Interoperability and Meaningful Use /
Keys to the Future of Health Information Exchange

July 2009

Prepared for:
The Federation of American Hospitals

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The Federation of American Hospitals provided funding for this research. Avalere maintained editorial control and the conclusions expressed here are those of the authors.

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Executive Summary / Summary of Challenges and Pathways to Interoperability

Congress and the Obama Administration see widespread health information technology (HIT) adoption and use as a critical component of efforts to improve the value and efficiency of healthcare delivery in the United States. For these reasons, Congress included provisions in the economic stimulus package – the American Recovery and Reinvestment Act of 2009 (ARRA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) – to jumpstart HIT adoption.

While ARRA and HITECH are certainly catalysts for progress, defining “meaningful use” of electronic health records (EHRs) is only the first step. To truly propel HIT, policymakers and stakeholders must ensure that systems are fully interoperable and that they support seamless data flow among providers and across care settings. The following table is a summary of the goals, objectives, and key issues that HHS and ONC need to address to make interoperable nationwide health information exchange a reality:

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Introduction

Given the potential of health information technology (HIT) to enable seamless exchange of health information among providers, sites of care, and patients, Congress and the Obama Administration see widespread HIT adoption and use as a critical component of efforts to improve the value and efficiency of healthcare delivery in the United States. For these reasons, Congress included provisions in the economic stimulus package—the American Recovery and Reinvestment Act of 2009 (ARRA) and the Health Information Technology for Economic and Clinical Health Act (HITECH)—to jumpstart HIT adoption.

ARRA has fundamentally changed the HIT landscape in the United States. As part of this legislation, Congress directed the Department of Health and Human Services (HHS) and the Office of the National Coordinator for HIT (ONC) to spearhead investment in a nationwide health information exchange infrastructure. Additionally, the legislation allocated unprecedented funding: more than $19 billion to help Medicare and Medicaid providers adopt electronic health records (EHRs) through bonus payment mechanisms. To receive these payments, physicians and hospitals must demonstrate that they are “meaningful users” of EHRs—a requirement that has three components:

1. Using EHRs in a meaningful manner
2. Supporting electronic exchange of health information
3. Reporting quality measures as selected by the HHS Secretary

While ARRA is certainly a catalyst for progress, defining meaningful use of EHRs is only the first step. To truly propel HIT, policymakers and stakeholders must ensure that systems are fully interoperable and that they support seamless data flow among providers and across care settings. As a result, interoperability, as an underpinning of meaningful use, becomes essential to realizing improved healthcare in America.
**Interoperability Defined**

The National Alliance for HIT defines interoperability as “the ability of different HIT systems and software applications to communicate; to exchange data accurately, effectively, and consistently; and to use the information that has been exchanged.”

Interoperability is imperative to achieve meaningful use of EHRs. Without the ability to communicate, exchange, and use health information, providers will not be able to meet the requirements for ARRA’s incentive payments, nor will they be able to provide more efficient, higher-quality care for patients.

**Progress to Date**

The federal government has been at work on interoperability for many years. The advent of ARRA, however, imposes new responsibilities and time frames for achieving success.

In recent years, the American Health Information Community (AHIC), the HIT Standards Panel (HITSP), and the Certification Commission for HIT (CCHIT) identified priority areas for harmonizing technical standards to assure interoperability. These areas – called “use cases” – were employed to incorporate functional standards into certification criteria for EHRs.

ARRA now puts this onus on HHS and ONC, with input from the new HIT Policy and HIT Standards committees. Under ARRA’s directives and funding mechanisms, these committees will oversee the standards and certification activities and coordinate the development of an interoperable HIT infrastructure necessary to promote the electronic exchange of health information.

**Lessons Learned from Existing Initiatives**

As HHS and ONC contemplate the ARRA directives, there is much to learn from existing initiatives, including the Nationwide Health Information Network (NHIN) trial implementations and regional health information organizations (RHIOs). RHIOs are trying to connect providers within their communities, and the NHIN created architecture to link these regional networks to each other. These initiatives can inform understanding of how data exchange works, the small yet measurable successes of these initiatives, and the areas where gaps or challenges exist.

