MARKLE FOUNDATION
CONNECTING FOR HEALTH

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# Achieving the Health IT Objectives of the American Recovery and Reinvestment Act

## A Framework for 'Meaningful Use' and 'Certified or Qualified' EHR

April 2009

# Health IT Provisions Under ARRA: Overview Consensus Statement

With the American Recovery and Reinvestment Act (ARRA), Congress established new Medicare and Medicaid incentives to stimulate critically needed investments in health information technology (health IT).

The law creates two key concepts to determine whether providers qualify for the health IT incentives: they must make "meaningful use" of IT and use a "qualified or certified EHR" (electronic health record). Besides incentives to providers and hospitals, the law also creates $2 billion in health IT funding administered by the Office of the National Coordinator for Health Information Technology (ONC). A significant amount of this $2 billion should lay important groundwork to help providers use health IT meaningfully toward the goals of improving the nation's health.

Under the auspices of Markle Connecting for Health, the signatories below have agreed on the following Seven Principles for Meaningful Use and Qualification or Certification of EHRs:

1. **The overarching nationwide goals of health IT investments are to improve health care quality, reduce growth in costs, stimulate innovation, and protect privacy**. The investments should be directed toward achieving clear, specific metrics toward these goals. If the goals and metrics are not clear before technology is commissioned and the incentives are offered, the government will risk wasting valuable resources and losing support from both health care providers and the public for further health IT investments.

2. **These goals can be achieved only through the <u>effective use of information</u> to support better decision-making and more effective care processes that improve health outcomes and reduce cost growth.** The goals cannot be achieved through the installation of software or hardware alone. Effective **<u>use</u>** of information is what enables a consumer to play an active role in maintaining health and getting the best care, prevents a patient from suffering a medical error, helps a clinician prescribe the right treatment at the right time, allows a care team to coordinate care in the most effective and affordable way, and benefits efforts to improve quality, accelerate research, and advance public health. The definition of "meaningful use" should hinge on whether information is being <u>used</u> to deliver care and support processes that improve patient health status and outcomes. The definition should focus on the needs of patients and consumers, not on the mere presence or functions of technology.

3. **Meaningful use should be demonstrable in the first years of implementation (2011-12) without creating undue burden on clinicians and practices.** The meaningful use definition must optimize <u>achievability</u> for providers and <u>benefits</u> to patients and consumers. Improving <u>medication management</u> and <u>coordination of care</u> provides early opportunities for such an optimization. Meaningful use should initially rely on standard information types (such as recent medications and laboratory results) that are electronic and already widely adopted — and that can support metrics to improve medication management and coordination of care.

4. **The definition of meaningful use should gradually expand to encompass more ambitious health improvement aims over time.** To support meaningful use goals that improve health and reduce the growth of costs, additional data types (e.g., problem lists, allergies, vitals, images, findings, procedures, care plans, hospital discharge summaries, patient registration forms) can become increasingly standardized over time to facilitate a set of defined measurements. The phasing-in of expanded requirements should be well-defined early in the process, so that those building or purchasing systems have a clear and realistic path to achieve meaningful use at each stage.

5. **The definition of "qualified or certified EHR technology" should support the goals of meaningful use, security, and privacy.** Processes for certification or qualification will be important to prevent fraud or faulty products (e.g., products that do not sufficiently protect sensitive health information), as well as prevent rewards for superficial or trivial uses of technology. For a technology to be "qualified or certified," it should embed the capability for clinical practices and hospitals to attain meaningful use, and demonstrate their levels of attainment of such use, without undue additional reporting burdens. It should also comply with the technical requirements for privacy and security under the Health Insurance Portability and Accountability Act (HIPAA) and ARRA. Processes for certification or qualification should allow for product and service innovation toward meeting the goals of meaningful use.

