-be finalized Security rules. We should note that the American Hospital Association and others continue to press HHS for changes to the Privacy rules. HHS promises to soon issue revised NPRM to fix some of the problems.

Final Security rules are still expected “early” in 2002. However, as noted in the last *Standards Insight*, security has taken on its own urgency since September 11.

## **WEDI SNIP**

The Workgroup for Electronic Data Interchange ([www.wedi.org/](http://www.wedi.org/)) is a voluntary initiative to support EDI standards and to promote widespread use of electronic commerce within healthcare. It works closely with ASC X12N, which is the leading SDO for healthcare financial transactions. WEDI's membership includes all segments of the healthcare industry, but with significant health plan and payor participation. WEDI is one of four organizations designated in the HIPAA legislation with whom the Secretary of HHS must consult. In fact, a WEDI study from the early 1990's is the justification and outline for Administrative Simplification. WEDI is thus concerned with policy and directions of healthcare EDI, but does not itself develop standards.

Somewhat more than a year ago, WEDI established the Strategic National Implementation Process to coordinate HIPAA Administrative Simplification readiness efforts. SNIP too is a voluntary cross-industry initiative. (<http://snip.wedi.org/>) Early on, SNIP recognized that implementing these standard transactions was not simply a technical issue of updating software. It established a sequence for implementing and testing the Transactions. It examined the organizational issues concerning trading partner agreements.<sup>2</sup> It has held hearings and published results and white papers concerning the detailed implementation of HIPAA. It encouraged and coordinated local and regional pilots and reported results back to NCVHS, WEDI and the Designated Standards Maintenance Organizations (DSMO). More than any organization, SNIP has uncovered implementation problems, such as use of NDC codes outside retail pharmacies, use of PKI, and conflict of consigned consents and first encounters. This local/regional reach and national forum strategy has been important in producing timely change requests to the implementation guides and recommendations through the DSMO process and in privacy guidance from HHS. Unlike WEDI, SNIP is much more agnostic toward policy and focuses on

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<sup>1</sup> Post publication, the President did sign the delay on December 27, 2001.

<sup>2</sup> Among the frustrations raised by HIPAA and its piecemeal release is the use of overlapping but not coincidental terms: trading partners (in the Transactions rules), business associates (in the Privacy rules) and chain of trust (in the Security NPRM).

implementation.

SNIP is organized into three work groups:

- ?? Transactions and Codes
- ?? Security and Privacy
- ?? Education and Awareness

### ***Transactions and Codes Work Group***

HIPAA mandates the use of standard transactions and code sets for designated managed care EDI transactions between covered parties. The transactions are based on X12N messages and include claims, eligibility, authorizations, status, etc. Historically WEDI had argued that if all payors agreed to use standard electronic formats, administrative costs could be substantially reduced. However, the “industry” could not agree to abandon their existing proprietary formats without government mandate. HIPAA gave “industry” what it wanted. It should be noted that HIPAA Transactions rules are directed at the payor side although both payors and providers will incur the costs of and gain benefits from the change.

### **Delay**

The WEDI-SNIP HIPAA Implementation Summit was held in November prior to Congressional action to delay compliance with the Standard Transaction and Code rules by one year. Publicly, WEDI-SNIP opposed any delays, but privately and in the sessions, one could see a concern that not everyone would be ready by October 2002. The problem that WEDI-SNIP and other leaders feared was that a delay would reward those who were waiting rather than those who had aggressively gone forward. One of the recurring themes at the Summit was “waiting”. Many covered entities were waiting, waiting final or clarified regulations and waiting for vendors<sup>3</sup>. This created a likelihood of a train wreck if the October 2002 date remained in place because everyone was waiting. In the end, WEDI supported the year’s delay.

The primary challenge is that there are more than 1 million providers, including physician and dental practices, hospitals, and other care facilities, as well as more than 20,000 health plans, including the Center for Medicare and Medicaid and state Medicaid agencies<sup>4</sup> that must be ready to submit and receive the Standard Transactions, within 10 months. Even today there is some disagreement about fundamental issues, such as when a selfinsured employer is a covered entity, and about important details, such as how and when do alternative care providers such as oral surgery or home infusion bill for institutional/professional services or for drug/medical benefits.

