

The Mt. Washington Vision: A Response to ONCHIT's Request for Information

The Mt. Washington Expeditionary Force

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Key Features:

- ◆ Radical simplification of the prerequisites for interoperability
- ◆ Minimal involvement of government at any level
- ◆ Optimal involvement by the consumer (patient) constituency
- ◆ Market-driven approach to interoperability
- ◆ Interoperable content-driven, based on HL7's Clinical Document Architecture (CDA) standard

Key Proposals:

- ◆ Information-based, rather than application-based, interoperability
- ◆ CMS create a progressive incentive structure for providers to produce progressively more useful electronic documents
- ◆ Patient-designated personal health record banks receive copies of electronic documents produced by providers

About the Mt. Washington Project and the Expeditionary Force

This proposal was conceived and formed largely outside the normal work responsibilities of each of the participants – in other words, on our own time – because of the shared perception that a radically different sort of proposal was called for and was, on some level, calling us. While, between the group of us and the organizations we work with, we had some small share in perhaps a dozen other RFI responses, we dedicated time and resources to this project on two grounds: we felt we had something unique to convey and we felt that even if not well received by its first audience, the articulation of a cohesive vision based on the key features and proposals listed here would be worthwhile in its own right.

We set out to answer three questions that we felt had been given short shrift consistently in the prevailing channels, the solution to which, we felt, lay in a re-thinking of basic premises. The three questions were: 1) what is the minimal necessary security structure to start moving information outside the enterprise? 2) how can we address the issue of overlap in RHIO jurisdiction in terms of governance, finance and technology? and 3) how can we create a critical mass of standard reports that will catalyze a self-generating network?

We met for two and a half days in the Mt. Washington conference room at the Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire.

In the course of our discussions, we spent relatively little time addressing specific RFI questions and most of the time addressing the latter issue: what happens when you prime the network pump, so to speak, and provide the raw materials on which the market, directed by the ultimate customer – the patient – can progress?

We feel that as of January 18, 2005, this is a work-in-progress and we plan to conduct a series of consultation and review sessions with different stakeholder groups – RHIOs in formation, quality monitoring groups, providers, patients, clinical researchers and public health officials – and we expect to continue to refine this approach, at the same time, priming the market for a pilot implementation.

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Request for Information

RFI General Questions

1. The primary impetus for considering a NHIN is to achieve interoperability of health information technologies used in the mainstream delivery of health care in America. Please provide your working definition of a NHIN as completely as possible, particularly as it pertains to the information contained in or used by electronic health records. Please include key barriers to this interoperability that exist or are envisioned, and key enablers that exist or are envisioned. This description will allow reviewers of your submission to better interpret your responses to subsequent questions in this *RFI* regarding interoperability.

Executive Summary

This response subscribes to all of the rationale in the ONCHIT's RFI for creating a NHIN, but suggests a radically simplified set of pre-conditions for doing so. In summary, we suggest:

- ◆ The creation of a critical mass of standard, persistent, application-independent, electronic documents based on Health Level Seven's (HL7's) Clinical Document Architecture (CDA) will catalyze the emergence of an array of interoperability mechanisms from which all the benefits that the RFI ascribes to a NHIN will be realized.
- ◆ Creation of a specialized national network is not required and would be a tremendous drain on scarce resources and attempts to do so could inhibit innovation.
- ◆ Widespread adoption of electronic medical records (EMR) systems by physician practices is not a pre-condition and a universal mandate would create a significant entrance barrier to the benefits of interoperable information.
- ◆ Increasing levels of encoding sophistication for these electronic documents will bring increasing benefit to different stakeholders, fostering incremental growth.

We propose that CMS, the de facto healthcare market master¹, catalyze the creation of a critical mass of standard, persistent, application-independent, clinical documents through financial incentives to Medicare and Medicaid participating providers. Production of HL7 CDA-compliant electronic documents summarizing the healthcare service should be differentially rewarded according to the level of machine-processible encoding. Eventually, baseline compliance will become a condition for reimbursement. This critical mass of interoperable clinical content in the hands of providers will catalyze the emergence of an array of complementary resources, mechanisms, initiatives, commercial products and stakeholder collaborations that will dramatically increase the exchange of healthcare information within the existing frameworks of the HIPAA privacy and security regulations and thereby deliver the benefits that the RFI attributes to a NHIN.

The author of a HL7 CDA-compliant document (i.e. a healthcare or ancillary service provider) must not only create and retain the original CDA document, but, if the patient designates a personal health record repository, must also deposit a copy into that bank. A personal health records bank is a new type of regulated, non-governmental organization created specifically to receive CDA documents from providers as the agent of the patient and store them in an Internet connected repository. Use of such repositories is discretionary and we anticipate a wide variety of such service provider to compete for this business, providers such as the RHIOs (as currently underway), commercial providers (Yahoo, Google), health plans (MyLifePath by Blue Shield of California) or PCPs and IDNs.

Information in patient-controlled, personal health records bank accounts will provide patients with an unprecedented ability manage their health and contribute to their own continuity of their care. Existing and ubiquitous Internet security technology, well proven in financial services applications, should be sufficient to ensure that CDA documents can be securely deposited and withdrawn.

¹ A market master is a purchaser who has such significant purchasing power that they can drive the behavior of a market. CMS is such an entity for US healthcare.

We propose to amend the HIPAA privacy regulation to recognize the special nature of personal health records bank accounts to guarantee that only patients and their designees can access them. HIPAA privacy regulation amendments or other legislation as may be required will afford the highest level of privacy protection to the contents of a individual's personal health records bank account, equivalent to that afforded records of the most personal nature stored in a safe in one's home.

The regulatory oversight proposed for personal health records banks is the type routinely administered by government to protect consumers from fraud and to verify that businesses meet minimum technical, operational and financial solvency standards to ensure that they can meet their obligations to their customers. The type of regulatory oversight envisioned for personal health records banks is analogous to that provided by the Federal Deposit Insurance Corporation in relation to financial institutions.

The Core Thesis

A single, centrally-architected NHIN for the U.S. is not required to proliferate appropriate exchanges of interoperable personal medical records information among providers, patients and other healthcare industry stakeholders.

We believe that a centrally-planned solution, even when such a solution eschews a national patient identifier, remains unfeasible in the U.S. Huge obstacles to the success of a centrally-architected solution are presented by the fragmented nature of the U.S. healthcare system and the extremely low level of adoption of electronic medical records systems outside of hospitals and large clinics. Furthermore, we have no evidence such a centralized EMR-driven system will work, while the preponderance of evidence from abroad suggests a simpler more cost-effective, market-driven path.

Virtually no EMR system in operation in the U.S. today interacts with an independent EMR system, even if it is the same vendor's system, without extensive prior negotiations between each source and each destination system. Furthermore, even predicating such interoperability, there are too few EMRs implemented to support ubiquitous interoperability.

We believe that the first problem that must be addressed nationally is that of creating a critical mass of application-independent, standardized *content* to catalyze market-driven processes which will in turn develop a variety of solutions for the appropriate exchange of individual medical records information. The essence of our proposal is to use the position of the Center for Medicare and Medicaid Services (CMS) as the market master in the purchase of healthcare services in the U.S. to drive the creation of a critical mass of electronic documents produced by Medicare and Medicaid participating providers. **We propose that CMS provide incentives, and eventually require, healthcare providers and key ancillary service providers, such as clinical laboratories and pharmacies to create and make available standard electronic documents.** The purpose of these electronic healthcare documents is to describe or summarize the care provided, the diagnostic test results generated, the medications dispensed, or the overall healthcare status of the patient, as appropriate to the role played by the provider of the services for which Medicare or Medicaid reimbursement is sought.

We share the concern of the authors of the ONCHIT RFI that no proposed solution to achieving interoperability of healthcare information be based on "dead-end" technologies. For this reason, we have chosen to recommend HL7's Clinical Document Architecture (CDA) as the primary standard for national-scale interoperability. For the purpose of this proposal the essential characteristics of CDA are:

- ◆ open, non-proprietary, platform-independent data standard (ANSI/HL7-2000 R1.0)
- ◆ 100% compliant with the HL7 Reference Information Model and Version 3 data types
- ◆ contents are always human-readable
- ◆ scalable in terms of encoding sophistication

This last point means that at the low end, virtually any provider with desktop technology can produce a minimal CDA document and at the high end, lab systems, pharmacy systems and EMRs can produce richly-structured, fully machine-processible CDA documents that remain human-readable on any system. In a system that rewards data encoding quality, this constitutes a type of "investing" in information such that users derive benefit according to the effort expended.

[See Appendix A for a brief description of CDA and the sections below on incremental development and managing information. See also Question 23 on Technical Architecture]

Putting Patients in Control of Their Own Records

Once providers begin producing standard, interoperable electronic records that documents care, patients can direct their provider to deposit the record in a personal health record bank. A patient-selected custodian for their personal health records will meet priorities laid out by the patient. Such custodians will specialize according to different types of clientele. For example, special security, such as biometrically activated smart cards for authenticating patient access, might be a feature of a service designed for celebrities. Blood sugar monitoring and patient-entered data might be a feature of a service designed for diabetics. Where the record is stored and managed is at the discretion of the patient, much like their choice of a bank to manage their money.