6. **Metrics for achieving meaningful use should account for the heterogeneity of the U.S. health sector and allow for a broad range of providers to participate.** Medical practices that are capable of installing and supporting a comprehensive EHR should be incentivized under ARRA to do so. However, assuming that only comprehensive EHR systems can achieve the goals of meaningful use might delay progress or lock out other lightweight, network-enabled solutions that may achieve the same goals in the near-term and can provide greater functionality over time. Small practices with less technical support should be able to qualify for incentives by using internet-enabled technologies that can help them to access and use information to help their patients. By emphasizing rewards for actual use of information, and not the mere purchase of specific hardware or software products, public policy can expand the potential of existing information networks and spur innovation to reach health goals and administrative efficiencies.

7. **Consumers, patients, and their families should benefit from health IT through improved access to personal health information without sacrificing their privacy.**[1] ARRA clarifies the individual's right to request electronic copies of personal health information from EHRs for storage by information services of the individual's choosing. This should be considered a form of meaningful use toward helping people prevent illness, manage their health-related information and transactions, coordinate care and communicate with clinicians, understand health care costs, and take better care of loved ones.

[1] Markle Connecting for Health has published a broadly endorsed, comprehensive framework for enhancing consumer access to electronic personal health information and protecting privacy. Available online at: http://www.connectingforhealth.org/phti/index.html.

# Health IT Provisions Under ARRA:
# Four Critical Strategic Areas

The U.S. Department of Health and Human Services (HHS), working with other areas of government, must set a strategic course for the health IT provisions of ARRA. In doing so, it must set its sights on overarching health improvement objectives and then coordinate and sequence the necessary activities to achieve them, including:

1. Issuing regulatory and technical guidance on the new privacy and security provisions of ARRA. *(See **Section 1**)*
2. Establishing a definition of meaningful use that achieves the strategic objectives set forth by ARRA. *(See **Section 2**)*
3. Establishing clear metrics for demonstrating meaningful use to achieve health improvement goals set forth by ARRA, and fostering broad participation and adoption by a diverse range of clinicians and practices. *(See **Section 3**)*
4. Interpreting "certified or qualified EHR technology" to mean a wide array of health IT tools and communications technologies that fully support the goals of meaningful use, and focusing on those technical standards and certification processes that are necessary to achieve and demonstrate meaningful use. *(See **Section 4**)*

# Health IT Provisions Under ARRA:
# Section 1: Privacy and Security Requirements

Consumers and clinicians must trust that personal data will be protected if they are to support electronic information-sharing in ways that improve the health and care of individuals and populations. Seen this way, policies to protect the privacy and security of an individual's health information are pre-requisites for meaningful use of health IT.

Strong and enforceable policies for the privacy and security of information are the foundational requirements for everything that Markle Connecting for Health has advocated since its inception in 2002. Our collaborative has developed a broadly endorsed and comprehensive Common Framework with detailed policy and technology resources for electronic health information exchanges (HIEs) and electronic personal health records (PHRs).[2] A critical requirement for the successful execution of any IT effort is the co-development of information policies to protect information with the selection of technology standards and infrastructure solutions that enforce and implement those policies.

The ARRA provisions make clear the critical importance of coupling technology and policy requirements. The new law enacts many of the principles and policies specified in the Connecting for Health Common Framework that had been previously unaddressed in regulation or federal law. HHS is charged with developing regulations and/or guidance for ARRA's new health information privacy provisions and enhanced enforcement, including the following:

- HIPAA security and privacy rules extended to business associates of HIPAA-covered entities.
- New provisions for notification to consumers of information breaches.
- Limitations on sales of protected health information.
- New guidance on "minimum necessary" (i.e., the notion that no more than the necessary information should be disclosed).
- Guidance on implementation specification to de-identify protected health information.
- Individual right to access personal information in electronic format.
- Annual guidance on the most effective technical safeguards for carrying out the HIPAA Security Rule.
- Recommendations on technologies that protect the privacy of health information and promote security.
- Restrictions on use of protected health information for marketing.

[2] See Connecting Professionals: Common Framework for Private and Secure Health Information Exchange (http://www.connectingforhealth.org/commonframework/index.html) and Connecting Consumers: Common Framework for Networked Personal Health Information (http://www.connectingforhealth.org/phti/index.html).