Interestingly, HIMSS presented vendor readiness findings to the NCVHS earlier this month. It stated that the “majority” of 28 leading software vendors sampled expected their products to be HIPAA compliant by October 2002. ([www.himss.org](http://www.himss.org)) This is good news and bad news, depending on whether one’s software was in the majority, and whether it would be received in time to implement and test. One of the major contributions that SNIP has made has been laying out timelines and key milestones. In these timelines, software remediation is early in the flow to permit implementation and testing, not at the end. Even if most software would be available by October, this is not the same as saying that the covered entity could go live.

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<sup>3</sup> A valid HIPAA strategy is that of the two campers meeting the bear in the woods – one stops to put on running shoes and the other remarks this is foolish since they could not outrun the bear. The first replied that he did not have to outrun the bear, just the other camper. In fact, Gartner consultants, among others, have made the point that being in the middle of the adoption distribution is okay since HHS is not likely to enforce rules against the entire healthcare industry.

<sup>4</sup> The state governors have been one of the most influential groups seeking a delay in the HIPAA Standard Transactions because of the expense to the states of bringing their Medicaid programs into compliance.

## Savings

Elsewhere we discuss the management issue of cost savings and return on investment. However, one of the fundamental decisions a covered entity must make in deciding how to comply with the HIPAA transaction rules is whether to remediate its current systems or re-engineer its processes and systems. The former strategy uses a clearinghouse or interface engine to map data from current patient accounting systems and processes to conforming transactions.<sup>5</sup>

The upside in this approach is lower front-end costs and disruption of current processes and systems. The downside is not realizing the full benefits of reengineering processes to support single transaction methods. It is not clear whether this strategy will reduce transaction costs at all over time. If a provider uses a billing service and clearinghouse, there is not likely to be much savings. Since HIPAA does not specify standards for networking and connectivity, providers may still wind up using private networks. We note in the ROI discussion, such a decision is part of the responsibility of management – trading off current costs and investments against future benefits.

The alternative strategy is aggressively reengineering internal administrative and financial process and workflow to support these standard transactions. Some HCIT consultants and leading healthcare organizations claim that this strategy will enable the organization to capture significant returns over and above the common savings, which might result from standard transactions. Again this is a management decision. A cautionary note is that, to the extent that the rules are delayed and changed so that everyone “benefits” and no one is rewarded for being an early adopter, aggressive investment is discouraged and the waiting strategy rewarded. Hence the frustration of leaders and early adopters in the delays that even the field for the laggards.

## **Security and Privacy Workgroup**

As with its work in identifying and solving issues associated with implementing the standard transactions, SNIP is also attempting to coordinate local and regional experience implementing the Security and Privacy rules to develop national solutions. Again, SNIP benefits from the wide cross section of participating healthcare organizations. However, unlike the Administrative and Financial Transactions, Security and Privacy rules have a disproportionate impact on the clinical workflow and processes within healthcare provider organizations. Thus, SNIP may not have the same de facto authority and recognition for internal security and privacy as it does for external or inter-enterprise security and privacy.

Still, SNIP has helped identify key security implementation issues. First, two factors, security and digital signature may not be ready for use in identifying and authenticating individuals across enterprise boundaries. What does work is institutional level Public Key Infrastructure (PKI), the FedEx model, which authenticates and secures the delivered electronic envelopes between sender and receiver. However, the contents are not transparently authenticated and secured but are the routine work product of the sending enterprise’s system. Based on several state pilots<sup>6</sup>, there are no current applications that appear to justify the expense and infrastructure of PKI for individuals. PKI requires certificate authorities (CA) to maintain up-to-date identity/authentication lists, possibly with authorizations, and interoperate with other CAs. Reducing the number of entities from all physicians, caregivers, and employees to enterprises, such as hospitals or physician practices,<sup>7</sup> makes the infrastructure manageable and does not raise the issue of electronic signature.<sup>7</sup> It is possible that e-scripts, if supported by DEA, could support a physician PKI.

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<sup>5</sup> One of the SNIP implementation pilot findings has been that many existing financial systems do not have all the data elements required in the standard transaction. The standard HIPAA transactions are not simply an electronic form of UB 92 or HCFA 1500. Thus, remediation may require added processes to collect and insert new data.

<sup>6</sup> Refer to the National Health Key Collaborative ([www.healthkey.org](http://www.healthkey.org)) for reports of state pilots.

<sup>7</sup> We have examined the issue of electronic signatures in prior *Standards Insight* and will again as they remain one of the core interoperability issues as we move toward clinical data standards.

