Advancing Interoperability, Information Sharing, and Data Access:
Improving Health and Healthcare for Americans

February 2019

BIPARTISAN POLICY CENTER

HEALTHCARE LEADERSHIP COUNCIL

Letter from Bipartisan Policy Center Healthcare Leaders

Paper-based medical records are mostly a thing of the past, thanks in large measure to the 2009 Health Information Technology for Economic and Clinical Health (HITECH) Act and the hard work of many individuals and organizations both within the government and the private sector. Today nearly 90 percent of physicians and hospitals in the U.S. use electronic health records.

This is significant and noteworthy progress worth applauding, but we cannot stop there. In order to leverage the power of EHRs to improve care, we must advance interoperability—enabling health information technology systems used across the continuum of care to connect with one another—to improve information sharing among the many professionals and organizations that provide care to a single patient and increase access to data for both providers and for patients themselves.
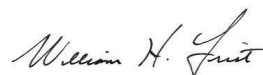
This report represents the collective insights of more than 100 leaders in health care regarding these challenges. Together they developed both a shared vision of an interoperable health care system and recommendations on priorities, private sector actions, policies, and measures of interoperability progress.

Supporting better care—higher quality, safer, more cost-effective, patient-centered care—and better health outcomes requires that we diligently pursue the vision of interoperability to make it a reality. It is a complex pursuit. This report recommends prioritizing two key areas: 1) giving providers easier access to clinical information at the point of care, and 2) giving patients easier access to their own health information. Improvements in both these priority areas will result in better care and better health outcomes.

As the science of medicine continues to advance and new delivery system and payment models take hold, the tools that support caregiving must keep pace. The recommendations in this report are designed to bring better data to the bedside, the exam room, and to patients. They lay the foundation for how we improve the health of populations and advance medical breakthroughs that provide new therapies for patients in need. Data is knowledge, and knowledge is power. Let's harness that power to provide all patients with better care, better information, and, ultimately, better health.

Senator Tom Daschle
Former Senate Majority Leader
BPC Co-Founder

Senator Bill Frist, M.D.
Former Senate Majority Leader
BPC Senior Fellow

Letter from the Healthcare Leadership Council

It is difficult to comprehend the sheer magnitude of data that exists in various repositories throughout our healthcare system. Every day physicians' offices, hospitals, clinics, laboratories, pharmacies, health plans, and home care providers are generating information about patients and the care they receive, and patients themselves are increasingly generating and transmitting health data through wearable devices. Some have projected that 30 percent of all data worldwide is health-related.

If that data can be more effectively shared and made accessible through interoperable systems, we can accelerate progress toward solving the critical and complex challenges facing American healthcare. Health outcomes can be significantly improved. The cost of healthcare delivery can be reduced. The patient experience can be greatly enhanced. Data interoperability also opens the door to new advances in biomedical and technological innovations, elevating population health. And with easier access to data, patients can better engage in their healthcare.

This future is within reach. Achieving it has long been a priority of the Healthcare Leadership Council, an alliance of chief executives from all sectors of American healthcare. We have been pleased to work with the Bipartisan Policy Center in developing a consensus understanding of the progress that has been made toward nationwide health data interoperability and improved information sharing, and overcoming the barriers that remain to attain that goal.

Healthcare leaders are unequivocally committed to removing all obstacles to the essential flow of health information while, at the same time, ensuring data security and patients' right to privacy. With our partners at BPC—and with research support from the University of California, San Francisco—we have crafted a report that not only describes the dynamic future that will take shape when electronic health systems can "talk" to each other, but outlines the private sector actions and public policies necessary to get there.

Today, consumers can change cell phone carriers without having to get a new mobile number. We can check our account balances no matter which bank's ATM we're using. It's time to bring that same 21st century interoperability to healthcare. The benefits to doing so extend well beyond simply convenience and will include better care, longer and healthier lives, and a more sustainable and innovative healthcare system.

Mary R. Grealy
President
Healthcare Leadership Council

Neil de Crescenzo
President and CEO
Change Healthcare, and Chairman,
Healthcare Leadership Council

Executive Summary

Information about an individual's health and healthcare is needed to support coordinated, safe, high-quality, cost-effective, patient-centered care. Much of this information resides in the multiple settings where patients receive care and services, including physician offices, clinics, hospitals and health systems, laboratories, pharmacies, radiology centers, health plans, and even with patients themselves. Interoperability of health information technology (IT) systems helps bring this information to the point of care to support clinical decision-making. It also supports individuals as they navigate their health and healthcare.

The vast majority of clinicians and hospitals have adopted electronic health records (EHRs).[1,2] The next step is to accelerate interoperability of EHRs and other health IT systems to bring information to clinicians and patients seamlessly.

Progress is being made. The percentage of U.S. non-federal acute care hospitals that electronically find patient health information, and send, receive, and integrate patient summary of care records from sources outside their health systems, has nearly doubled in the last four years, from 23 percent in 2014 to 41 percent in 2017.[3] Ninety percent of hospitals and 48 percent of office-based physicians are electronically sending or receiving (or exchanging) patient health information with health care providers outside their organizations.[4,5] Individuals are increasingly able to access their health information electronically.[6] But more work is needed.

The federal government has taken many actions to accelerate interoperability, including implementation of the bipartisan 21st Century Cures Act, which was signed into law in December 2016. On February, 11, 2019, the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) proposed new rules to support the access, exchange, and use of electronic health information. The private sector has also taken several actions.

The chief executives of organizations represented by the Healthcare Leadership Council (HLC) and the Bipartisan Policy Center came together in 2018 to identify ways to further advance the interoperability of systems and electronic information sharing to support better health outcomes and higher-quality, safer, more cost-effective, and patient-centered care for individuals and populations in the United States. HLC and BPC drew upon the experiences and expertise of more than 100 individuals representing every sector of health care, including clinicians, hospitals and health systems, long-term and post-acute care (LTPAC) providers, health plans, life sciences organizations, EHR and other technology developers, data analytics companies, and patients.

Supporting better health outcomes for individuals and populations requires an interoperable healthcare system in which the patient is at the center of care and the right data are available to the right person at the right time. Access to high-quality, accurate, and actionable data is seamless and integrated within clinical workflows, providing value and convenience, as well as reducing healthcare costs. There is trust in the system; privacy is protected, and information is kept secure.

Action to improve interoperability should initially focus on two priority areas: (1) bringing information to the point of care to support care delivery and (2) meeting the information needs of individuals to support their health and healthcare.

Advancing interoperability will require leadership and action in four key areas, outlined below.

1. STRENGTHEN THE BUSINESS CASE

1.1. Align Incentives Among Payers and Providers

Payers should collaborate with providers to gain agreement on and drive adoption of baseline expectations for interoperability and information sharing through payment incentives that focus on outcomes versus volume, contracts, and other mechanisms.