- Consumer access required to an accounting of disclosures of information maintained in EHRs.

Clearly, over the course of implementation of ARRA's health IT provisions, the regulations and/or guidance from HHS on these new information policies should drive the functional requirements of technology for compliance. In other words, the requirements of qualified or certified EHR technology should, over time, include capabilities to comply with the law's new privacy and security provisions. These requirements must be sequenced strategically so that they can be implemented in a timely way without creating unrealistic software upgrade and process burdens on clinicians and hospitals.

# Health IT Provisions Under ARRA:
# Section 2: What Is Meaningful Use?

**PROPOSED SIMPLE DEFINITION OF MEANINGFUL USE:**

**Patient-Centered, Meaningful Use of Health IT**:
*Demonstrates that the provider makes use of, and the patient has access to, clinically relevant electronic information about the patient to improve patient outcomes and health status, improve the delivery of care, and control the growth of costs.*

**Initial Meaningful Use Requirements (2011-2012):**
*Demonstrates that the provider makes use of, and the patient has access to, clinically relevant electronic information about the patient to improve medication management and coordination of care.*

## The Path Toward Early Progress Should Begin with Information That Has the Greatest Potential to Achieve the ARRA Goals

Given current economic urgency and ARRA's statutory deadlines, the HHS Secretary should focus initially on encouraging the use of information that:

1. Has the highest potential impact on health improvement and control the growth of costs.
2. Can be achieved with current technologies and made available at the point of care in standardized electronic formats in the near-term.
3. Includes flexible requirements that enable a broad range of providers and patients to benefit.

Based on these criteria, we recommend an initial focus on the use of standard information types or packages for recent medication histories, recent test results (particularly laboratory values, and when available, imaging and pathology text reports), and care summaries. These three classes of information hold significant potential compared with many other types of health information for improvements in coordination of care, medication management, and reduction in duplicative services.[3,4]

In terms of achievability, medication history and laboratory results are among the most electronically available, as well as among the most codified or formatted for readability by both

[3] Leape, L.L., et al. 1995. Systems Analysis of Adverse Druge Events. ADE Prevention Study Group. *JAMA* 274 (1): 35-43. Also: Kripalani, Sunil, et al. 2007. Deficits in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians: Implications for Patient Safety and Continuity of Care. *JAMA* 297 (8): 831-841.
[4] Walker, J., E. Pan, D. Johnston, J. Adler-Milstein, D. Bates, and B. Middleton. 2005. The Value Of Health Care Information Exchange And Interoperability. *Health Affairs Web Exclusive*. 10.1377/hlthaff.w5.10.

humans and machines. Standards exist for sharing this information and are in use in many places. For example, ARRA sets a clear expectation that electronic prescribing will be a form of meaningful use. In order to achieve health improvement goals, electronic prescribing systems can be used to improve medication management (e.g., enable drug-interactions checking, support evidence-based protocols, present therapeutic alternatives/most cost-effective alternatives, reduce errors due to illegible handwriting).[5] There has been significant progress in use of standards for patient information summaries for exchange during transitions in care. (See **Appendix A**.) The ARRA incentives should drive higher demand at the point of care by establishing quality-improvement goals that rely on these already-digital data types.

Similarly, early and widespread availability of these standardized, computable data formats can accelerate use of more robust clinical quality objectives. We envision a phased-in series of improved clinical data capture supporting more rigorous and robust quality measurement and improvement.

Although we have proposed a much-simplified definition of meaningful use, we fully realize the complexities of the U.S. health sector and the Medicare and Medicaid programs. It is likely that HHS will need to create different definitions and metrics to accommodate this complexity, such as different incentive structures for Medicare and Medicaid. Another consideration will be the base of clinicians who have already installed EHRs (even those certified by the Certification Commission for Healthcare Information Technology (CCHIT)) that are not yet capable of the basic information exchanges of these three priority data types.