A second finding was that practical application of mobile or roaming user security methods has not been demonstrated. In both cases, these studies showed that technology solutions did exist but that their deployment and management were too expensive to justify. As long as HIPAA rules are tempered by “reasonable and appropriate” language such pilots are useful boundaries on requirements – at least until courts find otherwise.

Before leaving security, we should note that SNIP and most standards initiatives have not had time to assess the impact of 9/11 on priorities. We would expect that homeland defense and public health infrastructure, such as the Health Alert Network, would draw resources and focus from HIPAA privacy and security implementations. For example, the North Carolina Healthcare Information and Communication Alliance ([www.nchica.org](http://www.nchica.org)) has piloted statewide immunization and ED databases. This might have a higher priority than systems to enforce minimums necessary within provider organizations.

### ***Education and Awareness Work Group***

As noted one of WEDI SNIP’s goals is furthering healthcare EDI. To that end the Education and Awareness Work Group reported on its September survey results. With roughly equivalent participation by providers, health plans, and vendors, the results are an interesting benchmark. Asked what their biggest success has been so far in terms of implementation, 21 percent, the largest plurality, reported “getting executive buy-in”. That is an amazing number if one considers the survey was taken 13 months after the final rule mandated use of Standard Transactions and codes and 13 months before the compliance date. One might interpret that the other 79 percent did not have any trouble with getting executive buy-in and so did not report it as a success. However, of these, 17 percent reported that their major success was getting started and 12 percent in obtaining internal resources.

SNIP had approximately 450 attendees at its November HIPAA implementation summit. Attendance was comparable to the HL7 fall plenary session. This interesting comparison points to a major opportunity. SNIP is focused on implementations, not concepts or policies. If SNIP seeks to move beyond enterprise-to-enterprise privacy and security implementation issues, it will have to move from the X12 financial realm to the clinical realm – HL7 turf. Since HL7 standards do not really address security and privacy, some other body will fill the void. Can security and privacy implementation be a simple add on to clinical systems? Or will SNIP, or another alternative such as IHE, move into implementing HL7 standards? Clinical implementation consortia would come into conflict with HL7 business plans and ultimately influence the direction of the clinical standards themselves, just as SNIP has influenced the Transactions and Code Standards.

### **IHE**

Integrating the Healthcare Enterprise (IHE) is a joint initiative sponsored by RNSA and HIMSS. It presented its Year 3 interoperability demonstration at RNSA last month and which will be repeated at HIMSS 2002. IHE began in 1998 as a standards acceleration project for integrating radiology departments with the rest of the hospital. It was to build on existing standards, in this case DICOM and HL7, create detailed workflow and integration profiles, and create plug and play interfaces. Over the last five to seven years, radiology departments have been transformed by digital imaging. This shift from film-based manual systems to automated computers has created new workflows and the need for interoperability. The DICOM standard has matured to support intradepartmental flow between the radiology information system (RIS), the picture archiving and communications system (PACS) and the digital modalities, such as CT and MRI. However, radiology also needed to interoperate with the rest of the hospital to receive orders and other clinical results, to send back results, and integrate these with the patient electronic medical

record. Moreover, to realize the benefits of filmless systems, workflow had to change.<sup>8</sup>

IHE Year 3 is described as a year of consolidation. The demonstration by 30 vendors showed support by for seven profiles:

- ?? Scheduled workflow
- ?? Patient information reconciliation
- ?? Consistent image presentation
- ?? Presentation of grouped procedures
- ?? Access to radiology information
- ?? Key image note
- ?? Simple image and numeric reports

As one can tell from the list, the profiles attempt to close the loop from the procedure order to returned results. In fact, most of the profiles involve intra-departmental workflow. The profiles define actors in roles performing transactions. Within this domain, IHE has done an excellent job of defining interfaces that are plug and play among various imaging system vendors. Part of the Year 3 effort is to promote IHE compliance as a requirement during vendor selection.

IHE has attempted to take its methodology and extend it to other imaging intensive departments such as cardiology. So far, there has been limited interest outside radiology. However, horizontal and vertical expansion remain goals of IHE over its current time horizon.