Patient buy-in is critical to this effort, and, we believe, to any other system of widespread healthcare information interoperability. We strongly suggest that such buy-in is achievable through the following means:

- ◆ patient selects the custodian for their own record
- ◆ patient associates quality of electronic record with their personal safety and quality of care
- ◆ patient sees financial benefit to interoperable record either through reduced insurance costs or better basis for managing own funds in health savings account

The idea of an electronic medical record is hard to grasp for many consumers, but the idea that federal regulators can't adequately monitor the course of disease and the effects of new medications without knowing the outcome of treatment is increasingly easy to convey, thanks, unfortunately, to the recent high-profile drug withdrawals.

A Content-based Strategy Will Work, an EMR-based Strategy Won't

Much of the current thinking on integration suffers from a central flaw, that of taking what worked reasonably well within a single enterprise and attempting to scale it up to the requirements of cross-enterprise interoperability and doing so without a re-examination of basic operational requirements and assumptions. The essential difference between a document-based strategy for integration and one based on application functionality and application messaging is that in the wider context, the same degree of conformity may not be optimal and cannot be enforced and the same degree of trusted relationships cannot be instantiated.

Today's emphasis on standardizing and increasing the market penetration of applications like EMRs to drive the production of content and to facilitate interoperability is risky for several reasons. An insistence on the universal adoption of a single EMR, on standard EMR functions, or even on EMRs as applications is unnecessary and actually creates steep entrance and maintenance barriers, particularly for small physician practices. Only a small percentage of physicians currently use EMRs, a number that – by most accounts – has remained almost constant for the last several years. Thus, an application-based approach will be costly to the population who can least afford the cost: independent practitioners. The major cost of EMRs is not the initial investment in systems, but the ongoing cost of maintenance and integration. In addition, a frequently unacknowledged cost of an EMR is the initial, and sometimes permanent, decrease in physician productivity in the clinical setting through changes to the existing workflow.

Subsidizing major system purchases for providers assumes that the market is “wrong” in its widespread reluctance to adopt this technology. Many question whether the current generation of EMRs are truly innovative, or if they need to focus more closely on existing workflow in which documents (and the voice interface) play a central and highly effective role in many settings. Creating a critical mass of interoperable content will be a spur to application innovation where, in contrast, mandating application-based interoperability can act as a drag on technical and entrepreneurial innovation.

Unlike applications, standardized persistent objects – documents and image files – are an ideal starting point: they are how healthcare organizations communicate today, routinely exchanging documents via mail, fax and e-mail. Because of this ubiquity, many common healthcare documents (e.g., medical records, referral letters, immunization records, claims-related explanations of benefit) will become de facto standards.

The Clinical Document Architecture (CDA) allows users to take common documents and wrap them in metadata. The documents can be created through dictation / transcription systems, electronic forms applications, knowledge-based systems, and electronic medical records (EMRs) and enhanced by coders or natural language processing. The user can receive the file through many channels (portal, paper, fax, email, dongle, EMR import, etc). Most providers already have the basic technology required to create and view CDAs, namely, desktop applications, dictation services and browsers. Lastly, CDAs do not require that we solve every problem before we begin. CDAs solve the immediate interoperability problem, while being backward-compatible with traditional, paper-based processes and forward-compatible with EMRs.

In a cross-enterprise context, information must have a clearly-defined legal status. In CDA this is accomplished by restricting the unit sent as that which can carry an authenticating signature and further, defining clear, simple rules to define what must be available for display to a clinician by the receiving system. In an in-house, intra-enterprise environment, the level of trust and pre-negotiation is greater and the type of information on-demand at short notice is different, all aspects that support a higher level of synchronous integration than is desirable or feasible in the wider context.

HL7 Version 2 clinical messaging will continue to play a strong role in the areas served today, almost exclusively intra-enterprise application integration. New areas of application are being opened up by HL7 Version 3 messaging that can support complex information structures with a consistent data model. The messaging paradigm will and should continue to coexist with the document paradigm, but where users are not related by extensive clinical, technical and business pre-negotiation, where document characteristics of legal clarity and technical range are called for, that is, in the extra-enterprise sphere, information will be carried in CDA documents, some of which are the result of transformation from in-house HL7 messages. (See question 23, Technical Architecture, for more on the relationship of documents and messaging.)

How Does a CDA-based Network Achieve Incremental Development?

CDA was designed to scale up to accommodate the most sophisticated types of encoding and to scale down to the capabilities of simple document authoring applications that have loose or minimal definition of clinical content. The architecture allows both extremes to coexist in the same exchange network through enforcing a common, rigorously-defined metadata set for document indexing, storage, management and retrieval. Where clinical content is well-defined, the sender can encode information in “clinical statements” using the HL7 Reference Information Model (RIM) and controlled vocabulary and receivers can verify conformance through a clinical template. At the same time, CDA documents impose a minimal burden on receiving applications which can use a browser and a single style sheet to display required clinical content, regardless of encoding sophistication.

Several levels of encoding sophistication have been defined for CDA. The table below summarizes the different levels of encoding sophistication (semantic interoperability (SI)), associates it with typical document-producing applications for that level of interoperability, and describes typical functionality and applications, again for that level of SI.

Degree of SI	Required technology	Functionality	Sample Applications
CDA header + scanned document	practice management or web form and scanner	index and retrieve documents;	claims attachments (human readable); aggregate personal record; referrals
CDA header + text (ASCII, pdf, .doc...)	desktop applications with practice management or web forms	as above with full text search	as above, plus semi-automated surveillance
CDA header + XML structures (Level One)	XML desk top applications, dictation/transcription	as above, but more flexible display	as above, plus portable health data (on PDA, web phone) that can be repurposed for devices not originally identified
CDA header + XML structures, headings, simple coding (Level Two)	XML desktop applications, dictation/transcription with simple templates, vocabulary services	as above, but excellent basis for natural language processing; automated excerpts; document re-use at section level	as above , plus machine-readable claims attachments, quality monitoring; some interaction checking
CDA header + XML structures, headings, complex coding (Level Three)	XML desktop applications, dictation with templates, or EHR, all require vocabulary services	as above, with automated re-use at granular level	as above plus automated public health monitoring, clinical trials, patient safety

These apply equally to any clinical content and can be augmented and refined as consensus on content requirements is achieved. Encoding sophistication is independent of clinical content. For any given clinical information, a range of coding can be applied. The lowest level is a simple metadata set assigning a globally-unique identifier to the document and identifying patient, provider, encounter and clinical document type (e.g., referral, discharge summary, imaging report, etc.) linked to a scanned image of a paper document.

Note on document imaging: While we would like to deprecate and discontinue this process because it renders information intractable without potentially error-prone character recognition processing, we feel that until minimum-acceptable documentation practices can be enforced, it is better to integrate these records through a common metadata set, as classifiable, retrievable, human readable artifacts, than to prohibit them where no electronic alternative has been implemented.

Slightly more sophisticated, and much more useful, is the same metadata linked to a word processing or text file. These are called CDAs with “non-XML” bodies. Going to the next level of sophistication and utility is the simplest XML body which is roughly equivalent to an HTML document, but carries the required CDA header for document management. Once encoded in XML, there is actually a continuum of encoding sophistication that can be required and applied. If there are no requirements for semantic encoding, this is called Level One, and includes basic XML as well as non-XML. If all sections of the document carry standard codes to identify section type, it is called a Level Two document. If some of the section content is encoded, even just one medication or observation, it is called a Level Three document.

Permitting different levels of encoding sophistication for documents with equivalent (or distinct) clinical content allows document authoring, management and exchange applications to evolve, along with industry consensus on content requirements, while we derive significant benefit even from minimal conformance. Furthermore, simple coding can be achieved without disruption to the clinical workflow. Sophisticated coding, regardless of application, takes some incremental effort and must, in our healthcare system, be gated by corresponding incremental benefit to the information producer. It may take some time for benefits that accrue outside the provider’s office to migrate back to the information producer. National interoperability can be initiated before these market forces find their natural balance, in fact, a baseline interoperable set of documents will prompt the development of applications spawned from the value that such documents will confer.

Incremental value accrues to the patient as well, as electronic documents become more sophisticated. First, patients gain more fine-grained control over which portions of their record are seen and by whom. For example, with section-level encoding and the CDA confidentiality markers, current applications can display, hide or even encrypt sensitive information such as reproductive history. With content-level markup in the document, patients can do the same with results of genetic testing or other data elements.

How a Document-based System Manages Information

Working with potentially large numbers of standard electronic document records need not expose individual providers to information glut and, in fact, holds the potential to reduce and manage the current rising tide of artifacts that accumulate in an individual record and in a practice, large or small.

CDA sets a very low bar for definition of clinical content – the CDA “body”. Essentially, it must be readable in some form. The CDA “header”, on the other hand, is a rigorously-defined metadata set, derived from the HL7 Reference Information Model using the Version 3 process, including the rich data types. It was developed based on over a decade of experience in the standardization of medical records management within HL7 and in industry. Without giving a full tutorial on the CDA header, we should note the most salient features for information management and discovery:

- ◆ globally unique identifier (ISO OID)
- ◆ document type identifier, recommends use of LOINC identifiers for classification (e.g., referral, discharge summary, history & physical, imaging report, etc.)
- ◆ providers and patients identified as participants with scoped identifiers and roles
- ◆ related encounter and orders identified per HL7
- ◆ links to related parent documents in cases of replacements, addendums or transformations

Considering that practices today, like it or not, are likely to receive information by mail, fax or patient-delivered hard copy notes, getting all of the above as electronic CDA documents with a consistent header/metadata set will make possible much richer local management than is possible under the status quo polyglot of formats and media, whether the provider has an EMR, a practice management system or just a file server. As a minimum, having all documents available with the consistent header permits construction of natural drill down and organization by patient, date, document type and origin.