However, despite progress on the NHIN and RHIO fronts, challenges remain. The NHIN participants have not been exchanging real patient information, largely because they are unable to agree on how participants should use the data. RHIOs have also struggled to exchange data within and across different networks. Both the NHIN and RHIOs face challenges in financing, aligning incentives, and fostering trust among exchange participants, and they vary in how they engage patients, employers, and health plans in planning and implementation. Regardless of the vision and expectations for the NHIN and RHIOs, none of the initiatives is currently technically capable of achieving true interoperability.
Strategic Directions for HHS and ONC

HHS and ONC must implement ARRA with an eye toward the future. They must formulate a plan, not only to meet the goals of the legislation, but also to carry the vision for the HIT landscape into the future when the provider incentives expire. There are several overarching strategic questions that should inform HHS and ONC’s actions:

- Should the approach for HIT adoption and implementation be national, regional, or local in scope?
- Will the existing standards-harmonization and certification processes need to be changed to ensure successful implementation of ARRA?
- How will patient preferences and perspectives be reflected in the vision for the future?
- Do stakeholders need to reach agreement on a single model for information exchange, or can the environment accommodate multiple models?

HHS and ONC have a considerable amount of work ahead of them. Because ARRA’s new incentive payments to providers are slated to begin in 2011, ONC and its advisory committees are required to identify initial standards and certification criteria for EHRs by the end of 2009. ARRA’s ambitious timetable will require HHS and ONC to move rapidly and establish milestones for timely completion.

In setting these milestones, ONC and HHS may want to consider the different pathways and approaches, starting with “low hanging fruit” and incrementally adding more complex clinical information. HHS must balance the desire for robust information exchange with the operational realities faced by many providers. Setting the bar too high or too low could be a recipe for failure.

Pathways to Interoperability

As HHS and ONC contemplate the strategic questions, there are several immediate issues that need to be resolved to achieve interoperability and seamless health information exchange:

1. Reaching agreement on the standards and certification processes
2. Enabling communication between EHRs and personal health records (PHRs)
3. Resolving inconsistent use of medical terminology
4. Harmonizing disparate models of health information exchange
5. Creating a master patient index and a national patient identifier system

1. Reaching Agreement on the Standards and Certification Processes

Challenges and Key Considerations

CCHIT launched the EHR certification process in 2005 to set a clear bar for EHR functionalities, thereby reducing the purchasing risk for physicians. Simultaneously,
HITSP began harmonizing the standards for health information exchange across certified EHR systems to promote and ensure interoperability.

To date, CCHIT has certified dozens of inpatient and ambulatory systems; however, lack of consensus on the information exchange standards across different certified EHR functions has created real roadblocks to interoperability. For example, there are overlapping and incompatible standards for integrating EHR data across providers, including the ASTM Continuity of Care Record and the HL7 Clinical Document Architecture. ASTM and HL7 collaborated to resolve the conflict, creating the Continuity of Care Document, but several conflicting standards remain (e.g., the scripting standard created by the National Council for Prescription Drug Programs and the medication messaging standards defined by HL7).

Despite the interoperability tests in the certification criteria, most certified systems do not and cannot communicate easily with one another—even within a single provider organization. Anecdotal reports indicate that certified systems are not, in fact, interoperable and that data from one EHR system do not automatically populate the EHR system to which it is sent.

Additionally, it is unclear how well the certification criteria align with clinical needs. CCHIT is taking steps to create specialty-specific EHRs (e.g., cardiovascular, child health); however, smaller providers may not need or want all of the functions that CCHIT requires for certification. For example, a solo obstetrician may not need the functions that support multiple providers (required by CCHIT), but would want the system to be able to manage information from antepartum visits that could be transmitted to the hospital where the patient gives birth (not required by CCHIT). Taken together, these challenges call into question the overall value of certifying systems that may not meet basic interoperability and clinical utility requirements.