The HHS Office of the National Coordinator for Health Information Technology (ONC) should direct a significant part of $2 billion in ARRA's non-entitlement health IT funding toward laying the groundwork to help health care practices connect securely and effectively to networks, such as privacy-enhancing identity management protocols and directories that allow an authorized clinician to find the location of the right patient's records on a network. For example, HHS could support the development of interface standards that would facilitate the exchange of information to and from these systems so that the physicians who already have made considerable investments are not unintentionally penalized, and are able to participate in incentives to improve quality and care coordination.

Despite a need to accommodate exceptions such as these, HHS can send a strong signal to the marketplace by keeping its initial focus on improvements in care coordination and medication management, creating demand for better information and care processes to benefit large numbers of clinicians and consumers.

[5] See Markle Connecting for Health letter on CMS incentives for e-prescribing. Available online at: http://www.connectingforhealth.org/resources/20081229_cfh_eprescribing_response.pdf.

# Health IT Provisions Under ARRA:
# Section 3: Validation of Meaningful Use

An initial focus for meaningful use on care coordination and medication management using laboratory results, medication histories and care summaries fits well within the criteria for Medicare and Medicaid incentives under Sections 4101-2 of ARRA:

1. Meaningful use of certified electronic health record (EHR) technology, including e-prescribing.[6]
2. Connections to exchange information (e.g., laboratory, medication, or radiology data) to improve quality of care, such as care coordination.
3. Reporting on clinical quality metrics determined by HHS.

The goal of validation is to establish whether a certified technology was used to achieve the objectives of meaningful use. This is distinct from the process of certification, which relates to system capability. In other words, processes for "certification" ask the question: "Does the health IT system have the capability to achieve the objectives of meaningful use?" whereas processes for "validation" ask the question: "Is the provider using the technology to achieve the meaningful use?"

Therefore, the term "validation" refers to the processes to qualify clinicians and hospitals for ARRA incentives based on meaningful use of IT.

The law envisions an evolving set of validation requirements to improve health care quality over time. The approach to validating meaningful use in the three areas designated in ARRA should:

- **Allow for a broad range of providers to participate through a variety of mechanisms.** A range of metrics and validation mechanisms will be needed to enable a wide diversity of providers in different practice settings and with varying systems — including primary care providers, specialists and hospitals — to demonstrate meaningful use.
- **Clear and achievable.** The metrics and the approach used to validate them should be clear and goal-oriented, and be achievable whenever possible through automatic reporting from electronic systems to avoid creating additional unnecessary reporting burden for clinicians.
- **Motivate information use to improve health, but not over-specify how to get there.** The metrics should not focus on specific features and functions of technology or software, but rather on the use of information to innovate care processes that improve care coordination and medication management.
- **Stimulate market innovation and "information rich" health IT adoption and use.** The approach to meaningful use can motivate market innovation for the

[6] Fischer, M. A., C. Vogeli, M. Stedman, T. Ferris, M. Brookhart, and J. Weissman. 2008. Effect of Electronic Prescribing With Formulary Decision Support on Medication Use and Cost. *Archives of Internal Medicine* 168 (22):2433-2439.

development of increasingly usable, useful, and scalable technology approaches that can be used to achieve and demonstrate health improvement goals. Innovation toward high–value, more-affordable options is critical in the small-practice market, where adoption has been the slowest, costs for IT remain high,[7] and IT support is most lacking.

- **Consider ways to discourage fraud.** Early in the processes for validating meaningful use, HHS should announce efforts to detect inappropriate requests for incentive payments. For example, HHS could announce that a certain number of audits will be performed.

ARRA contemplates several mechanisms for validating meaningful use, including through attestations, submissions of claims with appropriate coding, survey responses, and other means specified by HHS.

One of the key objectives of the new HIT Policy Committee will be to help HHS set strategies for meaningful use metrics that become more stringent over time. This, in turn, will require additional standards and certification requirements that also tighten over time. This pathway must be well-defined early in the ARRA implementation process.

