# Achieving Interoperability that Supports Care Transformation

A Report of the American Hospital Association Interoperability Advisory Group



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#### **Executive Summary**

Hospitals and health systems around the country have made the transition to using electronic health records (EHRs). Now that we have large amounts of health information in electronic form, providers and policymakers are turning their eyes to the next goal of ensuring that the data can be easily and securely shared – also known as interoperability.

Hospitals and health systems cannot collect and share data across settings of care as easily as they want to, or without expensive and cumbersome work-arounds. At the same time, they face increasing needs to better understand their patients' conditions and care patterns to successfully manage new models of care such as accountable care organizations. In all endeavors to share information, they must maintain secure systems. For their part, federal officials are concerned that the \$30 billion invested in the Medicare and Medicaid EHR Incentive Programs has been wasted if the data cannot be shared easily.

The AHA formed the Interoperability Advisory Group (IAG) to better understand member priorities for information sharing, barriers to interoperability and specific actions that the public and private sectors could take to move forward.

The 24 members of the IAG represent a range of facilities from critical access hospitals to large academic medical centers, and from stand-alone hospitals to large integrated health systems. The group includes information technology, clinical and administrative leaders. The group deliberated over six months via conference calls, individual outreach and a one-day, in-person meeting.

Priorities for Information Sharing. While the data collected during the course of caring for patients may have many secondary uses, such as research, the IAG emphasized the need to focus first on ensuring that we can efficiently and effectively gather, share and use health information for its primary purposes:

- (1) To support care and patient engagement.
- (2) To support new models of care.

Barriers to Interoperability. As detailed in this report, the members of the IAG identified multiple barriers to interoperability that fall into three categories – insufficient infrastructure, technology challenges and unresolved policy issues.

Actions to Improve Interoperability. Creating a truly interoperable health information system will require action by both the private and public sectors. While the report contains detailed actions, in general:

- Hospitals, health systems and other providers must identify their priorities and make it clear to vendors that they want efficient and affordable information sharing.
- Vendors must take actions to enhance interoperability in support of the priorities set by hospitals, health systems and other providers. They must align their business case with the needs of their customers, so that information can be shared efficiently and effectively, without repeated and expensive "tolls" for creating interfaces and completing transactions.
- To be viable, health information exchanges (HIEs) must be able to share data across their organizations to create a network of networks.

- The federal government must continue to support advances in interoperability, but with a laser tight focus on standards, certification and testing. This focused approach will ensure that EHRs and other health information technology (IT) tools deploy standards to efficiently share information in support of care, patient engagement and new models of care.
- State governments should be discouraged from establishing unique requirements that increase

variation in standards and policies because variability diminishes the ability to share information across state lines.

Achieving the vision of health information that can be easily shared to inform care, engage patients and support new models of care will take hard work on the part of every actor. Through collaborative efforts focused on the highest priority actions, however, progress can be made.

### Introduction

America's hospitals and health systems play a central role in gathering and sharing health information that can be used by individuals and their health care providers to manage health and provide care. Recent years have seen a significant growth in adoption of electronic health records (EHRs) and other health information technology (IT) tools. While the adoption of EHRs continues, the ability of these expensive technologies to support the sharing of information across systems within a hospital or across care settings remains limited. And, despite buying EHRs that have been certified to meet government standards, hospitals are finding that they still cannot share data with others outside their own organization without significant work and expense. This is true whether providers are using the same vendor platform or different ones. In addition, policymakers are questioning why we do not have greater levels of information sharing given large federal investments in EHR adoption.

To address this issue, the American Hospital Association (AHA) convened an Interoperability Advisory Group (IAG) from its membership to better understand the challenges facing hospitals and health systems in sharing information and identify specific actions that the private and public sectors can take to improve interoperability. The IAG was established with the following goals:

 Identify hospital and health system priorities for interoperability of health IT and systems that address the needs of a redesigned health care system where health information is a valued tool in the containment of costs, delivery of quality care to patients and management of the health of a population.  Identify the best approach (or approaches) to improve interoperability and consider the timelines, implementation needs, and infrastructure gaps that must be met to support the health information sharing and management goals of hospitals and health systems.

The 24 members of the IAG (see Appendix A) represent a range of facilities, from critical access hospitals to large academic medical centers, and from stand-alone hospitals to large integrated health systems. The group includes IT, clinical and administrative leaders. This document is the result of six months of deliberation, including conference calls, individual outreach and a one-day, in-person meeting.

The group came to a clear consensus that the nation must make rapid progress on developing secure, efficient sharing of health information, not only for improving care, but also for engaging patients and supporting new models of care. Making progress on interoperability will support the Triple Aim of improving the patient experience of care (including quality and satisfaction); improving the health of populations; and reducing the per capita cost of health care. To make progress, however, we must have a well-defined scope of activity and a clear path forward. Certain activities will require federal government actions, but the private sector also should play a leading role.

This document lays out the group's starting definitions and principles, their priorities for information exchange and the current barriers to interoperability. It then identifies specific actions the IAG believes will further interoperability. This includes actions for those in the private sector – providers, vendors, health information exchanges and multi-stakeholder groups – as well in the public sector, including federal and state governments.

## Background

Hospitals and physicians have made great strides in implementing EHRs over the past five years. Indeed, the most recent AHA survey data shows that, by 2014, 75 percent of hospitals had at least a basic EHR in place – almost five times the share in 2010 (ONC Data Brief No. 23, April 2015). A key driver of EHR adoption has been the Medicare and Medicaid EHR Incentive Programs, which provide positive incentives for "meaningful use" of EHRs that have been certified through a program established by the Office of the National Coordinator for Health Information Technology (ONC), followed by Medicare payment penalties on hospitals and physicians that do not meet the requirements. To date, about \$18 billion in incentive payments has been paid to hospitals and \$12 billion to physicians; however, some hospitals and more than half of Medicare physicians will face penalties in 2015.