To address these shortcomings of the existing certification processes, new approaches are needed. With the advent of HITECH, ONC is now tasked with overseeing the standards and certification processes, which are necessities for interoperability. Initial standards, implementation specifications, and certification criteria must be adopted by December 31, 2009, and the HIT Policy and Standards committees will be continually recommending additional criteria. As ONC considers how best to leverage the standards harmonization and EHR certification processes to overcome these challenges, they should consider:

- How to balance the quantity of certification criteria with the utility of the requirements in supporting patient care;
- How to reconcile the urgency of ARRA’s timelines (which could mean implementing standards that are merely sufficient) with the desire to sophisticate HIT and health information exchange (which could mean developing new standards); and
- How the certification process can foster a robust market with diverse, interoperable EHR offerings.
Next Steps and a Phased Approach
ARRA and HITECH imposed timing, deadlines, and new processes for standards and certification, but the law does not explicitly address the question of whether the existing certification process will, in fact, facilitate reaching the goal of nationwide interoperability. To avoid building on a fragile foundation, ONC should reexamine the sustainability of the current certification framework. Specifically, ONC should pursue three objectives:

Objective 1A: Assess needs and finalize standards
- What are the most important clinical needs and critical data for providers? What is the best strategy to obtain this information (e.g., surveys, focus groups, town hall meetings)?
- Do existing systems and the current certification approach support these data needs?
- Will legacy systems need to be recertified against new standards and criteria? How will this impact both small and large delivery systems?
- Should the new standards process, as mandated by HITECH, establish a minimum standards set for all EHRs that reflects these critical needs?

Objective 1B: Establish a new and/or revised framework for certifying EHRs
- Could different levels of certification (e.g., basic, advanced) better meet the diverse needs of different types of providers?
- Could this tiered approach open the certification process to emerging vendors that offer more scalable and cost-effective solutions?
- Which of the existing certification criteria could be used to design these tiers? There may be no need to start from scratch.

Objective 1C: Create a roadmap for the future of the certification process
- How can the certification process continually evolve to build in innovation and fairness to create opportunities for smaller and emerging players?
- What is the appropriate role of the government in shaping the marketplace (e.g., tax incentives for vendors whose products are certified)?

2. Enabling Communication between EHRs and PHRs
Challenges and Key Considerations
Linking patient and providers is a critical goal of interoperability. As providers migrate to EHRs, patients increasingly want access to their health information in electronic form. The PHR emerged as a consumer-controlled, solution for granting consumers portable access to their own health information. PHR vendors vary in their offerings and some of the larger information service providers, such as Google and Microsoft, have recently entered the market. In the previous work of the AHIC, consumer access to data was identified as a priority, as was developing standards for PHRs to create greater
consistency across products. HL7 has a Personal Health Record Functional Model (approved in 2007), and CCHIT is launching PHR certification this summer.

While PHRs seemed appealing when they first hit the market, consumers have found them challenging to use because of the lack of integration with physicians’ EHRs. Physicians are not required to make EHR data available to patients for their PHRs. By law, the provider owns the record, and consumers merely have the right (under HIPAA) to request that their data be disclosed to the PHR. And until ARRA, providers were not required to make health information available to patients in an electronic format. Additionally, individual health systems may not even integrate their own data: within a single hospital, the emergency, radiology, and surgery departments each may have their own data systems that are not connected to one another. This provider-side fragmentation can make consumer access to comprehensive data even more difficult.

Because of the lack of EHR-PHR integration, consumers typically have to enter data manually, which can be time consuming and prone to errors. Some health plans or employers that offer PHRs may automatically populate them, but it may be with only administrative or claims data, which would not offer the full clinical picture, and, given the lack of standard clinical and coding vocabularies (see #3, below), can often yield inaccurate information. Moreover, if a consumer switches health plans or takes a new job, the PHR may not be transferrable, so the consumer would lose all that data and have to start fresh with a new PHR.

Consumers also have concerns about the privacy and security of their information. Third-party PHR vendors are not typically bound by the same requirements as providers or health plans because the HIPAA rules do not apply to them. Recognizing this dilemma, ARRA’s privacy provisions require the HHS Secretary and the Federal Trade Commission to contemplate how best to extend existing privacy rules to these entities – standalone PHR vendors not tied to providers or health plans – and to foster consumer trust of an electronic health information exchange environment.