While there is a large capacity for integration, providers receiving incoming CDA documents into local EMR, medical records systems must develop local policy that establishes the degree of segregation between internal and external documentation. By choice, externally-produced documentation can be stored, displayed and accessed separately or with the core medical record and can employ any number of flagging devices to indicate origin. This holds true not only for full documents, but for data fragments and excerpts taken from coded clinical statements.

Letting Market Forces Prevail

As the purchaser of over 50% of healthcare in the US, CMS is the market master. As such, it can drive the creation of electronic content by tying the provision of standards-based CDA documents to CMS reimbursement. At its heart, this is our proposal: that the CMS create strong incentives for the production of electronic documents as a condition of reimbursement. The graduated, incremental improvements in encoding quality, described above in the section on incremental development can be scaled to incremental incentives.

Electronic documents create the opportunity for asynchronous and spontaneous workflows, because staff can send, receive, track, and audit documents without radical change to their workflow. Thus, the first positive consequence: communication that was severely delayed or labor intensive can occur in a timely fashion.

Once the momentum toward a critical mass of CDA-based content is evident, market forces will lead commercial vendors and public-private consortia to offer products and services built on top of CDA. One can only speculate what these products and services will be or which will emerge first, but they are likely to include: document set organization, patient advisory services, content discovery, aggregation, and de-identification. As consensus emerges on the content and coding of clinical information, real-time access to terminology servers will become more important. This is not an immediate barrier and prototype systems have been deployed by NCI, Mayo and others. We believe this will become an area of rapid development by commercial and non-profit service providers.

Evidence that significant financial benefit can be derived from electronic healthcare information is clear:

Reporting and Population Health Management

Institutions currently have multiple public and private sector reporting requirements at the federal, state, and local levels for patient safety and quality, as well as for public health. In addition, the internal quality improvement efforts of many health care organizations include routine reporting of key quality indicators (sometimes referred to as clinical dashboards) to clinicians. Most of the data for these reports must be abstracted from claims data, paper records, and surveys, a process that is labor-intensive and time-consuming, and usually occurs retrospectively. Thus such reporting is often limited to entities that have sufficient administrative infrastructure to develop the necessary data (Institute of Medicine, 2002c). Additionally, chart abstraction has been shown to involve a number of significant errors (Green and Wintfeld, 1993). *Having clinical data represented with a standardized terminology and in a machine-readable format would reduce the significant data collection burden at the provider level, as well as the associated costs, and would likely increase the accuracy of the data reported.*² (our emphasis)

² Key Capabilities of an Electronic Health Record System, IOM Committee on Data Standards for Patient Safety Board on Health Care Services Letter to AHRQ, July 31, 2003.

Barriers and Enablers to Document-centric Interoperability: How Will This Change Occur?

Barriers: Current

- ◆ few current systems choose to produce standard documents
- ◆ lack of consumer understanding of the benefits of interoperability and therefore lack of consumer involvement in the management of their own health documents
- ◆ lack of alignment of payment for interoperable documentation
- ◆ the belief that large-scale system integration and/or ubiquitous EMRs are necessary to drive this change
- ◆ the belief that having the same application software guarantees interoperability
- ◆ status quo – the healthy skepticism of the healthcare community that this can be done

Barriers: Future

- ◆ consumer expectations rise too fast
- ◆ an early, high profile failure (or perceived failure)
- ◆ distrust of the consumer's ability to effectively manage their healthcare / documents
- ◆ non-CMS payers' failure to require comparable documentation

Enablers: Current

- ◆ can be jumpstarted in a low-cost or cost-neutral manner
- ◆ not burdened by distrust of government involvement in healthcare
- ◆ reduced technology and bandwidth costs
- ◆ existence and power and penetration of the Internet
- ◆ degree of administrative automation in provider offices (PMS, etc.)
- ◆ the ability to piggyback off paper-based processes
- ◆ prospect of cost efficiencies that improve quality of care
- ◆ existence of a simple, interoperable (human and/or machine readable) standard for electronic documents
- ◆ current political support for interoperability
- ◆ increased availability of digitized information (pharmacy, lab, radiology, etc.)

Enablers: Future

- ◆ rising awareness of the connection between standardized, interoperable data and our ability to monitor individual patient health and population safety
- ◆ market forces: viral growth based on the early successes of early adopters
- ◆ market value of de-identified data from clinical trials, public health channels back to provider and patient
- ◆ the ubiquity of standardized documents, improves the value proposition for constructing an EMR (virtual or facility-based), which will benefit the EMR market
- ◆ the network will grow through gradual adoption of increasingly more useful / interoperable data

Conclusion

At the time the web was created, the experts in electronic text were working with a rich, complex ISO standard (SGML) that required several hundreds of pages of documentation and specialized applications to deploy. Tim Berners-Lee took a radically simple subset of that language and created Hypertext Markup Language (HTML) catalyzing explosive growth through simple, innovative architectures and products that capitalized on the rich connectivity of the Internet, the familiarity of the document metaphor, and the extremely low technical barriers to the production of HTML documents. In the case of the U.S. healthcare industry in 2005, CDA is the innovative technology that can lead to the explosive growth in the exchange of healthcare information. CDA is a relatively simple to deploy, inexpensive yet scalable standard for clinical documents that can be linked through metadata and hypertext links with images to form virtual or local electronic health records.

The importance of aligning with existing processes was painfully demonstrated when General Motors launched an e-procurement service. Only a tiny fraction of the possible benefit from their \$85 billion annual spend was realized, because the e-procurement service failed to capture existing deal flow that was being managed with faxes and EDI. The lesson for healthcare is that interoperability solutions that derive benefit somewhere down the line must be as facile as current processes for the information producers. Only when, and in the proportion, that they accrue direct benefit can increased complexity be layered onto this process.

Put yet another way, to paraphrase Adam Bosworth, who wrote Microsoft Access and managed much of Microsoft's network strategy, "on the 'net, simple wins." We believe that in this instance, healthcare is no exception.

2. What type of model could be needed to have a NHIN that: Allows widely available access to information as it is produced and used across the health care continuum; enables interoperability and clinical health information exchange broadly across most/all HIT solutions; protects patients' individually identifiable health information; and allows vendors and other technology partners to be able to use the NHIN in the pursuit of their business objectives? Please include considerations such as roles of various private- and public-sector entities in your response.

We are not proposing a NHIN. We are proposing that CMS catalyze the market-driven emergence of an array of document-centric interoperability mechanisms in lieu of a NHIN. We propose that CMS catalyze a critical mass of documents which will provide the content for an array of document-centric interoperability mechanisms with financial incentives to Medicare and Medicaid participating providers to produce electronic documents compliant with HL7's Clinical Document Architecture (CDA) standard. Patients can then choose whether to deposit them in patient-designated, personal health record banks (i.e. Internet-connected, patient-controlled repositories) which may include a geographically-based RHIO or a specialty registry or repository. In any case, originals will remain under the stewardship of the author/provider where they can be used for direct communication with other providers for continuity of care. Medicare and Medicaid participating providers will be differentially reimbursed for producing CDA documents on a periodically updated schedule of CMS adopted CDA document types that summarize the clinical information describing the care or ancillary services for which the provider is seeing reimbursement.

The differential payment will be based on the re-usability of the electronic document, "re-usability" defined as the degree of machine-processible semantic encoding in the document. CDA documents are XML documents. All CDA documents have a mandatory human readable section and are renderable by any web browser. CDA Level One documents have no encoded clinical information. Level Two and Level Three CDA documents have progressively more of the content of their human-readable sections encoded in XML structures. We propose that the CMS incentives be greater for higher levels of CDA documents.

The widespread production of CDA documents in response to CMS incentives is assured because CDA documents are very easy to produce. Basically any system that can produce a printed report summarizing an event in the care of a patient can be easily enhanced to produce the report as a Level One CDA document. Dictation transcription systems can easily produce CDA documents as their output and some already do, others are waiting for demand. Virtually all dictation/transcription services and vendors use sufficient structure internally that they could easily output CDA. So even physicians without an Electronic Medical Records (EMR) system will be able to produce CDA documents to qualify for enhanced reimbursement.

For vendors of EMR systems, producing reports that are Level Two CDA compliant is just another type of report. Full support for Level Three CDA documents will take more effort because proper structuring of clinical statements is not trivial. By targeting areas like lab results where there is already some consensus on vocabulary and where HL7 V2 provides a high degree of coherence, vendors can provide just enough encoding to qualify their customers for a higher level of reimbursement. Providers will be given incentives to acquire or upgrade an EMR because of the immediate return on investment in the form of increased reimbursement from CMS through more richly encoded documents.

Almost all hospital and commercial laboratories and pharmacies already have highly functional information systems that automate almost every facet of their operations. These mission-critical applications are designed internally around encoded information. However, in 2004, few systems use nationally standardized codes. We believe the technical barriers to converting these systems to export standardized codes is actually low, but some incentive to do so and access to a non-proprietary drug formulary (RxNorm) and full LOINC compliance are required. This would enable these systems to provide diagnostic test results and medication dispensing certificates as fully encoded Level Three CDA documents.