1.2. Align Incentives of Providers and Their Technology Partners

Providers, including clinicians, hospitals, health systems, specialty societies, and group purchasers, should collaborate with EHR and other clinical software developers to gain agreement on and drive adoption of baseline expectations for interoperability for products through incorporation into contract language. Existing requirements, such as those included in the ONC Health IT Certification Program, should be leveraged. Clinical software and other technology developers and vendors should collaborate with their customers to integrate expectations for interoperability within their products.

1.3. Engage Individuals

Providers, payers, and technology developers should engage individuals to identify and prioritize information access expectations.

2. IMPROVE TECHNICAL INFRASTRUCTURE

2.1. Adopt Common Baseline Standards to Improve Patient Matching

To improve patient matching, providers, software developers, payers, and other health care organizations should collaborate on the identification and collection of a common set of data elements using federally adopted standards.

Providers, software developers, payers, and organizations representing individuals, should collaborate on efforts to explore, pilot, and evaluate the feasibility of widespread adoption of patient-centered approaches to identification.

2.2. Prioritize Interoperability and Standards Conformance in ONC Health IT Certification

ONC should prioritize interoperability and require real-world testing to assess conformance with interoperability standards in future editions of the ONC Health IT Certification Program.

2.3. Pursue Rapid Adoption of HL7 FHIR®-Based APIs to Accelerate Information Sharing

Providers, EHR and other software developers, payers, and other health care organizations should expand upon existing interoperability efforts by pursuing rapid adoption and implementation of HL7 Fast Healthcare Interoperability Resources (FHIR®)-based or other open standards-based application programming interfaces (APIs), to accelerate interoperability, data access, and information sharing.

3. IMPROVE POLICIES AND REGULATIONS

3.1. Implement a Common Notice of Information Access for Patients

Healthcare organizations should collaborate with organizations representing individuals as well as with the federal government, to reach agreement on a standard "Notice of Information Access Practices" and voluntarily make such notice available to patients to reduce confusion and make it easier for individuals to access their health information.

3.2. Align Privacy Laws with HIPAA

States should consider harmonizing privacy laws to align with the Health Insurance Portability and Accountability Act (HIPAA).

The Department of Health and Human Services (HHS) should align consent policies for substance use disorder treatment under 42 CFR Part 2—Confidentiality of Substance Use Disorder Patient Records—with HIPAA.

4. GOVERNANCE AND LEADERSHIP

4.1. Collaborate on Measurement and Improvement

Public- and private-sector leaders should collaborate on the identification and annual reporting of key measures that assess national progress on interoperability and information sharing to support bringing information to the point of care and providing individuals access to their own health information. They should convene efforts to define and launch the execution of private sector actions that will accelerate progress on measures.

Introduction

Interoperability of systems, information sharing, and data access play a critical role in improving health outcomes, lowering healthcare costs, and improving the patient experience of care.

Much of the information about an individual's health and healthcare reside in the many settings where care and services are delivered. This includes physician offices, clinics, hospitals and health systems, laboratories, pharmacies, radiology centers, health plans, and even with patients themselves. Mobilizing such information not only supports coordinated, safe, and high-quality care, it also supports delivery system and payment reforms, transparency efforts, advances in research and biomedical innovation, public health priorities, and the ability of individuals to manage their health and healthcare.

As a result of the federal government's investment of nearly $40 billion in health information technology (IT) through implementation of the Health Information Technology Economic and Clinical Health (HITECH) Act, the vast majority of clinicians and hospitals have adopted electronic health records (EHRs).[7,8] Efforts are now underway to improve interoperability of these systems to support improvements in health and healthcare and significant progress is being made. For example, the percentage of U.S. non-federal acute care hospitals that electronically find patient health information, and send, receive, and integrate patient summary of care records from sources outside their health systems, has nearly doubled in the last four years, from 23 percent in 2014 to 41 percent in 2017.[9] Ninety percent of hospitals and 48 percent of office-based physicians are electronically sending or receiving (or exchanging) patient health information with health care providers outside their organizations.[10,11] Individuals are increasingly able to access their health information electronically.[12] But more work is needed.

Several actions have been taken by both the public and private sectors to advance interoperability and information sharing. For example, the 2015 Edition of the ONC Health IT Certification Program contains several provisions designed to advance interoperability including new interoperability-focused standards and requirements associated with application programming interfaces (APIs).[13] The 21st Century Cures Act—a bipartisan bill passed nearly unanimously in December 2016—also contains several provisions designed to advance interoperability, including those related to reducing information blocking and advancing a trusted exchange framework and a common agreement for exchange between health information networks nationally.[14] Implementation of the Act is now well underway. On February 11, 2019, CMS and ONC released proposed rules to support seamless and secure access, exchange, and use of electronic health information.

The chief executives of organizations represented by the Healthcare Leadership Council (HLC) and the Bipartisan Policy Center came together in 2018 to identify ways to further advance the interoperability of systems and electronic information sharing to support better health outcomes and higher-quality, safer, more cost-effective, and patient-centered care for individuals and populations in the United States.

This report describes the results of this work, including a shared vision for an interoperable healthcare system, a review of public- and private-sector progress, the case for change, priority areas of focus, measures of interoperability progress, and recommendations for both the private sector and the public sector.

The report was informed by more than 100 individuals representing every sector of health care, including clinicians, hospitals and health systems, long-term and post-acute care (LTPAC) providers, health plans, life sciences organizations, EHR and other technology developers, data analytics companies, and patients. HLC and BPC engaged University of California, San Francisco (UCSF) researchers who interviewed more than 50 individuals representing HLC and BPC members, as well as other health IT and interoperability experts. Detailed methods, along with the UCSF report, can be found at Appendix II. HLC and BPC also gained input during multiple meetings with members—including CEOs—and public sector leaders, including an all-day roundtable discussion conducted in October 2018 with representatives of about 50 organizations which yielded valuable insights.

Shared Vision for an Interoperable Healthcare System

Supporting better health outcomes and higher quality, safer, more cost-effective, patient-centered care for individuals and populations requires advancing interoperability of systems and electronic information sharing. In an ideal vision for an interoperable healthcare system, the patient is at the center and the right data are available to the right person at the right time. Access to high-quality, accurate, and actionable data is seamless and integrated within clinical workflows, providing value and convenience, as well as reducing healthcare costs. There is trust in the system; privacy is protected, and information is kept secure.

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"The journey to a value-based, efficient healthcare system must be built on a foundation of seamless, interoperable health data. This research effort informs the industry of where we are today, and points to the roles private and public sectors can play to make further progress on interoperability—ultimately making the healthcare system better for all stakeholders—most importantly patients. We look forward to collaborating with policymakers and all industry participants on the path forward."