There are several major challenges facing IHE if it is to expand its scope. Foremost among these is that it represents some competitive effort with HL7 and its Version 3 efforts. Both IHE and HL7 are trying to fix the ambiguity in HL7 Version 2.x messages albeit with different commitments to DICOM. Both IHE and HL7 Version 3 are based on an information model/framework that defines entities, roles, and transactions/acts. In the case of the former, it applies the results to profiles built on current HL7 and DICOM standards. In the case of HL7, the modeling results are run through the Version 3 message building technologies. In theory, a systems vendor could support both workflow efforts, using IHE profiles for "current" RIS-like interfaces and Version 3.0 for future HIS interfaces. However, from a HIS or CIS vendor perspective, supporting IHE efforts to expand its domain to all HIS/CIS is duplicative of the Version 3 effort. Those vendors with strong presence in imaging and RIS must support IHE. Today, most other HIS and CIS vendors will muddle through with existing interface engines and HL7 Version 2.x mappings. As discussed in the last two issues of the *Standards Insight*, HL7 Version 3 may be emerging as the core national standard for the EMR. Thus, it is not clear what business value support of IHE for future interfaces outside imaging creates.

Moreover, HL7 and DICOM each have a SIG and Work Group respectively, made up of common members, who work on convergence and coordination of the two standards. If a vendor were interested in integrating DICOM images into hospital wide systems, these offer an alternative technical route. In particular, these groups are attempting to represent DICOM order messages for imaging within HL7 messages without using Z-segments, representing DICOM processes in the HL7 reference information model and RMIMs, and mapping DICOM Structured Reports (SR) to HL7 messaging results and Clinical Document Architecture. In other words, the DICOM and HL7 groups are working directly on converging DICOM with HL7 Version 3, which, if successful, would replace the need for IHE profiles.

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<sup>8</sup> At RSNA, Eliot Siegel of the University of Maryland/Baltimore VA reported that a filmless system cut 12 of 59 steps necessary to order, conduct, and report a radiology procedure. Reengineering allowed them to reduce the 59 steps to nine.

DICOM itself has its own agenda including adapting to the requirements of digital image processes and application of XML to SR and to imaging generally. The rapid shift to digital images has created a need for a new paradigm to detect and store relevant clinical findings among the hundreds of images and measurements produced by a single procedure. Security is another DICOM initiative, which may be ahead of the industry.

IHE has been very successful at applying workflow analysis to practical results in a limited domain, whereas HL7 uses more theoretic modeling in a wider domain. IHE has used leading customers to lean on the industry to provide significant support to its efforts. In many respects, IHE is a clinical analog to SNIP. In fact, IHE is beginning to wrestle with the workflow implications of security and privacy based on DICOM.

The strategic question for IHE is how to break out of its radiology confines by offering unique value to the HIS industry. Simply applying their technical framework and workflow methodology to an entire hospital is too complex and time consuming (and redundant of HL7 Version 3 efforts). We noted in the SNIP discussion that privacy and security may represent leverage on clinical systems. Is a security and privacy technical framework for an EMR that cobbles together existing systems, interface engines and HL7 Version 2.x messages a possibility? Does it represent a less costly and faster approach than betting on and waiting for Version 3?

### **ASTM E31**

ASTM Committee E31 on Healthcare Informatics held its fall working sessions in conjunction with AMIA in November. The meeting was lightly attended and much of the focus was on reviving and renewing E31's role within the SDO community. In the past, E31 has carried a large portfolio of areas of interest. It has published ANSI approved standards for clinical laboratory systems, for electronic medical records, for healthcare transcriptions, for security and privacy, and for XML-based medical record documents. Much of the HIPAA Security and Privacy rules were derived from ASTM standards. All of which should position E31 as a central SDO in HIPAA and HIPAA II. Instead it is seeing declining participation, which has forced it to cut back and focus its task groups to two areas:

?? Clinical documents and records

?? Privacy and security

Both areas offer opportunity for interoperability standards. Although HL7 has recently expanded its mission to include the electronic medical record, the RIM is not an EMR standard and their domain expertise is thin. The Clinical Document Architecture is not yet defined to a level of detail sufficient for implementation, e.g., Level 3. The E31 XML subcommittee has worked with the HL7 Structured Documents technical committee to align their DTDs with CDA Level 3 when it is defined. But the latter has developed a set of specific document standards, such as operative reports, that can be implemented now.