The widespread use of CDA documents is assured because recipients of CDA Level Two and Three documents who are incapable of processing the encoded information can safely ignore it and use it as an ordinary human readable clinical document. If you want to send a CDA document to someone who doesn't even have an e-mail account or a web browser you simply print it out and mail or fax it to them. The more encoded information a CDA document has, the more value its creator adds for the patient and his or her future healthcare providers and furthermore, investing in additional encoding of information never narrows the potential for utilization by recipients with lower levels of technology than the producer.

Clinical content in the form of application independent documents can take immediate advantage of personal computers, the Internet, and the numerous existing and emerging Internet communication, collaboration, information distribution and security standards, to make personal medical records information available wherever they are needed. For example, by placing patient-designated, Internet-based repositories that receive the provider-created CDA documents at the center of our proposal, it takes advantage of the Internet and the near universal support for encrypted links to servers using SSL to get clinical documents automatically accumulating under patient control without requiring either patients or providers needing to have digital certificates.

Additional examples of existing Internet standards that can be immediately leveraged include, e-mail with attachments, the World Wide Web (WWW) and File Transfer Protocol (FTP). Really Simple Syndication (RSS) is an example of an emerging standard with excellent potential to become an enabler of document-centric healthcare interoperability.

If the patient has designated a personal health record bank, the provider must deposit the CDA into that bank, but they will always keep a local copy of the document. In the case of an independent physician or member of a small practice who does not have an EMR, if they have even one PC in the office with a dial-up Internet account, they can store the documents in a file system and e-mail them to colleagues who need them or to hospitals for referrals. Of course they can also receive such documents from their colleagues or from laboratories and pharmacies, should they so choose. At a minimum, they can read and print and file these documents in the paper charts they currently maintain. See the section in Question 1 "How a Document-based System Manages Information".

If this proposal only succeeds in replacing faxing with e-mails containing attachments that are CDA Level One document with human readable XML bodies, an enormous step forward will have been made in healthcare connectivity and the foundation will have been laid for the explosive growth in the adoption rate of EMRs in individual and small group practices. While there will inevitably be some period of adjustment, once the critical mass of information is flowing in the form of even minimal CDA documents, relatively simple file management applications can organize and classify records according to multiple parameters: patient, date, type of document, provider and with greater clinical depth as the technology matures.

We believe that something like the following hypothetical sales pitch will become extremely compelling once a critical mass of CDA notes, lab results and pharmacy dispensing notices exists:..

"The brand X EMR can directly import all those lab reports the labs are e-mailing to you and which your new patients want to e-mail you or bring you on a memory stick, and we can analyze them and graph them and help you see relevant trends. And we can take all those dispensing reports that the pharmacies are producing now for your prescriptions and the prescriptions that other doctors write for your patients and not only automatically turn them into a medications list, but if you want, and only if you want, we will alert you when a prescription that you write using our e-prescribing function is not filled or refilled within a timeframe that indicates that your patient is not complying with the medication treatment you recommended."

Large providers including very large regional or national "integrated" delivery networks (IDNs) can use retained CDA documents to solve interoperability issues that they have among their numerous incompatible EMR systems.

3. What aspects of a NHIN could be national in scope (i.e., centralized commonality or controlled at the national level), versus those that are local or regional in scope (i.e., decentralized commonality or controlled at the regional level)? Please describe the roles of entities at those levels. (Note: ``national'' and ``regional'' are not meant to imply federal or local governments in this context.)

The proposal envisions a minimum of central coordination at any level above what exists today and apart from spontaneously generated market-driven organizations.

For the first wave of implementation, the government payer, CMS, should initiate a supply of standardized clinical documents as a condition of payment. The federal government should designate relevant standards, but need not play a role in their creation. Regional and non-geographic communities of interest may choose to develop data management organizations and applications, but no mandated coordination is required.

The second wave of implementation will probably benefit from an expanded federal role in establishing a network of reciprocal trust supporting interoperable digital identities for healthcare providers; and possibly regulatory oversight of business providing critical infrastructure services (e.g., de-identified of patient data, registries, etc).

RFI Concerning Organizational and Business Framework

4. What type of framework could be needed to develop, set policies and standards for, operate, and adopt a NHIN? Please describe the kinds of entities and stakeholders that could compose the framework and address the following components:

We are proposing that CMS catalyze the market-driven emergence of an array of document-centric interoperability mechanisms in lieu of a NHIN. We propose that CMS generate a critical mass of documents to provide the content for an array of document-centric interoperability mechanisms with financial incentives to Medicare and Medicaid participating providers to produce electronic documents compliant with HL7's Clinical Document Architecture (CDA) standard. Medicare and Medicaid participating providers will be differentially paid for producing CDA documents listed on a periodically updated schedule of CMS-adopted, CDA documents that summarize the clinical information describing the care or ancillary services for which the provider is seeing reimbursement.

In place of a hierarchical or central NHIN, patients will direct the safeguarding and distribution of their individual records. The government may choose to regulate a system of healthcare information repositories in much the same way it regulates and insures the banking system today through FDIC.

4a. How could a NHIN be developed? What could be key considerations in constructing a NHIN? What could be a feasible model for accomplishing its construction?

The benefits attributed to a NHIN will be realized through the emergence of an array of document-centric interoperability mechanism. No government investment in physical infrastructure is required.

4b. How could policies and standards be set for the development, use and operation of a NHIN?

CMS will work with HL7 and other ANSI-accredited standards organizations to insure that the evolution of the HL7 CDA standard, DICOM for images and standards for clinical content developed by appropriate clinical domain experts meet the needs of CMS.

4c. How could the adoption and use of the NHIN be accelerated for the mainstream delivery of care?

We believe that the best way to accelerate the realization of the benefits that the RFI attributes to an NHIN is for CMS to exercise its power as the market master in the purchase of healthcare services in the U.S. and reimburse for the creation of a critical mass of persistent, application-independent, clinical documents which summarize clinical encounters, diagnostic test results and medication dispensing events. The production of these documents is a necessary pre-condition for the network effect – the spontaneous growth of a network of interoperable networked applications that use a common data format.

4d. How could the NHIN be operated? What are key considerations in operating a NHIN?

CMS will need to manage the incentive program, provide some degree of supervision of personal health record banks, and the certification of relevant standards, including CDA, DICOM and possibly others. The federal government will have to provide some degree of supervision of the business processes of the healthcare information repository and the designation of selected data standards.

Once a critical mass of persistent, application-independent clinical documents are being produced, we believe that other payers will imitate the CMS's incentive programs, many types of entities will compete to be personal health record banks (i.e. patient-controlled repositories), and current and new product and service vendors will compete to provide a wide variety of valued services on top of sets of CDA documents.

5. What kind of financial model could be required to build a NHIN? Please describe potential sources of initial funding, relative levels of contribution among sources and the implications of various funding models.

We are proposing that CMS catalyze the market-driven emergence of an array of document-centric interoperability mechanisms in lieu of a NHIN. We propose that CMS play the role of catalyst for the generation of a critical mass of documents. These documents will stimulate an array of document-centric interoperability mechanisms as a result of the financial incentives to Medicare and Medicaid participating providers. Medicare and Medicaid participating providers will be differentially reimbursed for producing CDA documents listed on a periodically-updated schedule of CMS-adopted CDA document implementation guides or templates that define the clinical content and level of encoding. .

Given the same clinical meaning, not all electronic documents carry the same potential for reuse. The CDA documents in the schedule are designed to be documents that populate a lifetime personal health record. Until the industry as a whole can support a uniform level of encoding, the documents will, of necessity, have different value for quality monitoring, outcomes analysis, disease surveillance and clinical trials. Documents can be graded according to their value for downstream processing, analysis and reuse. And for each grade, the differential reimbursement would increase. Providers would get more for Level Three documents with rich RIM-compliant HL7 V3 encoding than for Level Two documents. Similarly, incentives for Level Two CDA documents would be better than for Level One documents.

A formal announcement or notification by CMS of its adoption of HL7 CDA Release 2 as the basis for a forthcoming incentive program should take place as soon as possible, well in advance of the beginning of differential payments. This early specification will give EMR vendors, laboratory information system vendors, pharmacy software vendors and transcription vendors sufficient lead to modify their products and that will allow their customers to participate in the incentive program.

Actual initiation of the program will likely require a modification to the HIPAA Transactions and Code Sets regulation to include the optional inclusion of the object identifier (OID) of the CDA document for which differential reimbursement is being sought and the CDA Level or template of the document.

We believe that once the details of the CMS incentive program are announced, other payers will imitate the CMS plan, and announce incentive programs of their own to encourage the production of CDA documents that summarize the clinical information relevant to the clinical encounters, diagnostic tests and medication dispensing events for which their affiliated providers are seeking reimbursement.

The announcement of the forthcoming incentive program and the specification of HL7 CDA Release 2 as the technical standard of the content will be the signal event for the formation of personal health record banks that will compete for the business of being the custodian of patients' lifetime personal health record.. We anticipate that competition will be vigorous, with provider organizations, payers, professional societies, pharmaceutical companies, patient cooperative organizations, and established Internet-centric business vying for this new business.

6. What kind of financial model could be required to operate and sustain a functioning NHIN? Please describe the Implications of various financing models.

There is no need for a centrally operated NHIN to achieve the clinical and economic benefits of interoperable, reusable healthcare information. Once the array of document-centric interoperability mechanisms has emerged through the catalytic intervention of CMS in the healthcare market as described above, there will be no further need for government involvement in sustaining the growth in interoperability.