—NEIL DE CRESCENZO, PRESIDENT AND CEO, CHANGE HEALTHCARE AND CHAIRMAN, HEALTHCARE LEADERSHIP COUNCIL

Progress on Interoperability

Numerous actions have been taken by both the public and the private sectors to advance interoperability in recent years.

Many of the federal government's activities related to interoperability have been centered on implementation of the 21st Century Cures Act, the key provisions of which are summarized below:

- Clearly defining interoperability: "[E]nables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and does not constitute information blocking."

- Requiring that health IT developers or entities, as a condition of certification: (1) publish APIs and allow health information from such technology to be accessed, exchanged, and used without special effort and (2) successfully test the real-world use of the technology for interoperability.

- Requiring the U.S. Department of Health and Human Services (HHS) ONC, within to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."

- Requiring the Office of the Inspector General to carry out enforcement activities related to information blocking, including working with ONC to issue rules on "reasonable and necessary" exceptions to the information blocking prohibition.

- Requiring the Government Accountability Office to conduct a study to review the policies and activities of ONC and other stakeholders to ensure appropriate patient matching and survey ongoing efforts to assess effectiveness.[15]

A proposed rule addressing interoperability, information blocking, and the ONC Health IT Certification Program was sent to the Office of Management and Budget on September 17, 2018, launching a 90-day timeline for the agency's review.[16] On February 11, 2019, CMS and ONC issued proposed rules associated with the use of APIs, information blocking, and the trusted exchange framework.

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> *"One of the most powerful levers we have to improve health outcomes and reduce health care costs is the seamless sharing of clinical data with consumers and providers, regardless of technology systems. To realize the potential of the digital health era, we must empower individuals with information to engage in their own health, while creating pathways to ensure the right information is available at the right place and time for high-quality, cost-efficient care delivery. These priorities have guided Cerner's work for decades, and an open and interoperable health care ecosystem built on commonly adopted information-sharing standards remains fundamental to advancing person-centric care today. I'm supportive of the policy proposals the HLC and BPC have suggested to encourage further progress toward meaningful interoperability of systems and electronic information sharing in the United States."*
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> **—BRENT SHAFER, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, CERNER**

On January 5, 2018, ONC released the Draft Trusted Exchange Framework, which outlines a common set of principles that networks will need to follow to engender trust, as well as minimum terms and conditions for trusted exchange that would be incorporated into a Common Agreement.[17] The Common Agreement, a national exchange agreement, is proposed to be a legal

binding contract that "qualified health information networks" and health information networks would voluntarily sign onto and agree to abide by. An updated version of the Trusted Exchange Framework and Common Agreement is expected to be implemented through formal rule-making and published in the Federal Register in 2019.[18]

The 2015 Edition of the ONC Health IT Certification Program includes provisions that will accelerate interoperability. For example, it contains additional advanced standards and implementation specifications to support interoperability and requires certified health IT to demonstrate that it can provide application access to a "Common Clinical Data Set" via an open API.[19] Open APIs are technology that allow one software program to access the services provided by another software program. Open APIs can support patients' ability to have greater access to their health information through, for example, smartphones.[20] They can also enable clinicians to access their patients' health information individually, and as a summary of care document that they can exchange with other clinicians.[21]

In 2018, CMS issued hospital and physician payment rules that prioritize interoperability requirements, changing the name of the CMS Medicare and Medicaid EHR Incentive Programs to *Promoting Interoperability* Programs.[22,23] CMS also launched the Medicare Blue Button 2.0, an API that provides access to four years of Medicare Part A, B, and D data for 53 million Medicare beneficiaries. This data includes the type of Medicare coverage, drug prescriptions, primary care treatment, and cost.[24]

The Administration also launched the *MyHealthEData* initiative, which aims to empower patients by ensuring that they control their healthcare data and can decide how their data can be used, while keeping that information safe and secure. The White House Office of American Innovation leads this federal government-wide initiative with participation from HHS—including CMS, ONC, and the National Institutes of Health, as well as the U.S. Department of Veterans Affairs. It is intended "to break down the barriers that prevent patients from having electronic access and true control of their own health records from the device or application of their choice. This effort will approach the issue of healthcare data from the patient's perspective."[25]

There are also a number of private sector organizations and initiatives focused on various aspects of health information exchange and interoperability, including the Commonwell Health Alliance;[26] The Sequoia Project and its two subsidiaries Carequality and eHealth Exchange;[27] the CARIN Alliance;[28] Integrating the Healthcare Enterprise (IHE);[29] and the Strategic Health Information Exchange Collaborative.[30] There are also more than 100 regional health information exchanges (HIEs)[31] and other private sector networks—such as Surescripts[32]—that facilitate data exchange.

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> "As patients become more actively engaged consumers of healthcare, and as the industry transitions to a value-based payment model, care providers must have the ability to easily access and share patient health information at the point of care. The Surescripts Network Alliance, including health systems, technology vendors, payers, pharmacies, and pharmacy benefit managers, is working to accelerate healthcare interoperability each and every day. With the right information, at the right place, at the right time, providers can make more informed care decisions which leads to better outcomes, reduced costs, and improved patient and provider experiences."
>
> **—TOM SKELTON, CHIEF EXECUTIVE OFFICER, SURESCRIPTS**

Open APIs, such as HL7 FHIR®, have rapidly become a key component of public and private sector efforts to accelerate access to and exchange of health information.[33]

The HL7 Argonaut Project, a private sector initiative, has been developing a core set of HL7 FHIR® implementation specifications which will enable expanded information sharing for electronic health records and other health IT solutions based on modern computing standards.[34] Substitutable Medical Applications, Reusable Technologies (SMART) Health IT is an open, standards-based technology platform that enables developers of apps to seamlessly and securely run across the healthcare system. Developed by Boston Children's Hospital Computational Health Informatics Program and the Harvard Medical School Department for Biomedical Informatics, SMART Health IT defines a health data layer that builds on the HL7 FHIR® API and resource definitions.[35]

SMART on FHIR is a set of open specifications to integrate apps with EHRs, portals, health information exchanges, and other health IT systems.[36] Apple has implemented SMART on FHIR integration between EHRs and the iPhone, enabling iPhone users to visualize, securely store, and aggregate their health records from multiple institutions alongside their patient-generated data. Apple's connection between EHRs and the user's health app utilizes HL7 FHIR® standard APIs as defined by the Argonaut Project. Apple is working with Cerner, Epic, athenahealth, and others in the healthcare community to enable this feature. Supported data types currently include allergies, conditions, immunizations, lab results, medications, procedures, and vitals.[37] Finally, HL7's DaVinci Project is working with ONC and multiple payers, providers, and technology organizations to accelerate the adoption of the HL7 FHIR® standard to support exchange of information for value-based care.[38]

A comprehensive list of public and private sector initiatives related to interoperability can be found in Appendix I.