As consumer empowerment and transparency continue to be priorities of policymakers and consumers, ONC will need a strategy for ensuring consumer access to data to ensure that consumers can be active and informed decision-makers about their healthcare. ONC should consider:

- How to leverage the meaningful use requirements to build in consumer access to data;
- Whether a new privacy and security framework is needed to boost consumer trust; and
- How the standards and certification processes can promote EHR-PHR integration and PHR innovation.
Next Steps and Phased Approach
ARRA and HITECH offer some guidance to HHS and ONC on how to approach privacy issues, but the consumer was largely left out of the picture. To ensure that the nationwide health information exchange strategy includes consumer perspectives and preferences, ONC should pursue three objectives:

Objective 2A: Assess consumer needs and technology capabilities
- What data is most valuable to consumers that can easily be made available?
- Are there existing standards to enable exchange of this data?
- What are the critical features and functions of consumer-facing technologies?
- Can current EHR certification criteria be leveraged to create a minimum set of PHR certification criteria?

Objective 2B: Formulate a strategy for integrating data sources within discrete healthcare delivery systems and/or facilities
- Should the definition for meaningful use evolve over time to require providers to make health information available to consumers in electronic format?
- How should existing privacy and security laws be modified or supplemented to ensure standalone PHR vendors are required to take the same precautions as providers and health plans?
- What degree of flexibility should be built into the PHR certification process to allow for innovations in consumer health information platforms (e.g., cell phone applications)?

Objective 2C: Launch a consumer-centric technology certification process
- Should EHR certification be conditioned on interoperability with PHRs?
- How can the certification process balance promoting consistent offerings with advancing capabilities of technologies and evolving patient needs/desires?

3. Resolving Inconsistent Use of Medical Terminology
Challenges and Key Considerations
The effective conveyance of healthcare information from one site of care to another requires that the sending and receiving sites understand the information. In human terms, if the message is sent in Russian, and the receiving provider speaks only Cantonese, the information, while transmitted, will not be useful. Interoperability requires that information is understood at the receiving point-of-care. A common vocabulary, then, is essential to interoperability. This feature is sometimes referred to as “semantic interoperability”—that is, the ability of different systems to understand the “meaning” of the data being transmitted or received.

A standard vocabulary can consist of agreed-upon values for certain measures. The measure “Medicare eligibility,” for example, would have three values: yes, no, and unknown. If each were coded as 1, 2, and 3, respectively, all health providers could understand the meaning of “Terry Smith, 2” as indicating that Terry Smith is Medicare-
eligible. In more complex cases, a standard vocabulary might require widespread agreement on how comorbidities are coded, or how a patient’s qualitative description of symptoms (e.g., “my left knee hurts when I run on sand”) is reduced to standardized language that can be coded into an EHR.

In response to the need for standardization of medical vocabularies, numerous models have emerged, usually focused on one or several areas of clinical interest. For example, in classifying diseases, nearly all U.S. healthcare providers and payers rely on the International Classification of Diseases (ICD) vocabulary. In the laboratory space, the emergent Logical Observation Name Identifiers and Codes (LOINC) is becoming a common vocabulary. Development of a single all-encompassing vocabulary may be unreasonable, so effective interoperability will likely require widespread agreement on application-specific sets of standard vocabularies, coupled with a “translation” mechanism for complementary or overlapping sets. More progress is needed on both fronts.

One of the major challenges in the rapidly evolving field of medicine is that new conditions and treatments arise daily, and old treatments and codes effectively disappear daily. Creating interoperable health information requires mechanisms to keep the codes and vocabularies up-to-date with current practice, and mechanisms to make sense of data definitions that, over time, may become obsolete. To continue the above example, if Medicare eligibility is expanded, “old” data for Terry Smith would need to be re-interpreted against the new definitions for eligibility, but not for “old” claims.

Each clinical application of patient-specific information tends to create its own vocabulary. The technical and clinical complexity of the different settings can derail efforts to create a single set of definitions across ambulatory, institutional, and home settings for the wide array of clinical conditions and providers. Structural resistance to embrace a single model within and across specific settings and provider types also may play a role in this inertia.

Importantly, if the vocabulary that enables interoperability is not adopted by clinicians and patients, adoption rates will suffer. In recent testimony, the American Clinical Laboratory Association (ACLA) identified the urgent need to move incrementally in deciding on new or replacement vocabularies to permit clinicians and their offices and systems to accommodate the change.