The on-going role for CMS will be to regulate the differential reimbursement scheme described in Question 5, according to increasingly sophisticated encoding requirements, paced according to market adoption.

7. What privacy and security considerations, including compliance with relevant rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are implicated by the NHIN, and how could they be addressed?

We see two very different classes of privacy and security considerations that are corollaries of our proposal. On the one hand, CDA documents will be deposited into patient-designated, Internet-connected repositories that manage and provide subsequent access to the information according to rules and practices negotiated with the patient as a condition of service. On the other hand, the original CDA document will be retained by the provider who authored it.

Current Internet Security Can Work for Personal Health Record Accounts

Current SSL technology is sufficient for management of patient-controlled health record accounts. web browsers are distributed with an user-editable list of trusted certificate authorities. When a client browser connects to a web site that supports Secure Sockets Layer (SSL), the web site presents a digital certificate. If the digital certificate presented was issued (i.e. signed) by one of the certificate authorities that the browser trusts, and the URL on the certificate matches the URL of the web site, the browser accepts that it is has connected to the web site it was trying to connect to. It uses the web site's public key (contained in the site's certificate) to encrypt a candidate symmetric key for encrypting the rest of the data in that session. Only the web site that presented the certificate has the corresponding private key required to decrypt the candidate symmetric key suggested by the browser attempting to establish a secure connection with the web site. Both sides then encrypt and decrypt the session traffic using the symmetric key.

SSL works very well for secure, HIPAA-compliant communication when the communication can be mediated by a coordinating web site known to all the potential participants. The major advantage of SSL-based communication is that only the intermediary web site, in this case the patient's designated personal health records bank, needs a digital certificate. We believe that SSL-based encryption will work well for the deposit of CDA documents into personal health records accounts. The federal government could issue digital certificates to personal health records banks as part of their regulator oversight function. Medicare beneficiary cards could be reissued to include the URL for the patient's account with his or her designated personal health records bank. The URL on the card would act like an external account number, "for deposits only" and would allow the bank to compare the patient identified in the header of the CDA document against the name of the account holder.

Patients could securely transmit any or all of the contents of their health records bank accounts to their own, Internet-connected personal computer, or to any recipient with a browser and an Internet e-mail account, without requiring the recipient to have a digital certificate. Competitive personal health records banks would provide staging server functionality to account holders. Patients would use the facilities of the bank to compose a message addressed to the Internet e-mail address of the intended recipient of their documents and attach the documents they wish to send. When the patient hits the send button, instead of sending an e-mail with attachments to the recipient, the bank places a copy of the documents on its secure staging server and sends an e-mail to the intended recipient that says, "You have a confidential communication of personal medical records information from ..., please click here to download these documents." When the recipient clicks as instructed their browser sets up an SSL session with the bank's staging server and downloads the documents over the encrypted channel. Additional security can be provided at the patient's option by including a one-time password in the notification e-mail, or communicating the password "out of channel", by a phone call to intended recipient. The recipient would have to provide the password to the staging server to initiate the download.

SSL does not address authentication of the patient to their bank, but the market can provide several methods. Some patients would be quite happy with ID and password authentication similar to what they use in self-service relationships with financial services companies, such as banks and brokerage firms. Other patients might demand, and be willing to pay for, stronger forms of authentication, including smart cards and/or biometrics.

Personal Health Record Accounts Can Work for Patient Safety, Quality and Public Health

In terms of guaranteeing the confidentiality of information stored in personal health record bank accounts, it is clear that the maximum protection afforded by law and regulation must be nearly absolute if patients are to trust and use these services. We foresee the need to modify the HIPAA privacy regulation and perhaps other legislation to afford the aggregate content of personal health records bank accounts, as distinct from the records held in distributed provider sites, the status of personal records stored in one's home.

However, we do not expect that most patients will take such a closed approach to storage of their personal health records. In fact we predict exactly the opposite. We expect that innovative organizations and a great number of independent physicians will compete vigorously for the patient's business. We anticipate that patients will embrace those health record services that provide them the best health information filtered by the knowledge of their health status contained in their personal health records. Services will compete to do the best job notifying patients or, at their direction, a designated provider, of preventative actions, opportunities to participate in health enhancing activities when they are well, and clinical trials when they are not. We anticipate that the accumulation of a lifetime of personal health information in these accounts will unleash a long pent up torrent of demand from patients for innovative services that allow them to participate effectively manage their own health.

We fully expect service-oriented, non-profit organizations to provide patients with high levels of service at little or no cost to the patient, because the trusted relationship that they will develop with patients will allow them to generate revenue by providing de-identified data to pharmaceutical companies and research organization with the informed consent of the patients they serve. We believe that only a patient-directed management strategy, where the patient understands the connection between access to aggregated de-identified information and the ability of regulators and researchers to monitor their safety will work within the privacy climate of the US healthcare system.

We caution the reviewer not to read too much into the analogy of a minimal-access bank that we have introduced here. Given the emphasis that patients put on privacy in polls about electronic medical records, and the enormous influence of a well-informed and very articulate privacy lobby, we felt it necessary to dwell at some length on how security and privacy issues could be dealt with. The banks and less restrictive record management services will act in many ways more like patient advocates than anything else. We hope and anticipate that primary care providers will gravitate to the role of personal healthcare records banker.

CDA Documents in the Hands of Their Authors

The other channel for distribution and reuse involves the exchange of the copies of the CDA documents that remain with their authors, the providers. Although this clinical content is in a fundamentally more interoperable format than paper or proprietary electronic counterparts, from the perspective of the HIPAA privacy and security regulations it is protected health information (PHI) like any other. We see no need to amend the HIPAA privacy or security regulations just because a more interoperable form of PHI is available.

We anticipate the CDA documents produced by providers will greatly simplify the efforts of large, diverse healthcare provider organization to support interoperability among the heterogeneous EMR systems within their organizations. When a single enterprise, even a very large one, builds a repository of patient information whether physical or virtual they are generally able to support a method by which all the individual healthcare professionals who require access to the system can be identified and authenticated to the system and granted appropriate access to PHI based on their role. This is never easy, but it is possible because the sponsoring organization has some kind of business relationship with the healthcare professions who require access. Since healthcare professions generally are affiliated with more than one provider organization, they are generally burdened with managing a constantly growing set of IDs and passwords and possibly smart cards or other tokens issued by the various institutions they deal with.

This situation is far from ideal. It is routinely made to work after a fashion, but it is clearly and impediment to interoperability that is not addressed by format of the clinical content to be shared. The problem enters the realm of the really hard, if not intractable when the set of possible participants is expanded to include all physicians, at any moment, anywhere.

It must be acknowledged that as interoperability begins to yield to the near universal availability of CDA documents summarizing care, lab results, and medication dispensing events, that lack of a national system for identifying and authenticating doctors and other healthcare professional will impose a practical limit on the scope of HIPAA-compliant exchange mechanism for PHI.

Therefore in the years ahead, after basic healthcare interoperability has been well establish, we foresee the need of the government to facilitate the emergence of an interoperable network of certificate authorities with the necessary chain of trust agreements to simplify the identification and authentication of doctors and other healthcare providers on a national basis.

8. How could the framework for a NHIN address public policy objectives for broad participation, responsiveness, open and non-proprietary interoperable infrastructure?

Broad participation and broad-based interoperability are a function of simple, open data standards. Complex functional architectures that impose major change on existing workflow will inhibit innovation and slow adoption. A mandate to produce HL7 CDA documents summarizing patient medical data for export to patients is at the heart of this proposal.

Evidence that CDA documents can be produced from a wide range of applications, from simple web forms to dictation/transcription to EMRs is available from many sites and vendors in the US as well as the most advanced national infrastructures abroad. In laboratory demonstration conditions and actual production applications, valid CDAs have been produced from:

- ◆ radiology information systems as a function of a transform from DICOM Structured Reporting;
- ◆ desktop applications including Microsoft Word and InfoPath
- ◆ dictation systems from small and large vendors using transcription, voice recognition and natural language processing
- ◆ web forms with scanned or text content for claims attachments
- ◆ EMRs, synthesized from both imported reports and internally generated data
- ◆ knowledge-based systems with and without natural language processing
- ◆ dynamic, template-driven assembly from distributed repositories
- ◆ translation on output from legacy systems
- ◆ several of the above aided by direct interface to vocabulary services

In more than one dozen national and trans-national interoperability projects, no barriers to CDA creation have surfaced. The flexibility of the specification which can be produced as the output from virtually any record system and integrated with minor or trivial changes to existing workflow is one of the strong reasons for adoption. The first release has been stable for four years and the second release is already being integrated into many of these projects.

Given the position of CDA at the core of the most widely implemented national projects (Finland, Germany, Greece, Denmark and others), it is possible, although not yet studied closely, that CDA is the most widely implemented specification for clinical information. This framework should not impose standards on applications or the functionality, other than the requirement they produce the appropriate CDA documents for export to patients. After priming the pump with baseline CDAs, CMS and ONCHIT may choose to differentially reward higher quality data encoding, spreading the benefits of machine-processible data available from lab, pharmacy and some EMR systems.

RFI Concerning Management and Operational Considerations

9. How could private sector competition be appropriately addressed and/or encouraged in the construction and implementation of a NHIN?