Case for Change

The benefits of interoperability and information sharing are well-documented. Bringing information about the patient—regardless of where care or services have been delivered—to the clinician and the care team enables well-informed, coordinated, patient-centered care. Supported by information from other care settings, clinicians can avoid duplicative tests, identify and address gaps in care, and avoid medication and other errors—all of which drive higher-quality and more cost-effective care.[39] Interoperability and the sharing of information are also necessary components of delivery system and payment models that reward value and outcomes versus volume, as well as transparency efforts. Interoperability also supports clinical research, post-market monitoring of medical products, and the detection of public health threats. Finally, interoperability and information sharing support individuals' access to their own health information, improving their ability to manage their health and healthcare.

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"Healthcare interoperability is a critical step forward in advancing more patient-centric care. At Pfizer, a patient-focused mindset is deeply embedded within our organization, and we believe it is essential to developing medical innovations that can have a lasting impact on society. However, these medical innovations can only be effective if they are used by the right patient at the right time. Interoperability gives patients, providers, and caregivers access to the right information at the right time for the right patient, to make the right diagnosis and treatment decision. Ultimately, this will lead to improved health outcomes for all patients."

—MIKE GLADSTONE, GLOBAL PRESIDENT, INTERNAL MEDICINE, PFIZER BIOPHARMACEUTICALS GROUP

Advancing interoperability across multiple settings requires cooperation and joint effort across several different types of entities. HLC and BPC members agree that progress toward widespread, nationwide interoperability has been slow because it is not yet driven by a clear, collective business need that ties together the interests of providers, payers, technology companies, and patients.

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"Interoperability of healthcare data will allow for more meaningful solutions to some of the biggest challenges in healthcare today. At Stryker, as we partner with our customers to make healthcare better, interoperability of data provides opportunity to create solutions that improve patient outcomes and bring new efficiencies to the delivery of care."

—TIM SCANNELL, PRESIDENT AND CHIEF OPERATING OFFICER, STRYKER

As illustrated in Figure 1 below, interoperability use cases that emerge from collective business need drive improvements in health outcomes and promote higher-quality, safer, more cost-effective, patient-centered care.

Figure 1. Addressing Business Needs and Improving Outcomes Through Interoperability[40]

Collective Business Need	→	Interoperability Use Cases	→	Better Outcomes: High-Quality, Safe, Cost-Effective, Patient-Centered Care

Payers generate aligned incentives by creating conditions that motivate providers to invest in and use interoperability and demand interoperability solutions from their vendors. This alignment of incentives, however, is not prevalent in the healthcare system. Large-scale investments in interoperability of systems and electronic information-sharing are rare due to higher-priority, competing business needs. As the U.S. healthcare system continues to migrate toward payment models that reward outcomes versus volume, organizations will have a stronger case for greater interoperability investment.[41]

Figure 2 summarizes the benefits of interoperability by stakeholder.

Figure 2. Benefits of Interoperability by Stakeholder

Stakeholder	Benefits of Interoperability
Individuals	When pertinent clinical information is available at the point of care, individuals benefit from care that is of higher quality, better informed, and timely. Individuals also benefit from improved safety, reduced costs, and fewer inconveniences caused by repeat appointments and unnecessary, duplicative tests, treatments, and services, which can be averted with complete clinical data at the point of care. Relevant, patient-generated data from all of a patient's medical services can also help prevent missed diagnoses and medication errors. Similarly, individuals with access to their own health information are more engaged, can make more informed patient and family care decisions, and can more easily share information among caregivers and providers.
Providers	Providers, including clinicians and hospitals, equipped with relevant patient information at the point of care are better prepared to provide high-quality, patient-centered care. Streamlined access to patient information from other providers, including hospitals, physician offices, clinics, as well as other care settings and ancillary service providers such as laboratories, radiology centers, and long-term and post-acute care providers, enables care coordination, improved clinical workflow, and better clinical decision-making. Improved interoperability can reduce provider burden and administrative costs. The typical primary care physician must coordinate care with 229 other physicians working in 117 practices.[42] Having access to patient information also supports quality measure implementation and compliance with government regulations and payment program requirements.
Payers	Payers—or institutions that pay providers for healthcare services, such as health plans, private sector employers or purchasers, the government, and in some cases, individuals—bear financial risk for the costs associated with their beneficiaries' healthcare expenditures. They benefit from lower costs associated with reductions in diagnostic errors, unnecessary tests, and duplicate treatments—which are more likely when providers have comprehensive information at the point of care. Greater information access enables better care coordination and the ability to both measure and improve health outcomes. Payers need to be able to measure health outcomes to implement new payment models focused on value. Payers also benefit when individuals become more engaged in their health and healthcare through access to their own health information. Improved provider and patient access to health information can also help assure that patients take their medications as prescribed. Medication non-adherence has been estimated to cost the U.S. healthcare system between $100 billion and $289 billion annually.[43]
Business/ Industry	Health IT developers and EHR vendors have the incentive to support interoperability if their customers demand it. Pressures from emerging legislative and regulatory payment and compliance regulations also play a key role, including ONC's Health IT Certification program and pending rules on information blocking, which carry potential fines of $1 million per violation.[44] Innovators in business and industry benefit from greater data availability, which supports innovative new products and services, including those focused on data analytics, artificial intelligence, and patient-facing applications.
Clinical Researchers and Manufacturers	Data from the clinical care process play a key role in clinical studies that support the development, regulatory evaluation, approval, and post-market monitoring of drugs, biologics, and medical devices. For example, access to clinical data can support the recruitment of patients for clinical trials. Clinical data can also be used to generate real-world evidence to augment and support clinical studies used for regulatory evaluation and approval, including a new indication for an approved drug or post-approval study requirements as referenced in the 21st Century Cures Act.
Public Health	Access to de-identified patient data across settings significantly improves public health efforts, including surveillance, preparedness, and response efforts for public health threats, such as infectious disease outbreaks, natural disasters, and epidemics.

Priority Areas

Despite the temptation to assess the interoperability of health IT systems for a broad range of use cases, HLC and BPC members acknowledge that prioritizing a few key areas is necessary to effect meaningful change through measurement and private and public sector action. HLC and BPC members, with input from other experts, determined that focusing on the following two key interoperability priorities would be most impactful:

- Information needs at the point of care to support care delivery; and

- Information needs of individuals to support management of their own health and healthcare.