Chair Peter Waegemann has sought authorization to revamp E31. ASTM has three fundamental strategy options: it can seek to compete with HL7 over the clinical information model or framework, it can seek to cooperate with HL7 and fill holes, such as in security and privacy and terminology, or it can ignore HL7 and seek to develop smaller, less complex standards that can be easily and quickly implemented, such as XML schemas for specific medical records and documents. In the first strategy, E31 would probably need partners to gain credible mass for its framework. Potential partners are DICOM/IHE, ebXML, OMG. In the second strategy, E31 would have to accept the HL7 RIM and seek to extend it by adding "data at rest" requirements. The third strategy, which also would benefit from partners, is to go after areas of opportunity, such as XML-based discharge plans. The strength and weakness of HL7 is its long-term RIM driven approach. If and when it achieves critical mass, it will be a powerful interoperability standard. However, in the meantime, neither information technology nor short-term opportunities will disappear. Moreover, E31 has both expertise and experience to question whether the HL7 RIM approach will work either as a model or as a basis for XML messaging.

Waegemann will seek to renew E31 by attracting more corporate participation by focusing on short-term business opportunities with ROI, by offering more cutting-edge expertise focused on market driven problems, and by increasing meeting fees but providing better work environments. E31 will try to both cooperate with HL7 while maintaining a separate identify. The success of such renewal will depend on the clarity of strategy and direction in circumstances that are inherently ambiguous.

### **Improving IT - Business Alignment**

Over the course of the last year (see the year in review below), our business analysis has noted the divergence between the HCIT industry and many of the business executives of its clients and customers concerning HIPAA. While not always a welcomed message, we have attempted to show why many end-user executives were reluctant to accept HIPAA.

It is important, if not for HIPAA I, but surely for HIPAA II, to understand executive decision-making. Healthcare providers are essentially in a "regulated" industry. Revenues are fixed by the buyers, whether MedPAC or large health plans or sponsoring employers. Winning financial strategies<sup>9</sup> are based on beating the averages. Having higher occupancy, lower costs, more outpatient visits, etc.<sup>10</sup> In the hierarchy of management fiduciary responsibility, resources first go to maintaining current operations, second to legal/regulatory requirements, third to strategic initiatives, and fourth to nice-to-have projects.<sup>11</sup> In most cases the first two allow for little discretion over what is done, but some options on how it is done. It is the third, strategic initiatives that management sets priorities and the fourth never happen. As we know, we have gone through a recent HCIT exercise in maintaining current operations, Y2K. Now we are looking at a far-reaching regulatory mandate, HIPAA. Meanwhile hospitals (outpatients), Skilled Nursing Facilities (SNFs), and home-care agencies are all undergoing overhauls of their Medicare reimbursement systems. Bio-terrorism and disaster response are making new and unanticipated demands. All of these initiatives must come out of the same capital and operating cash-flow pools. None of these specifically generate new revenue. They are costs of doing business and need(?)to be minimized. They also pre-empt other discretionary initiatives such as reducing medical errors and improving clinical workflow.<sup>12</sup> But why wouldn't executive management embrace the opportunity to invest in a cost-saving initiative such as HIPAA regardless of its mandated nature? Put it this way: if a hospital executive management team chose to invest in assuring a higher level of patient privacy than exists today rather than reducing the number of medication errors that occur today, would one judge that this decision best met their mission and service objectives?

A HIPAA-compliance strategy can take several forms as we discussed in the SNIP section above. These range the gambit from minimizing front-end investment and costs, to embracing it as a core strategy to re-engineer for e-health. These are executive management decisions and will be based on strategy (are they trying to beat the averages) and available resources and competing projects.

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<sup>9</sup> Healthcare provider strategies are very mission- and service-oriented. However, all must be grounded in providing sufficient cash flow to enable ongoing operations, replacement, and expansion.

<sup>10</sup> The foregoing are management strategy options. It also helps if one has the advantage of location, e.g., low managed-care regions or being a sole community provider.

<sup>11</sup> There are, of course, times and circumstances that require reordering priorities.

<sup>12</sup> This month, HIMSS released its HIT Forecast: 2002-2006. One of the predictions "The necessity to comply with federal HIPAA regulations by 2003 will compel many providers to postpone other improvements in their health information systems" was supported by 67 percent of the panel.