Private sector competition is at the heart of our proposal to have CMS use its economic power in the healthcare market to catalyze the emergence of an array of market-driven, document-centric interoperability mechanisms in lieu of try to construct and implement a NHIN.

10. How could the NHIN be established to maintain a health information infrastructure that:

10a. Evolves appropriately from private investment;

We believe that there is so much value in the information that will be deposited in the various patient-designated accounts, and so many value-added services that can be offered to patients by services built on these accounts, that there will be no need for the government to do anything to encourage these “banks” to form. If this proves not to be the case then it is certainly possible for a short period of time for CMS to provide a micro payment to the personal health record repository.

The development of personal health record services will be seeded with HL7 CDA compliant clinical documents created by Medicare and Medicaid participating providers responding to CMS incentives. HL7 is an ANSI-accredited standards development organization which ensures that the standards it develops are non-proprietary, and developed in a open, consensus-based process in accordance with the principles of ANSI and the International Organization for Standards (ISO).

10b. Achieves country-wide interoperability; and

Baseline interoperability through CDA documents is virtually assured. CDA Level One documents are no harder to create than a printed report. Several popular dictation transcription systems can produce them today. An EMR is not necessary to produce or to send, display and store CDA Level One documents.

Commercial and hospital laboratories and pharmacies should have no trouble producing Level Two or even Level Three CDA lab reports and medication dispensing notices, respectively. Labs and pharmacies are almost universally highly automated with information systems built on database management systems storing structured, encoded data. CMS incentives will induce labs and pharmacies to demand that their software vendors enhance their systems to support CDA Level Three compliant document output so that the labs and pharmacies can qualify for the highest levels of differential reimbursement.

Producing a Level Two or Level Three document does not impede the use of that document by a recipient that can not process the encoded section of the CDA document. In fact the document can always be printed out and sent by traditional means to recipients with no computer system at all.

10c. Fosters market innovation.

We foresee numerous healthcare market innovations springing up around the availability of a personal health record made up of, application-independent, interoperable clinical documents in patient-controlled, Internet-accessible “bank accounts”.

New technology

We contend that the technology market has been waiting for such a move. A stream of innovative products for document creation, management and security are looking for the kind of demand that will be spawned by this initiative. For example, Sybase systems demonstrated differential access to document contents using client-side encryption based on metadata contained within a CDA document almost three years ago at HIMSS 2002. At least two major dictation/transcription companies are actively developing natural language processing capabilities to enrich tagging of CDA documents. At HIMSS 2004, no less than five distinct types of CDA document creation systems were demonstrated, all shown by vendors volunteering time to show the HIMSS audience the potential for interoperability. These sources of CDA documents included:

- ◆ dictation/transcription with NLP
- ◆ dynamic creation from multiple sources including lab and orders
- ◆ EHR
- ◆ eForms
- ◆ transformation from RIS workstation DICOM Structured Reporting

The demand for vocabulary services and applications will also emerge, once there is a critical mass of electronic documentation and a set of premiums established for higher quality coded data.

Market services

There are a variety of services that personal health record banks can provide their customers (i.e. patients). Some patients will be interested in monitoring or alerting services that could be based on the contents of their account. Some patients will be interested in searches of medical literature filter by an awareness of their health history and status gleaned from the contents of their personal health record bank account.

Patients can choose to place their records with service providers who then make their de-identified information available to pharmaceutical companies or health research organizations for financial compensation or other consideration. Patients who allow their personal health record bank to make their de-identified data available for some explicitly approved purposes are unlikely to have to pay any fees to maintain their personal health record bank accounts. In fact, some patients may find that their de-identified data is so valuable to researchers doing longitudinal studies that they can receive net positive payments for keeping their personal health record data on deposit and allowing such access.

11. How could a NHIN be established so that it will be utilized in the delivery of care by healthcare providers, regardless of their size and location, and also achieve enough national coverage to ensure that lower income rural and urban areas could be sufficiently served?

The answer to this question is similar to the response to question #8 on encouraging broad participation.

12. How could community and regional health information exchange projects be affected by the development and implementation of a NHIN? What issues might arise and how could they be addressed?

Local and Regional information exchange projects are one of the many types of information exchange architectures that we expect will emerge once a critical mass of electronic document is created through the purchasing power of CMS. This proposal would allow them to become self-funding by accelerating the development of a critical mass of documents. With such de-identified repositories, they can create and sell valued healthcare information.

13. What effect could the implementation and broad adoption of a NHIN have on the health information technology market at large? Could the ensuing market opportunities be significant enough to merit the investment in a NHIN by the industry? To what entities could the benefits of these market opportunities accrue, and what implication (if any) does that have for the level of investment and/or role required from those beneficiaries in the establishment and perpetuation of a NHIN?

Document exchange plays into a market waiting to happen. Unlike the uphill battle for EMR acceptance, there is significant non-healthcare-specific expertise and tooling in document creation, management, security, digital rights management and display that can be immediately leveraged were a critical mass of standard, interoperable documents to begin to prime the marketplace.

Existing vendors and service providers will need to change their systems to produce the standard CDA documents. New market opportunities will be created for both existing and new vendors; huge value will be created from aggregating de-identified data. Incentives will be passed through to vendors via the providers' interest in upgrading their systems to be eligible for differential reimbursement for producing standardized electronic documents that summarize the care or services rendered for which reimbursement is sought.

RFI Concerning Standards and Policies to Achieve Interoperability

(Question 4b above asks how standards and policy setting for a NHIN could be considered and achieved. The questions below focus more specifically on standards and policy requirements.)

14. What kinds of entity or entities could be needed to develop and diffuse interoperability standards and policies? What could be the characteristics of these entities? Do they exist today?

HL7, NCPDP, X12, DICOM and other ANSI-accredited, consensus-based standards development organizations (SDOs) will be used to develop the standards that will be adopted by CMS. The market master, CMS will give select standards their endorsement and tie differential reimbursement to their support by Medicare and Medicaid providers. We believe that no new entities need be created. CMS may choose to be guided in this matter by existing advisory bodies such as NCVHS, CHI and others.

15. How should the development and diffusion of technically sound, fully informed interoperability standards and policies be established and managed for a NHIN, initially and on an ongoing basis, that effectively address privacy and security issues and fully comply with HIPAA? How can these standards be protected from proprietary bias so that no vendors or organizations have undue influence or advantage? Examples of such standards and policies include: secure connectivity, mobile authentication, patient identification management and information exchange.

Specified standards should be ANSI-certified, based on a broad consensus, non-proprietary and developed through an open and accessible process. The evidence of such a process within an organization are low financial barriers to participation and facilitation of remote participation so that travel costs and time away from work do not inhibit participation. For example, when addressing negative ballot comments, entities should provide meeting time with adequate notice to balloters and should respond to requests for teleconference participation.

The requirement for a broad consensus is hard to quantify, but should be considered nevertheless. While no absolute criteria exist for “broadness” and it would differ for different specifications, participation in standards development should include a spectrum of providers (large, small, geographically diverse, different business models and specialties); vendors (size, product line, healthcare-specific and general technology vendors working in healthcare); government representing local, regional and federal agencies; payers, consultants and integrators.

A transparent and open process is the best guarantee against undue influence and bias, but funding can also have an impact on the direction of an organization. Some baseline operational funding for SDOs whose output is crucial for this enterprise should be considered. While setting certain priority projects, ideally, this funding should not be tied to tightly-defined timetables and deliverables because this is antithetical to the broad-based democracy of a consensus organization. See also question 18, below.

16. How could the efforts to develop and diffuse interoperability standards and policy relate to existing Standards Development Organizations (SDOs) to ensure maximum coordination and participation?

To some extent, the HIPAA Designated Standards Maintenance Organization (DSMO) framework might provide a model here, but the key SDOs that we are aware of – HL7, NCPDP, X12, DICOM, CDISC, ASTM – already have memorandums of understanding (MOUs) in place and work together on a regular basis.

A more interesting and, at this stage, less well developed relationship is between the SDOs and domain experts. Some experts in clinical information participate directly in the SDOs, and this is vital. The large majority, however, may participate in their own professional societies, for example, the Informatics Committee of the College of American Pathologists, but do not work directly with an SDO.

As the technical framework for expressing, encoding and sharing electronic, computer-processible clinical data matures, the interface with the content experts becomes increasingly vital. Since, in this industry, the time of domain experts is at a premium, ways to involve them in information design that do not require a complete re-education in some kind of techno-speak is essential.

We should foster an environment and supporting technology so that standards experts create the technical framework (i.e. HL7 CDA) that recedes in the background, and allows the content experts to drive content standards.

17. What type of management and business rules could be required to promote and produce widespread adoption of interoperability standards and the diffusion of such standards into practice?

The answer to this question lies at the heart of this proposal, namely, that CMS, acting as market master, provide graduated incentives, possibly becoming mandates, placing provision of standard documentation as a condition for reimbursement. At some future point, CMS may choose to create a level of consumer protection through regulation of certain types of personal health information repositories in much the same way that the federal government today regulates the banking industry. While assumption of a new regulatory sphere is not in and of itself desirable, it is a more comfortable role for government than direct regulation or certification or standardization of computer system functionality.

18. What roles and relationships should the federal government take in relation to how interoperability standards and policies are developed, and what roles and relationships should it refrain from taking?