Focusing on these two priority areas, without losing sight of the individual as the ultimate beneficiary of interoperability, provides a manageable approach toward driving change. HLC and BPC members also recognize that other priority areas—including efforts to improve population health, research, and public health—will benefit from and leverage progress in the clinical and patient-focused priority areas.

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"Use of data, analytics and tools such as artificial intelligence will transform our ability to cure and prevent illness. This depends on interoperability, especially the ability of providers to access data at the point of care and within workflow. This report recommends essential steps by private and public stakeholders. We look forward to working with HLC and BPC to make this a reality."

SUSAN DEVORE, PRESIDENT AND CHIEF EXECUTIVE OFFICER, PREMIER HEALTHCARE ALLIANCE

Priority Area 1: Bringing Information to the Point of Care to Support Care Delivery

As illustrated in Figure 3, information from hospitals, ambulatory practices, laboratories, radiology centers, pharmacies, LTPAC providers, payers, and patients plays a critical role in assuring well-informed, patient-centered, safe, coordinated delivery of care. Information from patients can come in many forms, including data from wearables and remote monitoring devices, as well as health apps that capture health information from multiple sources. Increasingly, information from non-medical or social determinants of care is being used by providers to improve health outcomes and care. To be truly impactful, clinical data should be accurate, of high-quality, comparable (or standards-based), sourced, and complete. These data attributes will enable clinicians to filter and prioritize the data for more effective use in clinical decision-making. Access to such information should be seamless and integrated into clinical workflows. Given evolving trends in technology and care delivery, the point of care can extend beyond the office setting or the hospital into the home via telehealth and other digital modes of care. Information flows to the point of care reinforce the primary goal of supporting better health outcomes and higher quality, safer, more cost-effective, patient-centered care.
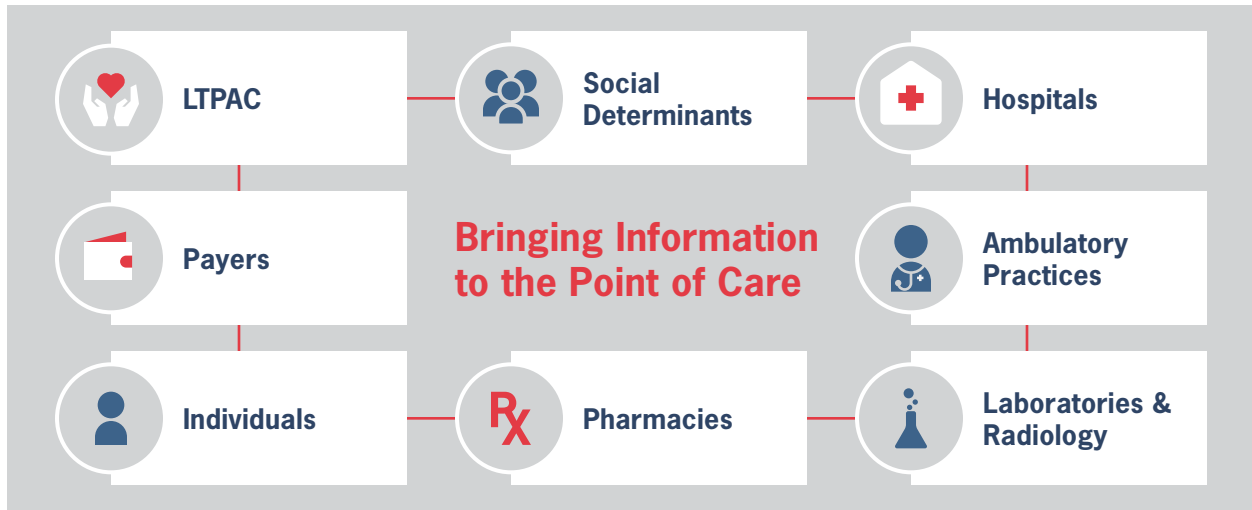
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"Interoperability is essential to achieve our quality and affordability goals."

—JAEWON RYU, INTERIM PRESIDENT AND CHIEF EXECUTIVE OFFICER, GEISINGER

Figure 3. Information Sources Needed at the Point of Care

LTPAC · Social Determinants · Hospitals · Payers · **Bringing Information to the Point of Care** · Ambulatory Practices · Individuals · Pharmacies · Laboratories & Radiology
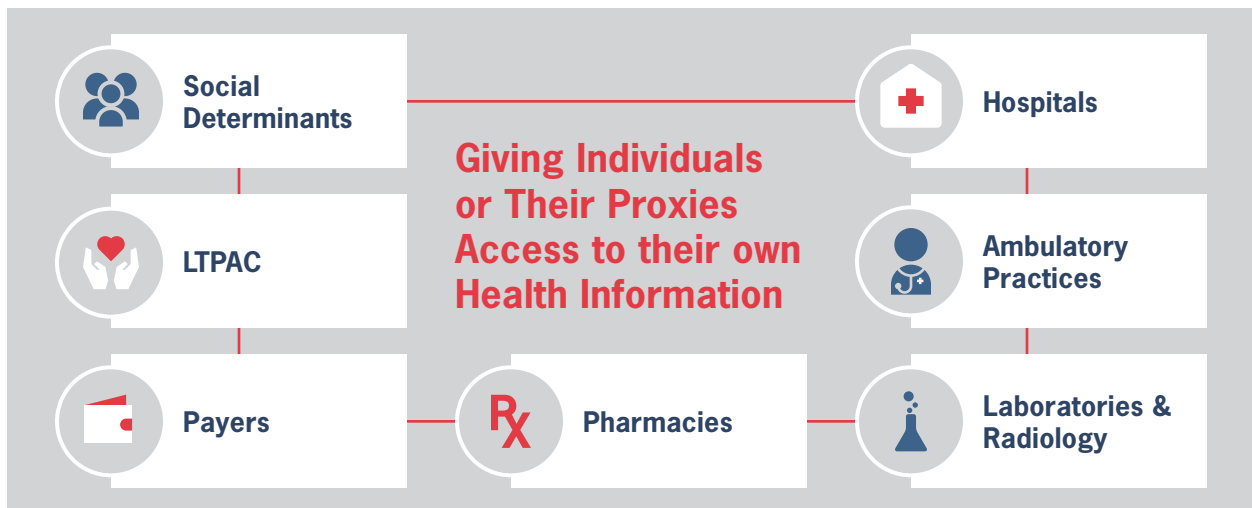
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"Interoperability matters because it allows us to harness clinical and real-world data to provide the information that empowers patients to make informed health decisions. This is personalized care management."