[7] Avalere Health LLC. 2009. New Stimulus Incentives Raise Serious Health Information Technology Implementation Concerns, Accessed on April 21, 2009 at the following URL: http://www.avalerehealth.net/wm/show.php?c=1&id=808.

# Health IT Provisions Under ARRA:
# Section 4: What Is a 'Certified or Qualified' Technology?
# Do We Have the Standards to Achieve an Initial Set of Health Improvement Objectives?
# What Is the Role of Certification?

In recent years, much of the debate around health IT has focused on existing electronic health record (EHR) software or ambitions for regional health information exchanges (HIEs). However, such systems are not the only way to achieve the objectives of meaningful use. The definition of "certified or qualified EHR technology" should not be narrowly construed within these contexts.

A broader view of IT would seed innovation[8] rather than lock in adoption of technology based on what is available today. Health information services and technologies need to innovate and evolve rapidly, as other sectors have transformed themselves by embracing and building upon the internet.

The needs of a large, integrated delivery network will differ greatly from those of small ambulatory practices. More complex, comprehensive EHR systems must be able to co-exist alongside just-the-basics health IT systems, personal health records (PHRs), and other internet-enabled technologies and networks, all of which could meet an initial set of requirements for secure transport of a core set of standard data types.

Medical practices and hospitals ready to install, support, and manage more complex EHR systems should do so and receive ARRA incentives for it. However, ARRA must also be an opportunity for smaller practices — which still account for the bulk of outpatient doctor visits in the United States[9] — to benefit from market innovation, Web-enabled tools, and lighter-weight approaches that can be demonstrated to improve health and health care outcomes.

For example, ancillary providers, health plans, national laboratories and pharmacy networks each may collect encounter, medication, laboratory result and registration data. Internet-enabled technologies that can connect to these sources and feed and manage this information securely on behalf of providers and patients should be encouraged so long as they achieve the objectives of meaningful use. There should be opportunities for these kinds of solutions to be made available or supported by the Regional Extension Centers enacted by the law, or by other community resources, new market innovations, or other secure, internet-enabled services.

The approaches to standards and certification described below do not take as a starting point everything documented to date by the HITSP standards-harmonization body, the CCHIT

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[8] Mandl, K.D., and I. Kohane. 2009. No Small Change for the Health Information Economy. *The New England Journal of Medicine* 360:1278-1281.

[9] Table 2 of the 2006 National Ambulatory Medical Care Survey says that in 2006, 76 percent of outpatient doctor visits occurred in practices of 5 or fewer physicians, and 92 percent of outpatient doctor visits occurred in practices of 10 or fewer physicians. Accessed on April 21, 2009, at the following URL: http://www.cdc.gov/nchs/data/nhsr/nhsr003.pdf.

certification body, or the AHIC/NeHC.[10] The enactment of ARRA creates new requirements and urgency that could not have been foreseen by these bodies. However, it is likely that particular aspects of work by these bodies can be leveraged or adapted to support the goals of "meaningful use" and "qualified or certified EHR technology."

Shortly before President Obama appointed him as national coordinator for health information technology, David Blumenthal, MD, MPP, wrote that some currently certified EHRs "are neither user-friendly nor designed to meet [ARRA's] ambitious goal of improving quality and efficiency in the health care system."[11]

To support meaningful use, HHS should endorse a simple specification for a minimal set of open technical standards for secure transport as well as a core set of data types. By creating an obvious and achievable starting place, HHS will enable many options for clinicians and consumers to retrieve and use information to accomplish the meaningful use objectives.

The standards that need to be defined to arrive at a simple but workable basis for meaningful use fall into three broad categories. The first is transport, a set of standards for the secure communication of the data itself. The second is packaging, a set of message headers for packaging health information messages that pass from sender to receiver. The third is the content itself, the standards defining the description of the health information itself.

1. **The transport or communication layer: Focus on basic standards and protocols for secure communication**. HHS should endorse a simple specification for a set of open standards necessary for secure transport of data, and for defining interfaces between applications exchanging this data over the internet.[12] In addition, HHS and other entities will have to define standard naming conventions and technical specifications for the use of these services by all participants in the system, in order to simplify the exchange of messages.