The federal government should:

- ◆ Precipitate the growth of the network through availability of simple, standardized clinical documents using the power of CMS as a payer to provide incentives and, at some point, a mandate for their creation.
- ◆ Designate a standard for these documents. HL7’s CDA meets the basic requirements and we advocate that it be designated the national standard for clinical documents.
- ◆ Encourage HL7 and other SDOs to work with domain experts to build increasingly broad consensus on content requirements.
- ◆ As the informal exchange network for clinical documents grows, consider designation of minimal criteria for a document registry and repository including possible certification of the entities, similar to FDIC certification.
- ◆ Develop a hierarchical network for trusted identity as outlined in the response to question 7.

At the same time, we do not believe that the federal government should standardize application functionality, certainly not as a precondition for network growth. As the network expands, some additional standards could be chosen, for example, the Web Access to DICOM Objects (WADO) for access to images and IHE's Cross Enterprise Document Exchange (XDS). In all cases, we believe such designations should follow, not precede, market acceptance. (CDA has passed this test by multiple vendor adoption and by four years of implementation both in and outside the US.)

RFI Concerning Financial and/or Regulatory Incentives and Legal Considerations

19. Are financial incentives required to drive the development of a marketplace for interoperable health information, so that relevant private industry companies will participate in the development of a broadly available, open and interoperable NHIN? If so, what types of incentives could gain the maximum benefit for the least investment? What restrictions or limitation should these incentives carry to ensure that the public interest is advanced?

We believe that financial incentives are necessary and in fact sufficient to drive the development of a marketplace for interoperable health information.

Specifically, we propose a graduated system of incentives with the following characteristics:

- ◆ tied to provision of standards-based, interoperable documentation
- ◆ graduated according to the level of coding sophistication of the electronic document where documents that are easier to produce, but have less potential for re-use are rewarded at a lower level than documents that are more difficult to produce and carry a higher potential for re-use. (See the response to question 1, the section "How Does a CDA-based Network Achieve Incremental Development?")
- ◆ rewarding early adopters

Finally, we suggest that a marketplace in persistent, interoperable, electronic medical records documents complying with HL7's CDA Release 2, makes a centrally architected and actively operated and supported NHIN unnecessary. This proposal recommends against providing incentives for hardware/software/system purchase because this would involve a difficult, lengthy and contentious application certification process. The only certification required is that currently practiced under HIPAA – recognition of a defined set of existing ANSI-certified standards.

20. What kind of incentives should be available to regional stakeholders (e.g., health care providers, physicians, employers that purchase health insurance, payers) to use a health information exchange architecture based on a NHIN?

No government-provided financial incentives will be required to induce providers to take advantage of the interoperable content produced in response to CMS incentives. In fact, we believe that the existence of a critical mass of such content will make the value of healthcare electronic connectivity and EMR systems will produce its own set of market incentives for participation, especially for providers in individual and small practices who have been reluctant to invest in such systems. The CMS incentives we have recommended in lieu of a NHIN apply only to the production of CDA documents for some initial catalytic period of time, after which the creation of these documents will become a mandatory part of delivering the service for which reimbursement is sought.

The interoperable content produced by Medicare and Medicaid participating providers will deliver excellent value to those who use it. It will provide significantly more value to users with EMR systems than those without them.

Health plans presently expend considerable resources to identify beneficiaries who are likely to be future high utilizers of health services, e.g. a person with recently diagnosed diabetes or other chronic illness. Typical current methodologies depend on analysis of medical claims data, the results of which are often misleading because of inaccuracies in the clinical fields of the insurance claims. Automating access to accurate clinical information would require a low-level CDA document with a clinician-entered diagnosis and would be far more efficient, timely, cost-effective and accurate than assessments based on claims-oriented coding.

21. Are there statutory or regulatory requirements or prohibitions that might be perceived as barriers to the formation and operation of a NHIN, or to support it with critical functions?

We believe that the special status of personal health records banks will require legal protection to insure that their contents are offered the same extremely high level of privacy protection as is currently afforded personal records stored in a safe in one's home. In addition it seems reasonable to subject personal health information banks to the usual and customary regulatory oversight for consumer-facing organizations that require the public's trust to operate effectively. The relevant model here is the relationship of the Federal Deposit Insurance Corporation to financial institutions.

Special consideration will also need to be given to the implications of Stark. A document exchange network, as described in this proposal, will engender benefits to providers who must be protected from regulations that would discourage their participation.

22. How could proposed organizational mechanisms or approaches address statutory and regulatory requirements (e.g., data privacy and security, antitrust constraints and tax issues)?

We believe that the HIPAA Privacy and Security regulations provide the necessary framework for use and disclosure by the providers who are the authors of the documents. An amendment to the HIPAA privacy regulation is suggested to cover responsibility of a personal health record bank to prevent disclosure of any patient information except at the explicit, specific, revocable direction of the patient, a much more stringent restriction than exists under HIPAA today.

All the data in a personal health record bank account either originates with the patient or as a copy of an electronic document generated and retained by a provider. The originals will continue to be usable and disclosable by their source in accordance with the provision of the HIPAA privacy regulation which provides for disclosure without patient consent in cases of public health, national defense, judicial process and other exceptions explicitly listed. Therefore we recommend that the HIPAA privacy regulation be amended to recognize the special status of a personal health record bank account as a kind of "Swiss Bank Account", and afforded the highest level of confidentiality equivalent to the contents of personal records stored in one's home.

We do not anticipate that any of the market-driven, healthcare interoperability mechanisms that will be developed as a result of CMS catalytic actions will raise any new antitrust or tax issues.

RFI Concerning Other Topics

23. Describe the major design principles/elements of a potential technical architecture for a NHIN. This description should be suitable for public discussion.

As we have stated above, we are not proposing a NHIN, but rather a national agreement on a basic form of clinical information, a CDA document, that will precipitate, through market forces, collections of records under the direct control of the patient. There are several aspects of the design that bear explanation from the perspective of standards-based interoperability.

The first HIMSS demonstration of the draft CDA, in 1999, showed Version 2 lab results and very early Version 3 lab results being incorporated into a CDA document for cross-enterprise distribution. The subsequent five demonstrations showed some version of the same, often more elaborate including dynamic query of remote lab information servers and linking of results to the documents containing the orders. This work was done, of course, in laboratory conditions, but is impressive nevertheless because after the first year, we were no longer soliciting vendors to fill these roles. They not only came to us volunteering to fill the lab/note, CDA/message integration functions we foresaw, but they came to us requesting that we match them with other players so they could demonstrate their vision for an extra-enterprise exchange network built on interoperable data standards.

Thus, CDA has a strong and well-defined relationship to clinical and administrative messaging and can act as a universally-readable document for lab reports and pharmacy orders with variable levels of semantic encoding. In a perfect world, the original format of the messages would suffice, but in the world that we inherit, the flexibility of CDA will solve many orders of complexity in integration while delivering the benefit that can be reliably shared between providers.

In terms of EMR integration, several types are possible and have been demonstrated with a variety of commercial systems. In brief, any EMR should import, store and produce as a report a standard CDA document of some pre-defined level of granularity.

Where is more work needed?

The existing document specification from HL7, the Clinical Document Architecture (CDA) provides the baseline specification for a document-based exchange economy. As such, it is at the core of the most successful national exchange programs to-date (see “ref IA/CDA conf) That said, much remains to be done.

First, we will need to broaden the consensus on what information needs to be captured and what needs to be exchanged in what context. Defining perfectly encoded information with complete semantic interoperability meeting the exact requirements for each recipient is a long process, however you attack it. There is much benefit to be derived, however, before we reach complete semantic interoperability and we can do so in a way that does not inhibit the growth of sophisticated applications. There are three areas where incremental development can be achieved.

Clinical content: it is a well-known phenomena in healthcare that clinicians, even within the same business unit and type of practice, differ on the type and extent of information required for a patient record. While much, if not all, content requirements may be standardized in an ideal world, it will take some time before we realize the optimum, maximal degree of conformity that can be achieved without inhibiting the recording of valuable information. Certainly, a greater degree of uniformity should be achieved, and would enhance patient care through adherence to reporting guidelines, but at the same time, legitimate reasons remain to allow a physician to record what they observe in their own words. Each specialty and discipline and professional group and public health and quality monitoring entity should work to achieve consensus on reporting requirements. Sorting this out – the relationship between overlapping sets of requirements and balancing competing time pressures will take some time.

Content encoding: Whether there is or is not consensus on the content of a record, there remains a range of options in the sophistication of the electronic format or encoding of that information. To get some initial benefit, before we reach perfect semantic interoperability, there are non-uniform requirements, differing levels of difficulty, in coding requirements for referrals vs. case review vs. decision support vs. claims attachment processing. We can take the paper-based delays out of claims attachment processing with a human-readable electronic document that is simple to produce. We can check for drug-drug interactions using a document with coded current medications even if the balance of the data is not as highly structured. For some types of public health monitoring, incremental enhancements in structure and coding would vastly improve automation, even if the documents fell short of full semantic interoperability.

Encoding method: Given consensus on the clinical content of a document and which portions are worth the effort to encode, there remains more than one option on how to encode that information, even within the constraints of the HL7 Version 3 framework. (See www.termInfo.org.) From the website:

TermINFO was formed July 2004 with the goal of bringing together terminologists, ontologists, logicians, and clinical application developers together to solve several challenges related to the use of terminological systems in clinical informatics.

TermINFO is currently focused on the following problems:

- (1) The appropriate integration of terminological systems (SNOMED CT) into clinical information models such as HL-7v3 RIM, and
- (2) Developing methods to compute semantic comparability of knowledge represented using post-coordinated concepts created using compositional terminologies such as SNOMED CT.