The meaningful use program includes some interoperability requirements. The 2014 Edition EHR certification requirements include 23 different standards for data vocabularies, content, transport and security that are built into and supported by certified EHRs. However, ONC generally did not provide implementation guidance for the use of the standards, allowed flexibility in how the standards are used by vendors and adopted relatively lax testing of EHRs for certification. As a result, AHA members report very limited actual interoperability today. Nevertheless, given the significant investments already made, the requirements of meaningful use and the capabilities of

the 2014 Edition certified EHRs must be a starting point for efforts to improve interoperability.

Beyond EHR adoption, hospitals and health systems face an increasing confluence of pressures to share information, but need the technical capabilities and infrastructure to do so. Market and policy drivers include imperatives to share information across the continuum of care in support of improving coordination and reducing readmissions. Increasingly, providers need to share data across settings as diverse as individual provider offices, general and specialty hospitals, skilled nursing facilities, other post-acute care settings and behavioral health providers, among others. They also face increasing demands to share information with individuals and their family members or other caregivers to further engage them in their health and care decisions.

In addition, new financing arrangements, such as accountable care organizations (ACOs), bundling initiatives and capitation arrangements, require a better understanding of where patients are receiving care and what care is being provided. This type of data must be shared among providers. Those engaged in new payment models also need clinical and financial data from insurers, as payers collect data from across settings. New participants in health care, such as retail health outlets, also need to participate in information sharing. For example, providers can use data from pharmacies on whether patients continue to take medications to better manage both an individual patient's chronic condition and the risk associated with caring for a population.

As announced by Department of Health and Human Services (HHS) Secretary Burwell in January 2015, Medicare has set specific goals for moving fee-for-service payments from volume to value by 2018, including tying 50 percent of payments to alternative payment models and 90 percent of payments to some type of quality or value metrics. In addition, patients and payers increasingly are interested in having access to the data held by health care entities to enhance transparency. The public health community also is looking to information collected by providers to address public health issues, while the research community sees tremendous value in patient data collected during care to enhance and speed up the discovery of medical knowledge. Furthermore, big data and other interests see potential in using health care data for commercial purposes, such as selling health-related "apps" or other services to educate consumers.

Currently, however, hospitals and health systems find it challenging to share information to support clinical care, let alone other uses, because of unique system configurations and a multiplicity of vendors with their own implementations of standards. This variability in vendor approaches requires numerous interfaces to support data exchange across disparate information systems. Changes to any one information system could affect many interfaces. In the current state, sharing and integrating data across EHRs is complex, time-consuming and costly. Sometimes, it is simply not possible.

Furthermore, the cost and complexity of the interfaces vendors sell to create work-around solutions are simply not sustainable. Similarly, the new transaction fees being imposed for information exchange also present an unsustainable model for widespread sharing of health information. Based on data from the AHA annual survey, we estimate that, between 2010 and 2013, hospitals spent an average of \$47 billion per year on IT operating and capital costs. More and more, hospitals report that they cannot sustain the level of capital and human resources needed to upgrade and maintain their EHRs. Efficient and affordable tools for sharing information are essential to care and care transformation.

As the need for information sharing accelerates, careful attention must be paid to keeping information secure. Recent years have seen a growth in bad actors looking to disrupt information systems and steal personal information. As we increase the sharing of information, new points of vulnerability emerge. Maintaining the balance between sharing information and keeping it secure will be an ongoing tension, and require growing amounts of resources. However, policy frameworks already exist to address this aspect, including the privacy and security rules under the Health Insurance Portability and Accountability Act (HIPAA) and the Cybersecurity Framework for Critical Infrastructure Programs developed by the National Institute of Standards and Technology (NIST).

## Definition and Principles

#### Definition

For purposes of this document, the IAG started with the definition of interoperability put forward by the Institute of Electrical and Electronics Engineers, which is the "ability of a system or product to work with others systems or products without special effort on the part of the customer. Interoperability is made possible by the implementation of standards."

However, the IAG noted that interoperability has many different components – such as the interoperability of data versus the interoperability of software systems. Ultimately, the test of interoperability is whether the end users can find, understand and act on information when they need it. In general, interoperability is best achieved by incorporating it into the design of information systems from the beginning, and not as an addon function.

While not part of the technical definition of interoperability, other factors affect the success of information exchange. For example, clinical members of the group noted that even systems that support technical interoperability will not support information exchange unless they are useable – that is, they support the end users (clinicians and patients) in accomplishing intended tasks efficiently and effectively. Further, there are policy issues, such as requirements for patient consent or reliable patient identifiers that impact the ability to share information. These are discussed more fully below.

#### **Principles**

In 2005, the AHA Board of Trustees adopted a set of principles on health IT (see Appendix B), three of which address health information exchange. The IAG found these three principles to still be relevant today, but modified them somewhat to account for recent changes in the health care field:

- Health information exchange should be promoted to improve care. Improved care will come when the right information is available to the right provider at the right time, and using the right modality. Sharing of information also may reduce costs by limiting the need for repeated tests.
- IT should be used to maximize individuals' participation in their health and care. Giving individuals access to their health information puts them at the center of their care and allows them to become more engaged in their health, and more informed of decisions regarding their own care or the care of their family members. Patients also can contribute valuable information to their health records.
- Standards for interoperability should be harmonized and operationalized. The exchange of health information requires that it be in a structured format that can be recognized and "understood" by a computer. Coming to agreement on the standards to be used will require collaboration and a private-public partnership that prioritizes where standards are needed. Implementation will require examination of the kinds of transactions that are likely to occur, what business processes support them, and what steps need to be taken to ensure that all end users are implementing the standards consistently.

### Field Priorities for Information Sharing

The members of the IAG identified two priorities for information sharing that must drive solutions to our interoperability challenges: sharing information to support clinical care and patient engagement, and gathering and using information to support new models of care.