***The HCIT industry did not “sell” executive management. We relied on Federal regulation to force them to implement HIPAA.***

With publication of final HIPAA rules for transactions and codes and privacy, many in the HCIT industry decided it was a done deal and time to move on from policy issues to implementation. This certainly makes business sense to many whose business plan or organizational role includes HIPAA. We, within HCIT, assumed that executive management would likewise accept HIPAA as an inescapable mandate and provide necessary support and funding. How many of us made the business case for a HIPAA strategy?

In a keynote session at the recent SNIP HIPAA summit, a keynoter was asked what was the business case for HIPAA. The response was essentially two negative incentives: avoiding law suits and reducing billing costs. It has not gone unnoticed in executive suites that HIPAA has created its own industry of lawyers, consultants, vendors, and regulators.

WEDI, HCIT consultants, and many others strongly preach that ROI can accrue to those organizations that take advantage of this paradigm shift to ehealth and approach HIPAA as strategic opportunity rather than a legal requirement. The ROI argument says that the mandated standard transactions will save so much money that they will cover the costs of the Privacy Rules. See the May summary below (see below).

The ROI argument, as any HCIT sales person knows, is a difficult case to make to an executive management team. HIPAA is particularly difficult because the costs are front-end loaded and the payback period stretches 10 years. Moreover, to calculate an ROI one needs to match the investment with future cash flow. It assumes that the investment and cash flow belong to the same entity. In the case of the future savings from reduced administrative costs, it is not at all clear that they will accrue to the healthcare organization. Rather, if health plans and providers do reduce their administrative costs, it is likely that the government and employers will seek to capture those savings. This is the nature of interoperability. Benefits go to the end user. Thus, HIPAA is a cost of doing business to be minimized, not an investment with high return.

## **Year in Review**

The following are excerpts from the 2001 issues of the *Standards Insight*. They trace the course of interoperability standards over the year.

### ***January***

Is HIPAA good or bad for the HCIT industry? It certainly depends on how complex the security framework becomes. It probably depends on one's products and services. Certainly the Privacy and Security Regulations will redirect spending priorities. Money for new applications will be directed toward insuring current applications can support whatever security framework is required. Probably good for those with large installed bases and bad for those depending on selling new applications. Y2K redux! Some new technologies, such as wireless, may see some repercussions in meeting industrial strength security requirements.

### ***March***

Bill Braithwaite, HHS's senior advisor on health information policy, appeared at several (HIMSS) venues. His basic message was that *HIPAA was here, why are you surprised because this is what you asked for; let's get on with it*. It is certainly understandable after the amount of work and effort invested in HIPAA by an under-funded HHS and by interested standards groups and lobbies, that its architects were sensitive to a rising storm of criticism. After all, Administrative Simplification did evolve from WEDI proposals to save significant healthcare dollars by standardizing administrative and financial electronic transactions. Part of the deal between “the healthcare industry” and Congress was that in return for mandated standards that the public's privacy would have to be protected – this requires security rules.

But this puts a spin on some regulation creep and HHS scope decisions that have sharpened a growing chasm between regulators and regulated. After all, WEDI primarily represented those whose business interests were managed-care transactions, the payers, not healthcare providers or others in the industry. Moreover, there certainly was no debate in 1996 on the scope and reach of the privacy and security regulations and their subsequent costs, particularly for providers.<sup>13</sup>

### **May**

HHS has estimated that all covered entities will spend \$17.6 billion to implement the Privacy Rules in addition to the \$7 billion for implementing the standard transactions. Through slight of hand, HHS avoids estimating the costs of its yet-to-be finalized Security Regulations. Instead it says that these are a cost of doing business and were included in the cost benefit analysis presented in the final Transaction and Code Rules.<sup>14</sup> Nonetheless, it is not difficult to see how the AHA might estimate that it would cost its hospitals \$22 billion to comply. Not only is this an unfunded mandate but it will displace other spending. Recall that the AHA estimated that its members spent \$8 billion for Y2K. Also, recall how this spending effectively stopped spending on new IT initiatives. Despite improving operating margins following the Balanced Budget Act (BBA) givebacks, capital availability is one of the highest concerns of hospital leadership. The total operating profits of all hospitals is now about \$10 – 12 billion a year. In this year's HIMSS Leadership Survey, not surprisingly, HIPAA was the highest priority of healthcare organizations. This represents setting real priorities. It displaces other IT related initiatives, such as medical error prevention.