Reaching consensus on what needs to be exchanged, how much of it is worth encoding and how to do that encoding will take time. EHR-driven solutions predicated on this consensus places an unnecessary drag on implementation of solutions that we can begin to roll out today. The immediate, low-activation-energy solution, however, must be scalable to the full, semantically-interoperable systems of tomorrow.

Further evidence that information interchange should not wait on the development of fully-encoded, semantically interoperable EMRs is the slow adoption rate for SNOMED, despite a \$14 million commitment by NLM to make this vocabulary available nation-wide. While we, too, applaud the SNOMED contract and the commitment it shows to interoperability, we would not like to see the terms of the contract expire with no significant increase in information interchange. We believe the way to create demand for controlled vocabulary is to create a critical mass of standardized documents that can take incremental benefit from the SNOMED license.

24. How could success be measured in achieving an interoperable health information infrastructure for the public sector, private sector and health care community or region?

Measures of success in achieving an interoperable health information infrastructure could include:

- The percent of Medicare and Medicaid encounters for which the provider produces a CDA document to qualify for the incentive.
- The extent to which commercial payers institute a similar incentive program to encourage providers to produce CDA documents
- The number and variety of different types of entities competing to provide the personal health records bank function.
- The judgment of advocacy groups representing patients with chronic conditions whether constituents health has improved and/or the efforts of their constituents to manage their health has been significantly enhanced by the availability of CDA documents.
- The judgment of quality monitoring groups and professional organizations (ACP, AAFP) concerning the impact that CDA documents has had on the treatment of senior citizens 18 months after the implementation of incentives

Appendices:

HL7's Clinical Document Architecture

From the specification³:

The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange. A clinical document has the following characteristics:

- ◆ Persistence – A clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements (**NOTE:** There is a distinct scope of persistence for a clinical document, independent of the persistence of any XML-encoded CDA document instance).
- ◆ Stewardship – A clinical document is maintained by an organization entrusted with its care.
- ◆ Potential for authentication - A clinical document is an assemblage of information that is intended to be legally authenticated.
- ◆ Context - A clinical document establishes the default context for its contents.
- ◆ Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- ◆ Human readability – A clinical document is human readable

The characteristics of CDA most relevant to this proposal are that it is defined by signature, addressing legal status and safe context for clinical information. It is defined by solid precedent in a form familiar and acceptable to all practitioners. And, as stated above [ref xxx], it is scalable in terms of implementation complexity, meeting the needs for both low cost, low-tech solutions and for full machine-processible semantic interoperability that can drive decision support, outcomes analysis and feed a host of other applications including clinical trials and public health surveillance.

& templates

CDA has been implemented at the core of the most advanced, widely-implemented and successful national health information networks⁴. Still, a single approach to 1) facilitating the incorporation of domain expertise; 2) automating the validation of domain-specific requirements is not yet available.

At the same time, there are several precedents for integrating domain expertise into specific CDA-based document types. One such example is the prototype for CDA as a tumor report conforming to CAP/ACS guidelines demonstrated at HIMSS 2004 by John Madden, MD, Duke University Medical Center⁵. Another example is the CDISC-sponsored Starbrite project at Duke Clinical Research Institute and Duke Clinic that specialized CDA authoring to conform to the requirements of clinical research. [see CDISC.com, "Single Source Project"].

doc type code

Key References on CDA:

³ CDA Release 2.0, December, 2004. DRAFT membership ballot. As of the date of this RFI, Release 2.0 has passed membership ballot and could be submitted for ANSI certification within the next two months.

⁴ See the presentations from the 2nd International Conference on the Clinical Document Architecture, October 20-22, 2004, Acapulco, Mexico, <http://www.hl7.de/iamcda2004/fprogram.html>.

⁵ In this project, John created a specialized, templeted CDA that was heavily coded reflecting the requirements of several constituencies. From that "single source", several versions of the information were conveyed: a human-readable report to a referring physician; a summary version to a local tumor board, conforming to reporting requirements and a fully-coded archival view to the local clinical document repository. Source documents provided on request.

HL7 Clinical Document Architecture, Release 2.0, December, 2004, DRAFT,
<http://hl7.org/library/Committees/structure/CDA.ReleaseTwo.MembershipBallot01.Jan.2005.zip>
“The HL7 Clinical Document Architecture”, R.H. Dolin, L. Alschuler, and others; JAMIA, 2001;8:552-569.
“[Doing Simple Things Simply and Complex Things Carefully: An Introduction to the CDA Value Proposition](#)”, L. Alschuler, October 22, 2004, Acapulco Conference,
<http://www.hl7.de/iamcda2004/finalmat/day3/Doing%20Simple%20Things%20Simply.pdf>

Continuity of Care through CDA

Proposed recommendation: ONCHIT and related federal agencies/initiatives (CCHIT and others) should recognize implementation of the Continuity of Care Record (CCR) *only* as a template (set of constraints) or family of templates applied to HL7’s Clinical Document Architecture (CDA)

The relationship of the Continuity of Care Record (CCR) developed under the auspices of ASTM with cooperation from several professional societies to HL7’s CDA illustrates the promise and pitfalls of simple, document-based interoperability and the needed interface between the standards-producing entities and domain experts.

CCR as a template or set of constraints applied to CDA represents a mutually beneficial collaboration between standards organizations and between domain experts and standards wonks. CCR without the HL7 CDA framework raises questions about long-term interoperability. CDA without input from domain experts will fall far short of its potential.

CCR’s Strengths

The CCR has advanced the standards and interoperability agenda in these respects: it galvanized support from diverse professional societies and caught the imagination of a wide range of providers, overcoming the inertia left in the wake of the CHIN failures of the 90’s. It seeks to combine a readily available, ubiquitous, open information standard – Extensible Markup Language (XML) – with content specified by domain experts. It has the added advantage of focusing on immediate goals, not waiting on ultimate solutions. At the same time, the basic design of CCR fails to take adequately leverage the experience garnered in two decades of building electronic document exchange specifications.

CCR’s Limitations as a Stand-Alone Solution

CCR relies on XML tag names (e.g., “<encounter>, <provider>”) to convey meaning without providing an underlying data dictionary or reference model. This is problematic because the same string of characters “orderNum”, for example, can be interpreted as the order number associated with an order for services or with the ordinal number of a visit sequence (this is an actual example taken from two XML specifications.)

Next, it attempts to standardize everything in a single, monolithic structure. This leads to a large specification (over 400 tags at last count) built at the level of the lowest common denominator (almost everything is optional). Without clear guidelines for constraints or extensions, it cannot specify or validate any single set of local requirements. At the same time, every time a new construct or term is recognized, the full ballot cycle must be initiated. To illustrate this point, consider the Commonwealth of Massachusetts paper referral form used as the initial design requirement for CCR. The most recent public ASTM draft specification cannot validate the requirements from this form because, while all constructs are reflected in the CCR, all the clinical content is optional and there is no mechanism to further constrain the universal common-denominator schema.

In addition, there is some ambiguity in the legal status of CCRs and the requirements for display – what exactly would a receiving application be required to render and how would it do so? The large number of optional, unique tags makes uniform rendering problematic. Finally, there is zero convergence between CCR and referral or continuity documents implemented outside the US. This may seem of little immediate impact, but the vendor market is international in scope and patients, and their charts, cross national borders. In addition, the growing movement to outsourcing patient care adds pressure for a trans-national approach to standard documents.

CCR’s Strengths as a CDA Template

The best of both efforts – CCR and CDA – can be realized through implementation of the domain content from CCR as a template, or family of templates, layered on CDA. This will provide the following benefits:

- ◆ validation against a minimum-necessary subset of requirements

- ◆ validation against multiple subsets of local or specialty referral/continuity requirements
- ◆ scalability down to the simplest “blob” plus metadata, read-only format where clinical content is present, but not machine readable
- ◆ scalability up, with full semantic interoperability, compatible the latest advances in HL7’s RIM, Version 3 data types and extensible, industry-standard controlled vocabulary
- ◆ clarifies legal status of clinical content according to CDA requirements for signature and rendering
- ◆ long-term validity for archival documents within and EHR repository
- ◆ clarification of receiver responsibilities under the CDA and V3 conformance requirements
- ◆ simplification of receiver implementations through option to use a single style sheet for display of any CDA
- ◆ consistency with international referral implementations throughout Europe, Canada, South America and Asia Pacific

Such an advance would provide a model for domain expert/standards entity collaboration. The CCR/CDA Template proof of concept project, reported on at the Acapulco CDA conference [ref], is a prime example of incorporation of domain expertise into CDA and the support that can be garnered from tooling that helps incorporate the domain requirements and tooling that validates the requirements have been met at the document creation and transmission stages.

What is needed to achieve this?

HL7 is considering a proposal for enhanced tooling support for integration of domain expertise into Version 3 templates. A fast-track modeling effort could bring CCR into conformance with CDA, the RIM and Version 3 within 6 months if adequately funded. The HL7 Board of Directors will be considering options for funding this initiative.

A Memorandum of Understanding between ASTM and HL7 is already in place laying the groundwork for this collaboration.

The Acapulco project presented the first proof of concept of this direction. This will be extended slightly and presented at the HL7 Booth at HIMSS 2005. Completion of the modeling of CCR should be followed by a series of full scale pilot implementations.