## Priority 1: Share information to support care and patient engagement

Hospitals and health systems want actionable data available to support safe and high-quality clinical care, both within a single hospital and across care settings. The growing recognition that we must integrate physical and behavioral health raises the importance of ensuring that behavioral health information also be shared, within the bounds of existing privacy laws. To be actionable, data must be easily incorporated into workflows and used to guide clinical care. For example, hospitals may want to electronically send hospital-sourced data to ambulatory physicians' EHRs, or access data from other providers when treating patients. Within the hospital, clinical care requires integrating data from laboratory, pharmacy and other ancillary systems and medical devices into the EHR. Across settings, information must flow to support better coordination, collaboration and integrated care delivery. As a result, the secure exchange of health information is essential and urgently needed. In an alternative model, some health systems are moving to shared access to a common data set for authorized users, rather than transactions that send data from one location to another.

Health information also must serve the needs of individuals to manage their own health and engage in clinical decision making. As we improve interoperability, it will become easier for individuals to bring together a more complete view of their health and health care. New modalities of information sharing, including mobile platforms, will be part of this evolution. Hospitals and health systems will need better tools to meet the growing consumer demand for easier access to electronic data.

## Priority 2: Gather and use information to support new models of care

To be successful in an ACO or to transition to being responsible for the health of a population, hospitals and health systems need data from multiple sources both inside and outside of their organizations. For example, they need to understand all of the care a patient is receiving – regardless of location – to best manage care and to predict and manage total resource use. This includes not only information from other providers, but also from insurers, government agencies, pharmacies and new retail settings. Additionally, as patient engagement in individual health increases, hospitals and other care settings will need to prepare to accept patient-generated data.

Therefore, hospitals and health systems need information systems that can receive, understand and use information from other sources. To be useful, data must be integrated in clinical workflows and care management assessments. To-day's technology is far from being able to provide a complete view of a patient's experience beyond a single hospital or organization. Significant evolution will be needed to support success with new models of care. Many organizations are building predictive modeling and other data analytics to support new models of care, but without easy ways to share data it is very costly and challenging, and the picture is often incomplete.

Hospitals and health systems also want to use their combined information systems to support transparency efforts. Beyond reporting for meaningful use, they should be able to use their systems to support the reporting requirements of other programs like e-measures in the Hospital Inpatient Quality Reporting Program and quality data for the Medicare Shared Savings Program or other ACOs. Better data from multiple sources also could support performance improvement initiatives.

The IAG discussed the many other potential uses of health information – such as research endeavors and economic innovations. However, the group concluded that, to make progress, interoperability efforts must focus first on the primary goals of health information – supporting care and patients. Secondary uses, such as research and reporting, are important but are dependent on our ability to successfully use information systems for their primary purpose.

### Major Barriers to Interoperability

The members of the IAG identified three types of barriers to interoperability – those related to missing infrastructure, challenges with current technology and outstanding policy issues. Table 1 summarizes the issues discussed.

**Table 1. Barriers to Information Sharing** 

Insufficient Infrastructure	Technology Challenges	Unresolved Policy Issues
<ul> <li>Immature and insufficient standards</li> <li>No reliable, consistent patient identifier</li> <li>Few reliable, efficient exchange mechanisms</li> </ul>	<ul> <li>Inconsistent standards use</li> <li>Insufficient testing of products</li> <li>Little integration of medical devices</li> <li>Poor usability</li> </ul>	<ul> <li>Limited provider resources</li> <li>Legal barriers to hospital-physician collaboration</li> <li>Evolving scope of the legal record</li> <li>Inconsistent privacy and security requirements</li> </ul>

#### Insufficient Infrastructure

The infrastructure to support information sharing has a number of component parts, including agreed-upon technical standards for how data are collected, stored, formatted, used, exchanged and secured; a way to identify individuals and match patient records; and efficient and affordable networks to send data. Many aspects of the needed infrastructure are currently incomplete or missing altogether.

To date, standards have been mandated before they were ready for widespread use and do not always meet clinical needs. Broadly speaking, a data standard is a well-defined and common way to refer to a piece of information or a set of information, or a common way to send it. Without standards, data will not have common meaning across users. While multiple standards have been mandated for use by ONC, many of them are immature, such as the Direct protocol

for secure e-mail, and lack the necessary level of specificity to ensure that vendors interpret and implement them the same way. While many providers have tried to use Direct to share clinical information, it has proven hard to use and does not always support existing clinical workflows. Further, the current iteration of content standards, such as the Consolidated Clinical Document Architecture (CCDA), do not meet the needs of clinicians for relevant clinical data. The CCDAs shared for meaningful use include large amounts of patient data, making it hard for clinicians to easily identify the information that is important. As a result, today's approach to data sharing relies on custom programming and additional configurations to accomplish each individual need for information. With the appropriate standards in place, interoperability could become a system of building blocks, where providers can build the tools they need for clinical care using standardized pieces of information that have been intentionally developed to fit together.

Providers have challenges identifying patients and matching records. The nation lacks a single national mechanism for identifying individuals such as a unique patient identifier. A single solution that will match individuals across IT systems would allow providers to know with confidence that the Sally Smith being treated in a Florida emergency department is the same Sally Smith that a physician in New York diagnosed with a heart condition last month. Patient safety concerns arise when data are incorrectly matched, so that, for example, a patient's current medication is not listed, or the wrong medications are included in the record. Solutions based on matching across a set of personal information (name, address, gender, etc.) have been proposed. However, organizations that have used such probabilistic matching for years report continued error rates that are unacceptable. This approach also creates security concerns, as sensitive data must be shared to facilitate a match. From a cost perspective, hospitals and health systems devote significant technical and human resources to avoiding both the creation of duplicate records and the incorrect merging of records. To date, Congress has not allowed the federal government to develop a unique patient identifier.