2. **The packaging layer (sometimes called the message envelope): Encourage standards for packaging of health information messages.** In addition to data standards needed to transport data over the network, there is also a need for standard descriptive data for the information contained in such messages, explaining what kind of data is contained in the message, and describing the time and source of its transmission. (See "package" section of table in Appendix A.) There is high potential

[10] HITSP stands for the Healthcare Information Technology Standards Panel. CCHIT stands for the Certification Commission for Healthcare Information Technology. AHIC stands for the American Health Information Community, which has been succeeded by the National eHealth Collaborative (NeHC).

[11] Blumenthal, D. 2009. Stimulating the Adoption of Health Information Technology. *The New England Journal of Medicine* 0: NEJMp0901592. http://content.nejm.org/cgi/content/full/NEJMp0901592 (accessed April 3 2009).

[12] A minimal set of standards that can transport any data format, present or future, between any two applications, from the simplest Web-based server to the most complex hospital IT system, is necessary to keep data flowing even as new standards appear, and new applications are created. These standards should be clear and discrete: the standards for secure transport of material between authorized health care entities should be insensitive to the applications any given site chooses to implement. Any given application should be able to consume and produce data in a standardized format, without knowing what other applications will make use of that data, now or in the future. Similarly, the transport of health data must be separated from its eventual use — the network must be able to pass any data unmolested among authorized users, so that individual institutions can create and evolve new data formats without having to change the underlying network.

value for HHS to explore standard packages, expressed as XML,13 for describing priority data types, such as care summaries, laboratory results, and medication lists.

3. **<u>The content layer</u>: Raise the bar for data standards (i.e., the health information content itself) over time**. It is important that the proposed work of 2009-2012 be achievable in this short timeframe. For that reason, the required content standards should be the simplest and most available at launch, focusing on priority information types. Over time, the bar should be gradually raised for increasing numbers of data types, expressed in increasing degrees of specificity, based on pockets of early adoption. Even as standards become more robust and detailed, there will always be lag times for implementation, and there will never be a time when health networking is "finished." There will be need for increased specification as well as innovation for the foreseeable future. Where no widely adopted open content standards exist, or where non-standard data is being transmitted, the messages should still be packaged with headers describing the nature of the contents, allowing for unstructured, semi-structured, and fully structured data to travel in the same information streams. The more that ARRA incentives motivate information sharing and use, the more likely that these content-packaging standards will tighten over time with adoption and use.

**It is essential that HHS and the other bodies responsible for specifying those standards keep these transport standards separate from data standards, and separate from application functions.** The approach must make independent the standards for <u>sharing any basic information securely over the internet</u> (i.e., the transport layer) from the standards that define how to <u>express the specific data being shared</u> (i.e., the packaging and content layers). Similarly, standards for packaging and describing the data should not make assumptions about how the data are to be routed over the network, nor about the functions of receiving applications.

By way of analogy, the Postal Service delivers mail without reading the contents, and without the sender or the Postal Service knowing what kind of mailbox the receiver has. The well-understood standards for sharing information securely over the internet are Hypertext Transfer Protocol Secure (HTTPS) for transport, using Secure Socket Layer (SSL) or Transport Security (TLS) to ensure that the data are encrypted in transit, and the formats for the medical data to be transported should start with a small core of working and application-insensitive standards, and expand over time, as described below. Of the entire stack of standards, the transport standards must be the most completely defined, aggressively enforced, and durable. This is because participants in a network who are not

[13] In order to electronically organize patient data and communicate it across a network, "XML packages" have been developed and deployed. At its most basic level, an XML (extensible markup language) package is simply a file that contains a set of structured data categories (e.g. patient demographics, medications, test results, allergies, conditions, etc.) in a hierarchical format. This hierarchy allows for the expression of "parent-child relationships" within data in a given category. For example, a "medications" section of an XML package may contain the entry, "Amoxicillin 500 MG," with related "child" data such as date/time stamp, information about the clinician who prescribed the medication, etc.