To address the challenges of creating consistent vocabularies, with appropriate “translation” capabilities, policymakers should resolve several core issues:

- What is the best balance between relying on existing “silicod” vocabularies (which tend to enjoy high acceptance within the specific silo of settings and/or providers and/or conditions) and deploying more encompassing vocabularies (which require less translation across settings, providers, and/or conditions)?
• What is the best balance between encouraging or permitting the development of “bottom-up,” perhaps competing, “dictionaries” of relevant clinical information, to assure innovation and market receptivity, and a more “top-down” approach that might reduce the complexity of translation?

• How much flexibility should EHRs have in capturing clinicians’ notes? For example, should systems force a clinician to describe all asthmatics using the same standard typology, or can expert systems equate “asthma” with “asthema?” (sic). Controlled vocabularies are easier to make interoperable; uncontrolled vocabularies are easier for physicians to adopt.

• Should proprietary vocabularies be encouraged, tolerated, or discouraged? Should “open” vocabularies be encouraged, tolerated, or discouraged?

**Next Steps and a Phased Approach**

While the stimulus package imposes requirements for standards and certification, the law does not address the means by which new standards enable “semantic interoperability.” ONC should consider pursuing the following objectives as it defines the level of specificity in the emerging certification processes:

**Objective 3A:** Engage stakeholders to define the true scope of the challenge

• What are appropriate and effective ways to engage diverse and disparate clinicians and healthcare institutions?

• How can HHS and ONC ensure transparent engagement with patients and their advocates, as well as purchasers of healthcare services?

• Should these efforts coordinate federal and state entities likely to produce and/or access health information (e.g., state boards of health, CMS, FDA)?

**Objective 3B:** Formulate a strategy for harmonizing medical vocabularies across specialties and care settings

• Can existing vocabularies be leveraged to limit the time and effort required for creating new standards?

• How can adoption of harmonized vocabularies be staged across behavioral, clinical, technological, and organizational constraints?

**Objective 3C:** Incorporate semantic interoperability into the standards harmonization and certification processes

• How can the meaningful use requirements promote rapid adoption of semantic interoperability?

• Should non-proprietary terminologies be preferred to reduce or eliminate the costs of acquisition by small providers?

**4. Harmonizing Disparate Models of Health Information Exchange**

Challenges and Key Considerations

Regional health information organizations (RHIOs) and health information exchange initiatives (HIEs) are multi-stakeholder initiatives typically including physicians,
hospitals, health plans, laboratories, consumers, and others who seek to share electronic health information about patients in a community, state, or region. These initiatives seek to facilitate access to and retrieval of clinical data to provide safer, timelier, and effective patient-centered care. HIEs also can provide the infrastructure for secondary use of clinical data for purposes such as public health, clinical, biomedical, and consumer health informatics research, as well as institution and provider quality assessment and improvement.

One of first organizational decisions HIE stakeholders make is defining a strategy for data storage. Generally, there are two current models in use: (1) a centralized architecture where all patient data are stored in a single location and accessed from that location, generally a central server that houses data and the applications; or, (2) a federated or decentralized architecture which is a network of individual data storage entities that are connected and share data. In this second case, data resides and are maintained locally within individual organizations but are accessible via the network. Either architecture requires a master patient index to identify and match patients (e.g., ensures John Smith is correctly matched to his data, not to the data of a different John Smith) and a record locator service, which provides information about where patient health information is located and where a patient has received care.

Each model offers pros and cons. For example, the centralized model is simpler from a systems management perspective with a single entity managing the process and offers the potential for greater security, yet it raises real concerns about who can access the data and who owns the data. The federated model offers greater privacy assurances because the data reside where originated and, therefore, present potentially fewer political concerns around data access. However, this model may require greater technical sophistication in matching patients’ data.

Taking these issues into consideration, HIEs typically select a model that best meets the needs and priorities of the individual community and stakeholders involved. The decisions are driven by the community’s desired goals and outcomes (e.g., data exchange across hospital systems, emergency departments, and labs; provider performance measurement), as well as sensitivity around privacy and security. Provider and community stakeholder buy-in is usually a critical driver in the model selection and a factor in the success of the HIE itself.