**Efficient exchange networks are not yet widely available.** Although significant federal, state and private funds have been invested in developing regional health information exchanges (HIEs), many hospitals and other providers still lack access to widespread, efficient and affordable exchange networks. Currently, they must rely

on a constellation of regional HIEs, vendors and private HIEs that vary in the services offered and prices charged. Most hospitals and health systems currently pay for many different exchange mechanisms, each of which meet some, but not all, of their information exchange needs. This patchwork of exchange mechanisms also creates waste.

#### Technology Challenges

Technology challenges that prevent information sharing include variability in how vendors use standards, the lack of testing infrastructure to validate conformance with standards, challenges integrating medical device data and lack of usability of EHRs.

Lack of consistency in use of standards. Vendors interpret data standards differently. At the same time, physicians and hospitals may choose custom EHR configurations that also negatively affect the ease of information sharing. As a result, providers must use interfaces to connect systems. Today's EHRs are like snowflakes - no two are alike, so building each interface is a unique challenge. The amount of effort required to integrate systems would decrease if there were more consistency in the implementation of standards by vendors and providers. The use of mapping across varying standards used by vendors or providers can allow data to be shared. but at an added cost to create and maintain the mappings.

Insufficient testing of EHRs and other IT solutions. Currently, one-time certification is the only widely used test of vendor product conformance to national standards. Vendors' adherence to standards would increase if certification of EHRs were tied to the EHRs' ability to continuously meet those standards, as affirmed by more rigorous and on-going testing. If providers could test systems post-implementation, they would be able to confirm installed systems work as advertised. Public reporting of testing data about how vendors support interoperability would inform purchasing decisions.

Little integration of medical devices. Within the hospital, barriers to interoperability arise from the number and variety of medical devices collecting data that should be integrated into the record. Examples of data from devices include blood pressure, temperature, heart rate, diagnostic images and doses of drugs, among others. This form of interoperability cannot be overlooked, as the lack of reliable connections means that data collected from a device may not appear in the EHR or may be incorrect. This creates safety risk, if, for example, a drug pump sends incorrect medication information that is then used in clinical decision-making. Providers need confidence that the data presented are trustworthy as they move from medical devices to the EHR or other information systems.

Clinicians find EHRs difficult to use. In many cases, EHRs lack good usability, so that clinicians must search for the data they need and spend considerable time entering information. In some cases, such as creating clinical quality measures,

data must be transferred from one part of the record to another, rather than having the information system populate fields with existing data. Clinicians also have concerns about the accuracy of data that are shared. The rush to implement technology to meet meaningful use timelines, receive incentives and avoid penalties placed IT adoption ahead of clinical usability and feasibility.

#### **Unresolved Policy Issues**

The meaningful use program has been beneficial in driving the adoption of EHRs and supports a limited degree of information sharing. Additional policy barriers exist, however, such as resource constraints, limitations on how hospitals and physicians can work together, legal concerns and privacy issues.

Some providers have limited resources at the same time costs are growing. The large and growing time, money and personnel costs of health IT implementations prevent investment in other priorities and risk creating "haves" and "have-nots." Small and rural facilities have patients that move between their setting and other hospitals as they receive care elsewhere and return home for follow-up care. Information sharing is a priority for these facilities, yet today they must prioritize their efforts on regulatory compliance with meaningful use in order to receive incentives and avoid penalties. For some rural providers, access to adequate broadband is still an issue. At the same time, larger systems, collectively, have invested billions of dollars and face unsustainable costs for maintaining and upgrading systems.

Regulatory barriers prevent hospital-physician collaboration. For many in the physician community, the cost of the current approach to information sharing, based on expensive, one-off interfaces, is unsustainable. However, current restrictions on hospital-physician arrangements are limiting the ability to complete "the last mile" in electronic delivery of hospital-sourced data to the ambulatory setting. Referral source restrictions like the Stark and antikickback statutes limit hospitals' ability to support physicians' ongoing challenges with IT.

The scope of the legal medical record continues to evolve. As clinical data are shared, legal questions arise about the responsibilities of individual clinicians to review and act on information about a patient. For example, an expectation that clinicians look at each piece of information available in an HIE raises significant time, workflow and liability risk issues. As we increase data sharing, clinicians will need additional guidance on the best use of large amounts of data from various sources. Similarly, debate continues about the ownership of medical records, which health care providers must gather, keep and make accessible to individuals.

Inconsistent privacy and security requirements limit data sharing. As attacks on health-related information systems grow, we see increased attention to the security of information. Existing policy structures provide a framework for security, including the HIPAA security rules, requirements for breach notification and enforcement of penalties for breaches. In addition, NIST has created a framework for cybersecurity across all critical infrastructures, including health care and public health. However, crafting agreements for information exchange within that policy framework remains challenging. For example, securing all of the necessary legal agreements to ensure all parties will keep information secure and will be protected in the event of a breach creates a stumbling block to exchange. Providers also face significant penalties of privacy laws are broken. The multiplicity of privacy laws across state and federal governments also creates significant challenges, as do the special considerations that must be taken when sharing especially sensitive information.

### Actions to Improve Interoperability

Creating a truly interoperable health information system will require actions by both the public and private sectors, including providers, vendors and other stakeholders. Appendix C provides background on efforts to improve interoperability. Table 2 on page 15 summarizes the recommended actions.

#### **Private Sector Actions**

Providers, vendors, health information exchanges and multi-stakeholder groups all have a role to play in improving health IT. As end users, providers must identify where interoperability is most important and clearly communicate those needs to their vendors and other supportive organizations, including HIEs. For their part, vendors and other supportive organizations must align their business cases with those of providers, and create tools and environments to support efficient and useful information sharing. For the purposes of this document, public-sector health care providers, including federal facilities, are included in this section. Public sector actions are limited to policy-making bodies at the state and federal level.