Using an XML package does not necessarily mean that the data within the package will be coded in a machine-readable way. For example, "317616" is code for "Amoxicillin 500 MG" in medication vocabulary called RxNorm. Such computer codes make data "computable," which enables more advanced decision support such as drug-interactions checking. Standard XML packages may carry such computer codes, but in practice they often carry data in text format only.

using the same basic communication (i.e., transport) standards will not be able to exchange any information, no matter how similar their use of other data standards may be.

## Effective Standards Are in Use and Can Be Specified to Achieve the Meaningful Use Criteria

1. **There is already a stack of standards in use for expressing the content of laboratory results and medication data**, including medication history lookup in the context of e-prescriptions. (See table in ***Appendix A*** for more information.) Given the heterogeneity of the health sector, the government's approach should be to specify the use of minimal but necessary standards. The computability of these standards, which is to say their expression in terms that both humans and computers can understand, will also open the door to innovation on novel uses of this data, from decision support to visualization to rapid composite analysis for research, quality, and public health.

2. **Progress under ARRA should not be tied to "harmonization" of these content standards.** Nor should the definition of meaningful use or certified systems be tied to complex use cases.[14] Open content standards for medications and lab results are already in use.

3. **The specifications and protocols for these standards can and should be tested, and over time be made more specific based on real-world use.** ARRA establishes a role for the National Institute of Standards and Technology (NIST) to pilot test standards and help drive evolution of the implementation specifications and protocols toward greater and greater specificity over time as user adoption grows.

## The Need for Certification Should Be Geared Toward the Objectives of Meaningful Use, and Not From Assumed or Existing Software Features

To protect taxpayers and clinicians against fraud or faulty products, there must be mechanisms to certify systems for capabilities to achieve meaningful use. The law is clear that incentives should not reward or pay for trivial displays of technology. There also must be mechanisms (including, but not limited to, certification) to ensure that systems and organizations comply with laws and regulations on information privacy and security. However, certification by itself is not sufficient to ensure compliance with privacy policies. Examples of other policy enforcement mechanisms may include strengthened enforcement of existing laws or new statutes (state or federal), procurement requirements and legal contracts, self-attestation with third-party validation, consumer or customer-ratings, enforcement of consumer-protection laws, etc.

[14] Use cases run the risk of focusing on narrow circumstances, pre-supposing what problems are to be solved, and presuming a group of users more homogenous than those represented in the real (and messy) world that is our health care system. The problems common to a large swath of health care practitioners are better solved by removing barriers and creating incentives for secure sharing and meaningful use of information that can improve health care, starting with those standard data types already in wide use today.

Despite these needs, it is important to recognize that the government's approach to defining the terms "qualified" or "certified" can either help or hurt our ability to achieve the objectives of ARRA.

As with standards, we recommend a minimally necessary approach to certification of interoperability. This paper emphasizes that ARRA incentives should neither require nor reward the mere purchase of specific applications based solely on their features or functions. Rather, the incentives should reward the capability for the system to enable a user to achieve and demonstrate meaningful use and to securely share priority information, with expectations of data completeness and quality rising over time. The solution for certification should also follow this logic.

We therefore recommend that HHS' initial approach to interoperability certification take the following steps:

1. **Certification for interoperability:** One key thrust of certification under ARRA should be to determine whether a system can **share information to achieve meaningful use objectives**, i.e., whether it can receive and send the priority classes of information, in standardized formats and using standard protocols for secure transport.

2. **Developing criteria for meaningful use, privacy, and security:**

    a. The requirements for "qualified or certified" technology should have the capabilities to allow a provider to achieve meaningful use, however defined by HHS. That is to say, "certified or qualified" technology should embed capabilities to achieve, measure, and report the meaningful use metrics without requiring undue extra work for the practice to show it merits health IT incentives under ARRA.

    b. For a technology to be qualified or certified, it also should meet the technical aspects of privacy and security requirements under HIPAA and ARRA (e.g., audit trails, data security, authentication of patients and providers).

    c. Processes for development of certification criteria must be open to public comment, and no single stakeholder group should be able to dominate the proceedings.