—MARC BOUTIN, JD, CHIEF EXECUTIVE OFFICER, NATIONAL HEALTH COUNCIL

Priority Area 2: Giving Individuals Access to Their Own Health Information

As illustrated in Figure 4, data from hospitals, ambulatory practices, laboratories, radiology centers, pharmacies, LTPAC providers, payers, non-medical sources that capture social determinants information, and patients also play a critical role in helping individuals and their proxies engage in and manage their health and health care. Individuals and their authorized caregivers should be able to easily obtain, use, and share their digital health information when, where, and how they want to achieve their goals. People who are actively engaged in their healthcare are more likely to stay healthy and manage their conditions by asking their doctors questions about their care, following treatment plans, eating right, exercising, and receiving health screenings and immunizations. Patients without the skills to manage their healthcare incur costs up to 21 percent higher than patients who are highly engaged in their care.[45] Enabling individuals' access to their own health information reinforces the primary goal of supporting better health outcomes and more cost-effective, patient-centered care.

Figure 4. Information Sources Needed by Individuals

Social Determinants · Hospitals · LTPAC · **Giving Individuals or Their Proxies Access to their own Health Information** · Ambulatory Practices · Payers · Pharmacies · Laboratories & Radiology

Measuring Interoperability Progress

Achieving success in any endeavor requires measuring progress. Recognizing this imperative, Congress—through the Medicare Access and CHIP Reauthorization Act—called upon the HHS Secretary to develop metrics and to publicly report on progress in achieving widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018.[46]

HHS both funds and reports publicly on key measures of interoperability related to several of the clinical and patient access priority areas described in this report. Measures associated with interoperability and information-sharing to support bringing information to the point of care are currently included in surveys of hospitals, physicians, and individuals; results are summarized in Figure 5 below.

Figure 5. National Measures of Progress for Interoperability

MEASURE	NON-FEDERAL ACUTE CARE HOSPITALS (2017)[47]	OFFICE-BASED PHYSICIANS (2015)[48]	INDIVIDUALS (2017)[49]
Electronically send (1) summary of care records in the case of hospitals or (2) patient health information in the case of physicians to any providers outside their organization	88%	38%	
Electronically receive (1) summary of care records in the case of hospitals or (2) patient health information in the case of physicians from other providers	74%	38%	
Electronically integrate (1) summary of care records in the case of hospitals or (2) patient health information in the case of physicians from other providers	53%	31%	
Electronically search for or find patient health information from other providers	61%	34%	
Electronically send, receive, integrate, and search for or find summary of care records of patient health information from other providers	41%	9%	
Offered online access to their medical record by a healthcare provider or insurer			52%
Viewed their online medical record at least once in the past year			28%
Used access to online medical record to:			
• View test results			85%
• Perform one or more health-related tasks			62%
• Download medical record			17%
• Transmit data to outside party			14%

In the past, HHS has also tracked measures associated with health information sharing among skilled nursing facilities and other providers[50] as well as patient access to test results among clinical laboratories.[51]
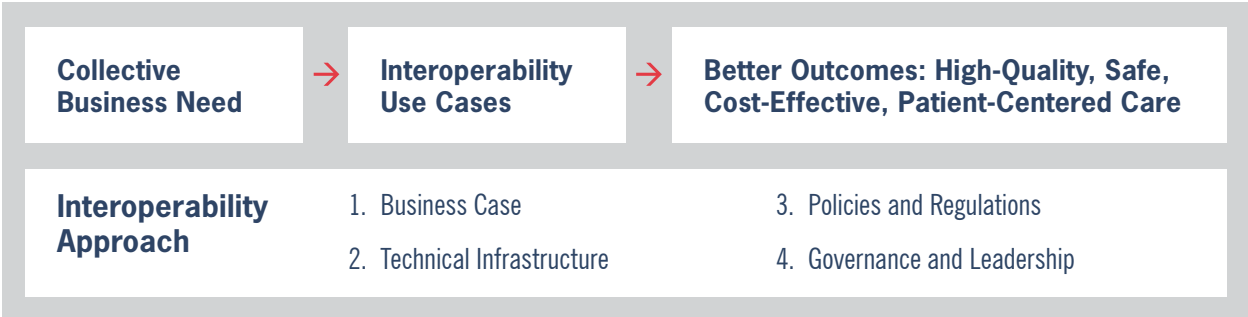
Measure results currently supported by federal dollars offer a national snapshot of interoperability and information sharing—particularly among physician offices and hospitals. More work is needed to measure national progress on other important data sources identified within the two priority areas described in this report—bringing information to the point of care and enabling individual access to health information.

Model for Accelerating Interoperability

While the lack of a collective business need that aligns the interests of payers, providers, technology companies, and patients is the primary barrier to widespread interoperability, additional challenges exist. The costs associated with developing and implementing modifications to support interoperability; the lack of capability to either receive or send data among trading partners; difficulty finding providers' addresses; technical barriers, including slow and inconsistent adoption of standards, concerns about data quality, and challenges with accurately matching patient data; and the need for trust to address concerns about privacy and security all serve as barriers to interoperability and information sharing.[52,53,54]

As illustrated in Figure 6 below, achieving better outcomes through interoperability requires actions that address the multiple barriers to interoperability, including those related to developing a shared business case; technical infrastructure issues, such as those related to standards development and adoption; policies and regulations; and governance and leadership.[55]

Figure 6. Model for Accelerating Interoperability

Collective Business Need	→	Interoperability Use Cases	→	Better Outcomes: High-Quality, Safe, Cost-Effective, Patient-Centered Care

Interoperability Approach	1. Business Case	3. Policies and Regulations
	2. Technical Infrastructure	4. Governance and Leadership

HLC and BPC have identified a set of private and public sector actions in each of these areas—business case, technical infrastructure, policies and regulations, and governance and leadership—to accelerate progress toward nationwide interoperability.

Recommendations

Advancing interoperability to support better outcomes through the delivery of care and access to information among individuals will require leadership and action in four key areas, outlined below.

1. STRENGTHEN BUSINESS CASE

Interviews with members revealed a shared perspective that the U.S. health care system is not pursuing interoperability effectively because it isn't using approaches that have proven successful in other industries and contexts. This is apparent in the lack of widespread business incentives to achieve interoperability. Many efforts to pursue interoperability today pull the key market players along—sometimes unwillingly and sometimes willingly—but with little sense of urgency. This lack of commitment is a symptom of the reality that interoperability is "nice to have" but not a "stay in business" issue. The private sector should use the tools at its disposal to change market dynamics in ways that create a widespread business need for broad-based interoperability.

Key levers to strengthen the business case include healthcare purchasers' and payers' expectations of providers, including those that support delivery system and payment reforms, as well as providers' expectations of their software vendors. In an era of greater financial responsibility and increasing out-of-pocket costs for healthcare, patients can also exercise leverage through purchasing behaviors with their providers and payers.