In the current landscape, both models are widely in use. For example, HealthBridge in Ohio, the Indiana Health Information Exchange, Northwest Inland RHIO, and the Bronx RHIO successfully use a federated approach, while Michiana Health Information Network and Taconic Health Information Network and Community use a centralized approach. There is no real agreement or consensus on the “right” or “best” model, and different stakeholders continue to advocate for one model or the other.
Despite great effort and investment from public and private stakeholders to advance health information exchange, these initiatives continue to struggle to connect to one another, hindering progress toward interoperability and true nationwide exchange.

As HHS and ONC move to embrace the goals of ARRA, they should look to both the RHIO and NHIN experiences as potential guideposts. Policymakers will need to assess which architectural models will be required and/or sufficient to exchange patient data nationwide while still addressing the needs of healthcare stakeholders locally and regionally:

- Can successful nationwide information exchange occur across HIE initiatives with both centralized and federated models? If so, how can we begin to connect these disparate architectures?
- How can we balance local values and priorities with the architectural and technical needs to support nationwide information exchange?
- If information exchange takes place “on the backs” of a single architectural model, which one should dominate? Does this become a federal mandate or utilize incentives under ARRA or other regulation? How does a transition or migration like this take place given the privacy and security concerns, the infrastructure needs, and the associated costs and implementation requirements?

**Next Steps and Phased Approach**

ARRA and HITECH articulate the goal of nationwide health information exchange to improve quality care and manage cost. However, the lack of interoperable systems or agreed upon technical and architectural models to get us there represent legitimate issues to overcome. At the same time, one of the greatest challenges facing RHIOs today is accurately linking electronic records across the disparate health information systems of participating members—the premise of a decentralized model. Healthcare stakeholders, policymakers, and technicians must all understand how to manage these issues on small and large scales. They must also assess whether the multiple architectural models in use today will suffice or if they must migrate to a single model. ONC should pursue three objectives:

**Objective 4A**: Inventory and assess existing architectural models in fully operational HIEs/RHIOs
- What is the success rate of HIEs using centralized versus federated models? What data are currently being exchanged across what borders (e.g., intra-system, inter-system, intrastate with these distinct models)?
- Are there models or examples where RHIOs with these varying architectures successfully access and retrieve data from one another seamlessly? If so, what are the key success factors (e.g., specific technology, policy/procedure, other)?

**Objective 4B**: Understand requirements for a standard architectural model or models to support nationwide health information exchange under ARRA
Against requirements for meaningful use, what gaps must be addressed, regardless of the architectural model? What is required to address these issues (e.g., technology development, policy development)?

Who will lead/oversee this and ensure there is sufficient and appropriate HIT infrastructure to support the goals of ARRA?

Should exchange across these models be piloted on a larger scale to test the ability to use different models for inter-system exchange and interstate exchange?

Objective 4C: Establish criteria for adoption of a discrete model or approach and develop a roadmap for migration toward this approach

Based on the understanding of existing models and ability to exchange information as well as the goals of ARRA, what is the optimal approach to developing a roadmap or plan toward a single model?

What should the certification process for this look like? Is there a need for one? What roles should CCHIT and EHNAC (both of whom certify or plan to certify networks) play?

Does adherence to a model occur through a mandate, incentives, or market forces such as a certification process?

5. Creating a Master Patient Index and a National Patient Identifier System

Challenges and Key Considerations

Interoperability works only if the correct data are stored in the correct patient’s record. Correctly linking patients to their unique health data across multiple settings and providers is critical and remains a significant challenge to true interoperability, even within a single hospital. For example, the emergency department may record a patient’s first initial and last name, while the radiology system requires a full first name. There are two primary mechanisms to link, file, and retrieve electronic records across disparate health information systems: a unique patient identifier (UPI) and statistical matching based on multiple personal attributes, such as name, address, birth date, and part of a Social Security Number (SSN). There is not yet agreement on which of these two approaches will be used to assure accurate and timely storage and retrieval of information.

HIPAA outlined a process to achieve uniform national data standards and information privacy for healthcare in the United States. HIPAA required the Secretary of HHS to adopt standards that provide for a “unique health identifier for each individual.” A number of standards development organizations and industry associations supported creation of a UPI, citing that it would reduce administrative costs and expedite efficient, electronic access to health information when and where it is needed.