3. **Testing criteria and network interfaces:** In order for a system to be certified, it would have to pass a testing regimen for the transport and security protocols, as well as the minimum protocols (patient identity management, location of patient records, authentication of system users, etc.) for interfacing to laboratory and medication data. These protocols are definable today, require no new standards or harmonization, and could be validated using Web-enabled testing environments.

4. **Pluralistic approach to applications**: This certification testing step should be open to a broad range of applications (e.g., EHRs, PHRs, HIEs, e-prescribing, Web-browser-based applications, etc.) that are capable of achieving the goals of meaningful use.

5. **Pluralistic approach to certification testing:** The method must be market-ready, low-cost, and nimble so that certification itself does not become a vehicle, intentionally or unintentionally, for unduly slowing innovation. As with the issuing of domain names or SSL Certificates for the Web, a single set of clear criteria for certification, could be clearly defined and then administered by multiple entities.

   The government should publish minimum certification and testing criteria, and then identify any entities qualified to test and certify products meet the criteria. NIST or another appropriate agency could set the core criteria for certification of meaningful use functionality, and allow multiple entities, both public and private, to do the actual certification testing. So long as these testing services all work on the same definition, these entities can then compete on their ability to provide value-added services above the minimum requirements. Once the certification protocols are defined, the door should be left open to a plurality of private certification organizations, including ones like CCHIT, to compete for public and private sector business, as there are now for other IT products and services.

## Appendix A:

| Purpose | Available 'Good Enough' Standard(s)* |
|---|---|
| **Transport** | |
| Enable server to server security | SSL, TLS |
| Enable secure file transport | HTTPS** |
| **Codify Content** | |
| Codify diagnostic tests | LOINC, CPT4, Snomed CT |
| Codify medications[1] | RxNorm (or RxTerm), NDC |
| **Package** | |
| Create a clinical summary data package (XML) | CDA CCD, CCR standard |
| Create an e-prescribing data package (XML) | NCPDP SCRIPT |
| Create a lab data package | HL7 v2 (XML serialized version preferred when feasible, but delimited data acceptable) |
| Create an administrative data package | X12 |
| **Images** | |
| Facilitate image interoperability between medical imaging systems | DICOM[2] |

*In several cases, the HIT Standards Committee will need to recommend specific versions of standards. Mappings between vocabularies (e.g. CPT4 ←→ Snomed CT), although never perfect, can be accomplished via efforts such as the Unified Medical Language System (UMLS), or via proprietary solutions. It is assumed that these standards will continue to evolve and adapt. Most of the standards listed here have implementation guides (e.g., NCPDP SCRIPT).

** Specification of transport and security standards will need to be accompanied by definitions of network interfaces, specified as uniform resource locators (URLs) and the way of methods or processes that can be invoked at these network interfaces. This degree of specification will be required if any two participants in the system are to be able to work together without requiring advance coordination for each potential pair of communicating entities (which would create impossible complexity as the network grows large).

Notes:

[1]Medication notes:

- NDC includes prescription medications only; RxNorm includes OTC medications.
- RxNorm allows for varying hierarchical representations of medication data (from name to name, strength and form).
- Pharmacists have greater use for the non-clinical information within an NDC code than other clinicians: e.g. packaging type/size, manufacturer, etc.
- The medication SIG (i.e., doctor's instructions for taking the medication and other data) is not covered here, but needs to be part of a retail medication feed in order for doctors, pharmacists and patients to maximally benefit from medication information. The NCPDP Structured and Codified SIG Standard is being piloted.

[2]Because DICOM (Digital Imaging and Communications in Medicine) is both a communication and content standard, 'images' have been categorized separately.

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** Federal and state employees collaborate but make no endorsement.*