#### Hospitals, health systems and other providers must identify their priorities and make it clear to vendors that they want efficient and affordable information sharing. Providers must:

• Set an expectation that vendors adhere to standards. Providers can promote the adoption of agreed upon standards by vendors via procurement specifications and contract language. For example, hospitals and other providers could individually provide specific requirements for interoperability that are communicated to vendors.

- Identify the highest priority information sharing activities (or "use cases") they want their health IT systems to support. Providers are best suited to identify and prioritize the areas where improved interoperability is most needed and will provide the greatest value. For example, sharing laboratory data, imaging results and medication information to support care continues to be more challenging than it should be. Agreement on providers' priorities will signal an expectation that vendors must address them to support their customers. Rather than identifying discrete use cases, providers should consider a set of related use cases and clinical scenarios to identify where and how data should flow. Detailed use cases that map from current realities can then feed into a systems approach for designing IT solutions that starts from the core set of data that is most important to meet clinical needs. Providers also can inform development of better products by providing insight on how data are used and what best supports workflow.
- Contribute their requirements for testing as the end-users of health IT systems. The only way to demonstrate adherence to standards and interoperability is through robust testing. Providers must work with federal and private sector partners to identify what they want systems to be able to accomplish and how they should perform so that more robust test beds that meet their needs can be developed.

- Invest in standardizing care processes and use of systems. Once vendor systems accommodate standardized implementations that support information sharing, end users will need to adopt them as well. These changes may require significant efforts to educate workforce and establish a culture that embraces standardized approaches.
- Actively identify and share lessons learned and best practices. The health care field has experienced several areas of success that could provide lessons learned. Two examples of success are barcode medication administration and e-prescribing. Continued efforts to learn from others' experiences and distill best practices will foster progress.

Vendors must take actions to enhance interoperability in support of the priorities set by hospitals, health systems and other providers. They must align their business case with the needs of their customers, so that information can be shared efficiently and effectively, without repeated and expensive "tolls" for creating interfaces and completing transactions. Vendors must:

 Commit to consistent use of standards and implementation specifications, participate in testing and provide documentation on adherence to standards. In addition to undergoing federal certification, vendors should participate in more robust testing and provide additional documentation on how they are deploying standards.

- Share expertise during development of standards, implementation specifications and use cases. Vendors should provide technical input into specifying standards and use cases based on their experience to date and changes they are making to data architectures to support a more standardized, interoperable approach.
- Be more transparent about technical solutions. Vendors should disclose technical details about the interfaces to their products, systems or devices so that providers can understand how a given technology interprets and uses national standards. This includes providing information on the development of new ways to allow for exchange of data elements and more nimble access through application programming interfaces or other ways of making data more accessible. As new approaches are developed, close collaboration with the provider community and more openness about technical solutions will better ensure that end user needs are met.
- Align their business case with the needs of their customers. There is currently a distinction between the business case for the provider (interoperability in support of clinical transformation) and the business case for the vendor (interoperability that is sufficient to meet meaningful use regulatory requirements). Vendors must start with the needs of their provider customers in mind, and prioritize interoperability that supports information sharing for care and new models of care. Simply stated, vendors should be required to implement standards-based approaches to information exchange without exacting tolls on development of interfaces or individual data transactions.

#### Table 2. Summary of Actions to Improve Interoperability

#### **Private Sector Actions**

Hospitals, health systems and other providers must identify their priorities and make it clear to vendors that they want efficient and affordable information sharing. Providers must:

- Set an expectation that vendors adhere to standards.
- Identify the highest priority information sharing activities (or "use cases") they want their health IT systems to support.
- Contribute their requirements for testing as the endusers of health IT systems.
- Invest in standardizing care processes and use of systems.
- Actively identify and share lessons learned and best practices.

**Vendors** must take actions to enhance interoperability in support of the priorities set by hospitals, health systems and other providers. They must align their business case with the needs of their customers so that information can be shared efficiently and effectively, without repeated and expensive "tolls" for creating interfaces and completing transactions. Vendors must:

- Commit to consistent use of standards and implementation specifications, participate in testing, and provide documentation on adherence to standards.
- Share expertise during development of standards, implementation specifications, and use cases.
- Be more transparent about technical solutions.
- Align their business case with the needs of their customers.

To be viable, health information exchanges (HIEs) must be able to share data across their organizations to create a network of networks.

• HIEs have begun to coordinate, but the work is not yet complete.

A multi-stakeholder group would foster further collaboration.

Given the many actors involved in supporting health information exchange, a multi-stakeholder group may be needed to drive progress on interoperability.

#### **Public Sector Actions**

The federal government must continue to support advances in interoperability, but with a laser tight focus on standards, certification, and testing. This focused approach will ensure that EHRs and other health IT tools deploy standards to efficiently share information to support care, patient engagement and new models of care. The federal government must:

- Focus interoperability efforts on accelerating exchange of data currently collected.
- Improve certification, based on more robust testing.
- Create and support robust testing tools to ensure systems conform to standards that support interoperability.
- Increase public reporting on how vendors support interoperability and information sharing.
- Lead selection of standards, including continued development and maturation of needed standards.
- Actively support adoption of standards by providers.
- Address patient identification and matching.
- Rely on existing polices and the incentives of new models of care to encourage information sharing by providers.
- Adopt a reasonable timeline for change.

**State governments** should be discouraged from establishing unique requirements that increase variation in standards and policies because variability diminishes the ability to share information across state lines.

• HIEs, to be viable, must be able to share data across their organizations to create a network of networks. HIEs have begun to coordinate, but the work is not yet complete. In some regions, the information exchanges are facing significant challenges with data sharing because they have been built with different platforms. Information exchanges also should share their provider directories, to facilitate the identification of exchange partners.