There is a further perversion in federal regulations, particularly in the area of technology. They lock in the technical solution set to that available and in an existing ANSI standard at time the Rules were enacted. An example of this is XML. Not an approved standard at the time the transaction rules were written, XML is written out of use in the covered transactions until such time as standards are developed and incorporated in changes to the federal rules. Who will be willing to demonstrate the use of XML, which now is explicitly not permitted by law? The Security Rules will similarly freeze innovation and/or force marketing efforts to be directed at selling the regulators and their SDO proxies, not customers. Smart SDOs are turning their focus to the next things that the federal government will mandate, such as digital signatures and the electronic health record data elements.

### **August**

This month's (NCVHS) hearing provides a framework for briefly updating the state of clinical interoperability standards. First, let us put the NCVHS initiative into some perspective. There is a general perception among some in HHS, NCVHS, and the SDOs, the emerging "standards-industrial complex," that the HIPAA model for managed-care standard transactions represents a significant and successful break-through in healthcare informatics. The Congress and HHS responded to the pleas from the payor and provider industries to mandate standards, which the industry was unable to impose on itself despite the claim of immense financial savings. The *Standards Insight* and others have examined these premises in many other forums and we will not repeat these here.

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<sup>13</sup> This might be an excellent learning experience for "industry" and who is reported to be speaking for them, particularly in an era of activist use of regulations to establish standards. This should be kept in mind as the NCVHS goes forward with developing recommendations for standards for personal healthcare record elements. There is great interest in mining clinical data by all types of researchers. The costs of getting that data at the source will not be born by those with vested interest in data standards.

<sup>14</sup> The cost benefit analysis of the Security Rules component of Administrative Simplification only included the costs of securing the specific transactions, not all forms of electronic data stored and used by covered parties. It is this latter overreach of the federal regulators that has caused the industry reaction.

However, the lesson learned is that with government coordination and regulation, we can improve and speed the results of voluntary standards initiatives. NCVHS is generally applying this lesson to the EMR and clinical systems. The voluntary SDOs do not have the resources to produce widely used standards in a timely fashion nor are they able to coordinate their activities in areas of overlap. Voluntary, uncoordinated standards initiatives are no way to develop an information infrastructure for 14 percent of the GDP.

The standard PMR will not happen in the next several years. Developers cannot begin to use it as a template for product design. With more immediate business concerns, why spend time on the PMR now? Because now is a time for the HCIT industry to evaluate these issues of voluntary or mandated standards and to help shape direction. Certainly individual industry companies will want to decide if they are leading players, or seeking competitive advantage, or willing to accept what comes along.

### **October**

In the aftermath of September 11<sup>th</sup>, the proposed HIPAA Security Rules do not appear either onerous or sufficient. In fact, information system security initiatives will move forward rapidly with or without final rules from HHS. However, security has become an enterprise endeavor of executive management and their boards, not just an IT effort managed by CIOs.

While it is difficult to sort out the overall validity of these trade-offs, it is clear that the slowing economy, perhaps tipped into a recession by the terrorism, will reverse the profit recovery of healthcare providers. Healthcare is a lagging industry in the business cycle. Rising unemployment reduces health insurance coverage. Rising premiums drive employers to reduce benefits and shift costs. Falling tax revenue squeezes Medicare and Medicaid spending. Bottom line, healthcare providers will have less funds to devote to discretionary projects.<sup>15</sup> *Ultimately, the economy and changing national priorities will likely delay HIPAA implementation.*

### **December**

And so we end the year with new national priorities, with HIPAA delayed, with several standards initiatives seeking new direction and leverage. WEDI-SNIP has been focused on HIPAA administrative simplification and the financial side of healthcare. Will it try to become a player on the clinical side? ASTM E31 was a leader in electronic medical records, privacy, and security but has lost ground to HL7 and is trying to recover. IHE, despite impressive plug and play results in radiology systems workflow has not been able to break out into the "healthcare enterprise." Does it align itself with HL7 directions, as the clinical SNIP?

### **Next Issue**

The next issue of the *Standards Insight* is slated for mid-February. We will cover developments from HL7's winter meeting, from NCHVS hearings, and from HIMSS. EMR standards will be a focal point of analysis. Please direct any questions or comments regarding *Standards Insight* to Joyce Sensmeier (jsensmeier@himss.org) or its author, Ed Larsen (erlarsen@erlinc.com).

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<sup>15</sup> It should be noted that hospitals non-operating funds from investments have also been negatively impacted by the stock market declines.