Continued movement by payers toward value-based care delivery and advanced payment models that reward outcomes versus volume provide greater incentives for information-sharing across an individual patient's multiple providers and ancillary service providers. Just as public and private sector payers are collaborating through a multi-stakeholder, voluntary effort created to promote measure alignment and harmonization through the *Core Quality Measures Collaborative*[56] and its predecessor organizations, providers, payers, and vendors have opportunities to promote uniformity in information sharing.

As software purchasers, providers and clinicians can also play a key role in ensuring greater interoperability of systems, particularly as they replace and upgrade existing systems. The National Academy of Medicine recently published *Procuring Interoperability: Achieving High-Quality, Connected, and Person-Centered Care*, which details approaches for health care organizations to ensure interoperability, including an interoperability needs identification process and a procurement specification process.[57] To help providers select and negotiate the acquisition of an EHR system, ONC published a guide offering strategies and recommendations for negotiating best practice EHR contract terms, including example contract language for promoting interoperability.[58]

Recommendation (Private Sector) 1.1: Payers should collaborate with providers to gain agreement on and drive adoption of baseline expectations for interoperability and information sharing through payment incentives that focus on outcomes versus volume, contracts, and other mechanisms.

Recommendation (Private Sector) 1.2: Providers, including clinicians, hospitals, health systems, and group purchasers, should collaborate with EHR and other clinical software developers to gain agreement on and drive adoption of baseline expectations for interoperability for products through incorporation into contract language. Existing requirements, such as those included in the ONC Health IT Certification Program, should be leveraged. Clinical software and other technology developers and vendors should collaborate with their customers to integrate expectations for interoperability within their products.

Recommendation (Private Sector) 1.3: Providers, payers, and technology developers should engage individuals to identify and prioritize information access expectations.

To facilitate this process, HLC commits to convening providers as well as EHR and other health IT developers to develop baseline expectations of and requirements for interoperability for inclusion in sample model contracts.

2. IMPROVE TECHNICAL INFRASTRUCTURE

Adopt Common Baseline Standards to Improve Patient Matching

Getting to nationwide interoperability and information sharing requires the ability to match a patient's data across health settings and information systems accurately. Unfortunately, patient matching rates vary widely, with health care facilities failing to link records for the same patient up to half of the time.[59] According to a study by the Pew Charitable Trusts, patient matching typically occurs through the use of algorithms, unique identifiers, manual review, or a combination of these methods. Innovation in this area is expected in the future, which may include patient-empowered approaches such as the use of smart phones.[60] Standardizing a set of data elements that providers collect to support patient matching, whether through algorithms or other methods, is expected to significantly improve matching.

The current ban on the federal government's ability to conduct work on a unique patient identifier has limited the federal government's ability to fully collaborate with the private sector on solutions. However, report language contained in appropriations legislation over the last three years encourages the HHS Secretary, working through ONC and CMS, to provide technical assistance to private-sector led initiatives focusing on a coordinated strategy for a patient matching solution.[61] CMS' proposed rule on interoperability issued on February 11, 2019 seeks comment on ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy. Providers, software developers, and other healthcare organizations should therefore collaborate on the identification of a common set of data elements all of which should be collected by providers—using federally adopted standards (such as those contained in the ONC Interoperability Standards Advisory) to support matching. Private sector collaboration involving multiple stakeholders, including health care providers, technology vendors, payers, and health information exchange networks with technical assistance and support from HHS can help to drive a de facto standard for patient matching.

Recommendation (Private Sector) 2.1: Providers, software developers, payers, and other health care organizations should collaborate with technical assistance from HHS on the identification and collection of a common set of data elements using federally adopted standards, to improve matching.

Recommendation (Private Sector) 2.2: Providers, software developers, payers, and organizations representing individuals should collaborate on efforts to explore, pilot, and evaluate the feasibility of widespread adoption of patient-centered approaches to identification.

Prioritize Interoperability and Standards Conformance in ONC Health IT Certification

The ONC Health IT Certification Program is meant to signal which EHR and health IT systems meet federal requirements and include useful functionality. The expense of implementing, maintaining, and updating EHRs and other health IT systems is significant. The ONC Health IT Certification Program is a valuable indicator of whether the EHR technology being purchased meets all federal requirements. In addition to assuring that EHRs meet these requirements when purchased, users expect the EHRs they implement to function at their expected performance level *after* implementation. This expectation was codified into law under the 21st Century Cures Act, which requires "real-world" testing of health IT products under the ONC Health IT Certification Program.[62] ONC's proposed rule issued February 11, 2019 includes provisions for testing. As noted by the National Institute for Standards and Technology (NIST), "[W]ell-defined standards, and conformance to those standards, provide the foundation for reliable, functioning, usable, and interoperable healthcare information systems...the proliferation of healthcare information systems designed without compliance to standards will likely exacerbate, not lessen, current patient care challenges by creating a landscape saturated with systems lacking usefulness, usability, and interoperability...standards must be used and deployed as intended, and conformance testing is the process that helps ensure adherence to the standards."[63]

ONC collaborates with organizations such as NIST as part of program operations to develop functional and conformance testing requirements, test cases, and test tools, and to conduct surveillance of certified health IT.[64] The current 2015 Edition ONC Health IT Certification includes updated criteria that support electronic exchange of interoperable health information.[65] CMS rulemaking to date signals increased emphasis on interoperability.[66,67] To drive closer to the goal of interoperable health IT, ONC should also prioritize interoperability and assure continuous, real-world testing of health IT systems in future rulemaking to ensure that certified products meet the real-world expectations of their end users.

Recommendation (Public Sector) 2.3: ONC should prioritize interoperability and require real-world testing to assess conformance with interoperability standards in future editions of the ONC Health IT Certification Program.

Pursue Rapid Adoption of FHIR-Based APIs to Accelerate Information Sharing

There is growing momentum behind the broad adoption and use of open APIs and specifically HL7 FHIR®, to build upon existing efforts toward advancing interoperability. The 2015 Edition of ONC Health IT Certification requires capabilities for open APIs. However, ONC regulations do not specify HL7 FHIR® for these APIs, as it was an emerging standard at the time the regulations were developed. The expectation is that most certified health IT will use FHIR as the basis for open APIs, and that future regulations and requirements may consider updates to technology standards, including FHIR.

There is still substantial opportunity for organizations to engage more actively in API-related efforts, beginning with engagement in HL7 FHIR® development and implementation processes, and working with groups like the Argonaut Project to operationalize the standards. Also critical is engaging vendors to prioritize which available FHIR-related activities to implement and support in their future upgrades. Ultimately, it is most critical that organizations holding healthcare data turn on all available HL7 FHIR®-based APIs to make the greatest breadth of data available for exchange. Proposed rules issued by CMS and ONC on February 11, 2019 contain several provisions designed to accelerate the adoption of HL7 FHIR® among technology developers and payers.[68]

Recommendation (Private Sector) 2.4: Providers, EHR and other software developers, payers, and other health care organizations should expand upon existing interoperability efforts by pursuing rapid adoption and implementation of HL7 FHIR®-based or other open standards-based APIs, to accelerate interoperability, data access, and information sharing.