### A multi-stakeholder group would foster further collaboration:

 Given the many actors involved in supporting health information exchange, a multi-stakeholder group may be needed to drive progress on interoperability. Solutions to the current interoperability challenges will likely require coordination and consensus across stakeholders to continue making advancements in standards maturity, identification of the interoperability issues to be solved, and the requirements for more robust testing tools. Examples exist in health care of public-private organizations to advance the maturation of technical standards or address discrete interoperability solutions. For example, CAQH CORE identifies and promotes standardized business rules to facilitate standardized administrative transactions. In this model, federal funds could be directed to a private sector organization that would identify the appropriate use cases, standards, and operating rules to create interoperability that is focused on the needs of the end user. In this and other examples, the provider community must have a large role in the advancement of standards and interaction with technology early in its development.

#### **Public Sector Actions**

The federal government must continue to support advances in interoperability, but with a laser tight focus on standards, certification and testing. This focused approach will ensure that EHRs and other health IT tools deploy standards to efficiently share information in support of care, patient engagement, and new models of care.

As the federal government clarifies its role in advancing interoperability, it should expressly emphasize the role of technology in supporting a culture of safety. Interoperability requirements must be grounded in the foundation of safety first. The federal government must:

· Focus its interoperability efforts on accelerating exchange of data currently collected. The federal government must continue encouraging interoperability, but with a focus on sharing the data that today's EHRs can collect in support of care, and not secondary uses of the data. Given the significant investments made to date, the requirements of meaningful use and the capabilities of the 2014 Edition certified EHRs must be a starting point for efforts to improve interoperability. To make short-term progress, ONC will need to limit its scope and focus its efforts on a small prioritized set of use cases that accelerate the exchange of the meaningful use data set that is currently being captured to support care. Initial success will build confidence and support for tackling additional use cases.

- Improve certification, based on more robust testing. The primary tool the federal government currently uses to ensure vendors support interoperability is the certification program run by ONC. Significant improvements to certification focused on interoperability and based on robust testing would demonstrate the government's commitment to making progress. While the current certification process involves some testing, it is not sufficient to meet the needs of the end users.
- Create and support robust testing tools to ensure systems conform to standards that support interoperability. This role will shift the federal government from regulating how technology is used to focusing on how well technology performs. Federal agencies such as NIST have a history of working with standards development organizations and others in the private sector to support a world-class infrastructure for product conformity to standards. This model should be replicated to support conformance testing for interoperability. Conformance testing for interoperability prior to EHR certification will communicate to vendors that the products required for use in federal programs must have interoperability built in, rather than added on via multiple point-to-point interfaces post certification. Robust testing tools also should be available to vendors during product development and providers after implementation.
- Increase public reporting on how vendors support interoperability and information sharing. The federal government should make

- publicly available the information submitted by vendors in support of EHR certification and testing results. Transparency of both the testing and certification processes will build assurance that the certified products providers must buy will work as intended. ONC also should provide additional transparency metrics about vendor actions to support interoperability, similar to the quality reporting required by hospitals and health plans and shared on Medicare websites like *Hospital Compare* and the star-ratings on *Plan Choice*.
- · Lead selection of standards, including continued development and maturation of needed standards. To date, the federal government's selection of standards for inclusion in the certification of EHRs has vielded mixed results. Future activities must be more grounded in whether standards are ready for use and accompanied by sufficient implementation guidance. The federal government should support the maturation of standards through pilots or demonstrations to determine the viability of the standard before inclusion in a federal regulation that mandates use. For example, ONC could support voluntary certification of draft standards that are being matured in pilots or demonstrations projects, which would signal federal support for innovation without imposing an immature standard on the entire provider community. With evidence from real-world pilots that a draft standard can be scaled for ubiquitous use and has moved to become a mature standard, the federal government can then consider whether regulations are needed to advance use of the standard.

- Actively support adoption of standards by providers. In addition to selecting standards, the federal government should provide training and other educational support on the use of standards by health care providers. Physicians and other clinical staff are not experts in standards but must use them to document care. The National Library of Medicine and the Agency for Healthcare Research and Quality have undertaken some work to share information about the standards required in meaningful use. More visible and larger efforts are needed, however, to improve the use of standards that have been adopted.
- Address patient identification and matching. The need for a patient identifier was consistently identified by the IAG as an issue that requires immediate attention. While the HIPAA statute laid the groundwork for a national patient identifier, Congress has repeatedly used budget policy to block HHS from working on the issue. Nevertheless, a national solution is needed, and federal action is the logical solution to a national challenge. Given the public sector reluctance to move forward on a patient identifier, however, the private sector could consider advancing a solution. Market actors such as Surescripts have created individual identifiers to support information exchange.
- Rely on existing polices and the incentives of new models of care to encourage information sharing by providers. Federal policies play a dominant role in establishing the business case for information sharing, infrastructure development and education on how to use standards

correctly. ONC and others have suggested that the federal government could use payment policy and other regulatory efforts, such as the Medicare Conditions of Participation, to compel information sharing. The IAG, however, concluded that the existing market pressures from consumers, the meaningful use program, and new models of care delivery are already motivating information sharing sufficiently, and will continue to do so in the coming years as payment systems move from rewarding volume to rewarding value and consumers exert increased demand. Adding additional payment policy drivers aimed at providers is unnecessary, and could prove counterproductive if they become overly proscriptive or contradict the larger set of incentives.

While the need for action is urgent, many federal initiatives in the health IT space, and particularly meaningful use, have experienced unintended consequences because the timelines set in policy were unrealistic. Future efforts must be mindful of the scale and scope of change being con-

templated, and allow for the many steps required

for product development, financing of systems,

work flow design and workforce training.

Adopt a reasonable timeline for change.

State governments should be discouraged from establishing unique requirements that increase variation in standards and policies because variability diminishes the ability to share information across state lines. State policies also may play a role in establishing the business case for information sharing and infrastructure development.