Despite this support, a 1997 analysis completed for HHS flagged some practical challenges with instituting a UPI. In addition, comments at a 1998 National Committee on Vital and Health Statistics raised significant concerns that a national health identifier would enable medical theft and privacy and security breaches. In 1999, Congress delayed
implementation of the UPI section of HIPAA, effectively prohibiting HHS from funding further study of a UPI. HHS has since released its privacy rule, which did not address this issue, and has funded efforts to develop prototypes for the NHIN. Numerous local, regional, and state information exchange initiatives have flourished with the goal of facilitating electronic health information exchange.

Proponents of a UPI argue that it could reduce medical errors and increase efficiencies in healthcare delivery and administration, but controversy over the adoption of a national UPI has focused largely on privacy concerns. Some believe that any unique identifier for individuals poses inherent threats to privacy and that different identification schemes across disparate organizations create information silos that protect the individual. Patient advocates, arguing that overuse of the SSN for purposes other than its original intent has created opportunities for identity theft and privacy breaches, say unique identifiers in healthcare would have similar risks.

Statistical methods require multiple patient data elements, which change over time and are frequently missing or entered inaccurately into electronic records. The need for regular collection, updating, and storage of this data can heighten the risk of identity theft. And, while the complexity of the matching algorithms can vary, two types of errors can occur: false positives (i.e., when two different individuals’ records are erroneously declared a match) can result in the use of the wrong health data, and false-negatives (i.e., when two records for the same individual are thought to relate to separate individuals) can result in omission of part of an individual’s health data. Some believe the only way to eliminate these errors is to require the use of a UPI. In acknowledgement of the associated privacy and security concerns, other organizations are allowing individuals to opt-out of a common patient identifier.

Today, healthcare delivery organizations and payers commonly assign unique identifiers to individuals for use within their systems, and as a result patient identifiers typically differ across organizations. Multiple identifiers for the same individual can prevent or inhibit timely access to critical health information, which can negatively affect efforts to coordinate care. Some integrated health systems and regional health information organizations employ a local master patient index in addition to statistical matching to improve accuracy and reduce the chance of medical errors resulting from incorrect record linking. Nevertheless, statistical matching continues to be the only viable option for nationwide information exchange, absent a change in law.

Next Steps and a Phased Approach
Achieving nationwide interoperability and secure exchange of electronic health information is a priority for the federal government. HHS continues to develop the NHIN, but it arguably has not sufficiently addressed the underlying privacy concerns that caused Congress to halt efforts to develop the UPI. To avoid building a system that could unduly put patients at risk for medical errors, HHS and ONC, under guidance from Congress, should reexamine the feasibility of a national UPI and establish a common
solution for electronically identifying patients. Specifically, HHS should consider pursuing three objectives:

Objective 5A: Reassess needs and public concerns around use of patient identifiers
- What are the major privacy and security concerns associated with a UPI and how should they be resolved?
- What uses should be approved for the authorized and appropriate use of a UPI?
- How do healthcare organizations currently use UPIs to securely exchange health information?
- Should new standards and certification processes establish a minimum set of standards and security protocols for all EHRs to address these privacy and security concerns?

Objective 5B: Establish a new patient identity solution
- What are the critical implementation issues for a unique patient identity solution?
- Who will operate the system and what are the underlying infrastructure and technology certification requirements?
- What will the transition process entail?

Objective 5C: Phase in implementation of the patient identity solution as a requirement for meaningful use
- What level of enforcement is required to protect against privacy and security breaches, medical identity theft, and misuse of the health identifier for individuals?
- How can the meaningful use process validate that a provider is using the patient identity solution?

Conclusion

ARRA and HITECH shifted the HIT landscape significantly; however, significant challenges around interoperability must still be resolved in order for HIT to have the desired effect. The considerations and questions raised in this memo should be top of mind for the HIT Policy and Standards committees as they define policy priorities and identify standards and certification criteria.

HHS and ONC need to tackle these issues now, not only to ensure that providers are able to meet the initial requirements for meaningful use, but also to guarantee long-term success of the vision for a fully transformed healthcare system supported by nationwide health information exchange.
Endnotes


3 Statement of the American Clinical Laboratory Association before the National Committee on Vital and Health Statistics, Standards Subcommittee, February 24, 2009: “Enhancing Standards Adoption by Users.”

4 Drawn from Taylor.