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## Appendix B. American Hospital Association Principles for Realizing the Promise of Information Technology

Many hospitals and health systems have been pioneers in harnessing the opportunity of information technology (IT) to improve patient care and quality. We are now challenged to extend the use of IT and integrate it into routine care processes in hospitals big and small, in both rural and urban areas. The Administration and Congress have prioritized adoption of IT, and in particular electronic health records (EHRs). The AHA will be a leader and partner in bringing the promise of IT to health care. The following principles will guide the association's efforts:

## (1) IT is an enabling tool for improving quality and safety.

The work of hospitals is caring for patients. Every day they strive to improve the safety and quality of that care. Research has shown that certain kinds of IT—such as computerized provider order entry (CPOE), computerized decision support systems, and bar-coding for medication administration—can limit errors and improve care. But IT adoption alone is not the goal. Rather, investments in IT should be driven by the quality and safety improvement opportunities they bring. IT can help ensure that the right information is available in the right place at the right time to treat patients. IT can also be a tool for improving efficiency.

#### (2) Standards for interoperability should be harmonized and operationalized.

The full promise of health IT will come when health information can be easily transferred from one computer system to another. The ability to easily exchange health information in a meaningful way-or interoperability-is needed both across departments in a single hospital and among health care providers. The exchange of health information requires that it be in a structured format that can be recognized and "understood" by a computer. Standards are needed for the vocabulary, content, and messaging of information, so that data from one system can be seamlessly incorporated into another. Given the complexity of health care, standards are needed in many different areas, but coming to agreement on a set of standards is crucial. It will also encourage further use of IT by decreasing the costs and facilitating the exchange of data.

Standards-setting organizations have already developed many different standards, with multiple standards to choose from in some areas. For example, LOINC is a standard vocabulary to describe laboratory values. DICOM is a standard for transmitting digital images. SNOMED provides a vocabulary for medical practice. The HL7 standards address messaging. In other areas, such as clinical documentation, no standards have yet been developed.

Coming to agreement on the standards to be used will require collaboration and a private-public partnership that prioritizes where standards are needed, follows a consensus-building process to determine which standards to adopt, and ensures that they can be operationalized. Key stakeholders, including providers, payers, standards organizations, vendors, and regulators must be part of the discussion and agree to an implementation process. This process has begun under the American Health Information Community established by the Administration, and must move as quickly as possible. An early task for the group will be development of a timeline that is realistic, and sets out goals for reaching agreement and moving forward.

As was learned through the HIPAA administrative simplification process, standards adoption must also be accompanied by detailed guidance on how they should be implemented. Hospitals will also need to provide continuity of operations as they transition from their legacy systems to the adopted standards. Implementation will require examination of the kinds of transactions that are likely to occur, what business processes support them, and what steps need to be taken to ensure that all end users are implementing the standards consistently.

## (3) Information exchange should be promoted as a public resource.

Use of EHRs within hospitals and physician offices promises to improve quality of care. However, even greater benefits can be obtained from the

sharing of information across health care providers, so that, for example, emergency department staff can see medical histories, and primary care physicians can know what medications were given during an inpatient stay. Some hospitals have more advanced IT systems than the physicians practicing in their community. To facilitate sharing of clinical information and improve patient care, hospitals may want to provide community physicians with hardware, software, or other assistance that would allow them to maintain EHRs for their patients. However, hospitals in this situation must be careful of the Stark and anti-kickback laws. which prevent physicians from referring patients to hospitals or other providers with which they have a financial relationship for most services. Obtaining exceptions and safe harbors to these laws is essential to facilitate IT adoption and information exchange.

Health information cannot be seen as belonging to an individual organization. Improved clinical care will come when the right information is available to the right provider at the right time, so that it can be used in caring for the patient. Achieving that goal requires a model where the data do not belong to an individual organization, physician, or vendor, but become a public resource that facilitates information exchange. Local and regional networks for information exchange have begun to emerge, but are still in their infancy. More work is needed to understand the governance structures necessary to promote information exchange and the financing strategies needed to build this kind of public resource. Having standards for information exchange will also be necessary.

## (4) Privacy and security of electronic records are paramount.

Americans trust hospitals with their lives. Hospitals are committed to protecting that trust — both in the care that is provided and in the protection of patients' health information. Historically, hospitals have worked diligently to ensure the privacy and security of personal health information and continue to do so under the provisions of the Health Insurance Portability and Protection Act of 1996. They must be vigilant in maintaining and upgrading those systems over time. However, the multiplicity of privacy rules from states, local governments, accrediting bodies, and other organizations that can be laid on top of the HIPAA requirements makes compliance difficult and can interfere with patient care. Simply laying out all of the relevant state, federal, and other rules can be a monumental task, let alone determining how to comply when they may conflict. A single set of privacy rules is needed to facilitate the use of IT, ensure access by health care providers to needed information at the point of care, and allow patients and families to share information about themselves with their care providers.

## (5) IT should help maximize patient participation in care.

Today, medical records primarily reside with the providers of care. However, giving patients access to their health information can help them become more involved in their care, and make decisions regarding their own care or the care of their family members. Patients can also contribute valuable information to their health records that can help in choosing treatment plans, such as

which medications they are actually taking, or frequent measurements of weight, blood pressure, or blood sugar levels. Some people are adopting personal health records that they maintain, either on their own or with their insurers. As hospitals and other providers adopt EHRs, they should consider how and when patients could access them, and whether they can interact with personal health records maintained by patients.

## (6) Successful IT adoption requires addressing barriers.

It is time for the benefits of IT to be realized throughout the health care system. Encouraging adoption by hospitals will require lowering critical barriers, such as the high costs of acquiring, maintaining, and upgrading systems of IT and the lack of financing to do so. IT products currently on the market do not routinely work together, so that connecting separate systems requires expensive customization. In addition, they often do not meet the needs of healthcare professionals and may not always add value. Availability of welltrained IT staff may become a constraint as more hospitals implement IT. Finally, successful implementation of IT that improves safety and quality requires significant changes to work processes. Hospital staff, IT professionals, and physicians must work together to create better ways of caring for patients.

Ultimately, IT should be a tool not only for improving quality, but also for improving the professional lives of our care providers. It should enable them to be more efficient and effective, find their jobs more rewarding, and engage in continuous learning.

Adoption is likely to be incremental and evolutionary, with hospitals focusing on applications that add value and that make sense given their stage of adoption and quality improvement priorities. Hospitals can help each other through sharing lessons learned and peer-to-peer connections, which AHA will facilitate. We must also work with Congress, plans, employers, and vendors to lower the financial barriers. Technical assistance on how to work with clinical staff and vendors may increase the odds of successful implementation. Certification of IT products can build confidence among buyers in their ability to perform and give vendors guidance on the functions to build into their systems.

#### (7) IT must be a shared investment.

Hospitals and health systems currently bear the sole burden for implementing costly IT systems in their facilities. The costs of implementation and ongoing maintenance vary by the size of the hospital, as well as by the functions to be installed. A full clinical IT system that includes CPOE and an

EHR will cost tens, if not hundreds, of millions of dollars. CPOE on its own has been estimated to cost about \$8 million for a 500-bed hospital (First Consulting Group 2003). And, of course, initial investments must be supported by ongoing maintenance and upgrading.

Hospitals make these investments because they improve quality and safety and because it is the right thing to do. However, in a world of shrinking margins and competing demands for capital, not all hospitals can finance these systems. Moreover, the financial benefits of IT investment often accrue to payers, employers, and other purchasers of care through decreased lengths of stay and fewer admissions, not to hospitals themselves. As major beneficiaries of IT investments, employers and payers (including the federal government) must share in the costs of investment. Possible mechanisms for the government, employers, and payers to finance IT include low-interest loans, targeted grants, and increased reimbursements for those using IT.

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#### Appendix C. Efforts to Improve Interoperability

Federal Government Initiatives. The federal government has used the requirements of meaningful use and related certification criteria to promote interoperability, with limited success. Stage 2 of meaningful use established a reliance on Direct, a version of secure email to share information. As a result, exchange across settings for meaningful use is generally point-to-point exchange of a document, with limited ability to integrate and use the data received. The Direct requirement also has led to the need for a new set of email addresses for all providers that meet the Direct standards, and contracts with health information service providers (HISPs) to facilitate the exchanges. HISPs may be run by a vendor, provided by an HIE or be a separate network, such as Surescripts. To facilitate exchange, HISPs must be able to exchange with individual providers and among themselves. Sometimes, the EHR vendor chosen by a hospital or health system determines the HISP that can be used.

The federal government also invested in state-designated Health Information Exchanges (HIEs). From 2010 to 2014, ONC provided \$570 million to 56 states and territories to fund to state-level HIEs, as called for in the American Recovery and Reinvestment Act of 2009. While there are some state-designated HIEs that are moving forward, many have not matured to a state where they can

meet provider needs for information sharing. And, with federal funds depleted, some are challenged to find a sound business model for the future.

In April 2014, a group of scientific advisors commissioned by HHS, called the JASON group, released a report that was highly critical of the current state of interoperability in health care. The group recommended that ONC create an overarching data infrastructure for health care, and require software vendors to create and publish standard application program interfaces (APIs) that would allow others to access data contained in their systems, and use it for additional programs via standard protocols. This approach is being explored but is still in a draft stage.

ONC released a "10-Year Vision to Achieve an Interoperable Health IT Infrastructure" in summer 2014, followed by a January 2015 report titled "Connected Health and Care for the Nation: A Shared Interoperability Roadmap." These reports have placed interoperability into a very large frame – a learning health system – that addresses many different objectives and proposes many new policy levers. A more narrow approach focused on standards, implementation guidance and efficient exchange networks could lead to early success, which would build a platform for future efforts.

Private Sector Initiatives. Over the past five years, many private sector initiatives have been undertaken to enable information sharing. Facing the need to share information without access to an existing exchange infrastructure, a number of health systems have established their own HIEs to support their needs to share information across the continuum, and to support new care delivery and financing models. Not all hospitals and health systems, however, have the ability to do so. In addition, health information will likely need to cross system boundaries to truly follow the patient.

Groups of vendors or providers also have come together to develop a common approach. The CommonWell Health Alliance, for example, is addressing some of the major interoperability challenges, such as identity management, record locator services, consent management, and authentication. The Care Connectivity Consortium (CCC) brings together major health systems to create effective health information exchange. The CCC operates a learning lab to develop and share HIE solutions and actively collaborates with HealtheWay. Healtheway is a non-profit, public-private collaborative that serves as a network of networks. The organization supports the eHealth Exchange (formerly referred to as the Nationwide Health Information Network Exchange) that was started by ONC in 2007. HealtheWay participants operate under a common set of standards and specifications. They use exchange standards that

have been adopted by HHS, but were deemed optional for 2014 certification by ONC. While these initiatives are underway, they have yet to result in widespread improvements in interoperability.

Other groups are addressing specific aspects of interoperability. For example, the Healthcare Services Platform Consortium is focused on creating a new marketplace for plug-and-play interoperable healthcare applications. The consortium is focused on standards selection, testing, conformance evaluation, certification of software, and commitment from vendors to support the standards chosen. Similarly, the Center for Medical Interoperability seeks to provide a "neutral environment for health system stakeholders to develop standards-based technical solutions to increase interoperability of medical technology" that spans medical devices and enterprise systems. For administrative transactions, CAQH and CORE support adoption of standards and operating rules to facilitate information exchange.

The private sector also includes multiple standards development organizations (SDOs), such as HL-7, which develop many standards used in health care. HL-7 is developing a new standard – Fast Healthcare Interoperability Resources (FHIR) to help address the barriers to interoperability. HL7 also maintains other standards used for meaningful use, such as the Consolidated Clinical Document Architecture.