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"Greater interoperability will improve care quality and continuity and enhance market transparency, so that consumers can better understand costs and evaluate quality. More accessible information also allows Hearst Health's companies to deliver new tools to help positively impact the quality and cost of care."

—GREGORY DORN, MD, PRESIDENT, HEARST HEALTH

3. IMPROVE POLICIES AND REGULATIONS

Implement a Common Notice of Information Access for Patients

Individuals need access to their own health information to help them make decisions about their health and healthcare. Individuals are beginning to take advantage of these capabilities. The Health Insurance Portability and Accountability Act (HIPAA) gives consumers the right to access their health information. In 2017, half of Americans reported they were offered access to an online medical record by a provider or insurer, up from 42 percent in 2014.[69]

A patient's health information ordinarily resides in multiple places, such as the offices of primary care providers and specialists, clinics, hospitals and health systems, laboratories, pharmacies, radiology centers, and health plans. Obtaining access to this information can be confusing and challenging for patients. Instructions and processes can vary significantly across entities.

Creating and adopting standard language for how patients can gain access to their health information across providers and other health care entities can increase clarity and improve patient access. A standard "notice of information access practices"—like the Model Privacy Notice Forms adopted by eight federal agencies in 2009—can make it easier for consumers to understand how they can obtain access to their health information.[70]

Recommendation (Private Sector) 3.1: Health care organizations should collaborate with organizations representing individuals as well as the federal government, to reach agreement on a standard "Notice of Information Access Practices" and voluntarily make such notice available to patients to reduce confusion and make it easier for individuals to access their health information.

Align Privacy Laws with HIPAA

It has been nearly 20 years since the implementation of HIPAA privacy and security rules. The HIPAA privacy rule has established a uniform framework for acceptable uses and disclosures of individually-identifiable health information within healthcare delivery and payment systems for the privacy and security of information.[71] The healthcare industry has become accustomed to and supportive of the HIPAA privacy and security rules framework and the strong protections it affords consumers. This has a direct impact on the flow of electronic health information. Yet, variations and inconsistencies in consent laws, including those for substance use disorder treatment under 42 CFR Part 2, remain a barrier to interoperability. Varying state and territory laws often serve as a bottleneck to information flow and add to the administrative and legal costs associated with complying with the patchwork of state-specific laws. In order to fully achieve nationwide interoperability, further alignment of state and federal privacy laws is necessary.

Recommendation (Public Sector) 3.2: States should consider harmonizing privacy laws to align with HIPAA.

Recommendation (Public Sector) 3.3: HHS should align consent policies for substance use disorder treatment under 42 CFR Part 2 with HIPAA.

In December 2018, the HHS Office for Civil Rights (OCR) issued a Request for Information, seeking input from the public on how the HIPAA privacy regulations could be modified to drive more care coordination and value in the healthcare system.[72] While HIPAA has served as a constructive and effective framework to protect the privacy and security of individuals' health information, HHS has noted that the privacy rule may impede other forms of care coordination that can drive value.[73] Fine-tuning HIPAA's requirements to improve information-sharing for treatment and care coordination is a necessary step to advance the interoperability of health systems nationwide.

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"Health data interoperability helps assure that our nation's citizens, veterans, and soldiers receive the best care available, even as they move from one provider to another. At Leidos, we believe that the best care is possible only when the consumer is placed at the center of his or her own health and well-being. Data interoperability is essential in making this a reality. Improving and promoting policy and standards to assure that health data is shareable and shared is something we take seriously at Leidos."

—JONATHAN SCHOLL, PRESIDENT, LEIDOS HEALTH GROUP

4. GOVERNANCE AND LEADERSHIP

The Trusted Exchange Framework and Common Agreement (TEFCA)—once finalized—will provide governance for interoperability and health information exchange. Private sector leaders should fully engage in offering comments on the proposed TEFCA once published in the Federal Register, and work together to advance successful implementation of the effort.

Public and private sector leaders can also demonstrate leadership by focusing the U.S. healthcare system and their individual organizations on key measures of interoperability progress and the actions that can be taken to drive improvement on those measures.

While the United States has made progress toward nationwide interoperability, raising awareness of progress and galvanizing private sector action will help the healthcare system overcome remaining barriers and advance efforts to improve information-sharing and interoperability.

Many measures already exist with progress tracked by federally funded efforts. These include measures associated with interoperability and information sharing among hospitals and physician practices.

Additional measures will be needed—many of which can be captured and reported by the private sector—to measure national progress on the information sharing practices of other data sources identified within the two priority areas identified in this report—bringing information to the point of care and enabling individual access to health information. They include the level of information sharing among clinicians and patients with laboratories, pharmacies, radiology centers, behavioral healthcare providers, LTPAC providers, and health plans, and the ability for individuals to access their health information via open APIs with all of such sources, as well as with physician offices, hospitals, and health systems.

Some experts call for additional measures that address the impact of interoperability or methods that eliminate confounders. Others call for methods that do not rely on self-reporting. Measurement can be complicated and difficult. Expanding the number or complexity of measures must be carefully considered, weighing the benefit versus the increased burden of data collection.

Private-sector leaders should highlight a small, impactful set of progress measures—captured at both the organization level and nationally—with their internal staff, as well as with their EHR vendors, customers, and information-sharing partners, to encourage both action and improvement.

Focusing on the key areas listed below, private sector health care leaders—including hospitals and health systems, physician practices, health plans, laboratories, LTPAC providers, pharmacies, radiology centers, and clinical software developers and vendors—should collaborate with federal government leaders to leverage federal measures and reporting where they do exist; develop and implement measures where none exist; convene efforts to identify and take private sector actions to improve performance on measures; and publicly monitor progress on an annual basis.

Key areas of focus should include the level of:

- Clinician and patient access to information from independent laboratories and radiology centers.

- Clinician access to pharmacy data indicating that a prescription has been filled.

- Information sharing between behavioral healthcare providers and primary care physicians, hospitals, and individuals.

- Information sharing between LTPAC providers and clinicians, hospitals, and individuals.

- Clinician and patient access to information from health plans.

- Physicians and hospitals that connect to at least one network.

- Individual electronic access via an open API to health information contained in physician offices, retail clinics, hospitals and health systems, laboratories, radiology centers, health plans, and LTPAC providers.

Recommendation (Private and Public Sectors) 4.1: Public- and private-sector leaders should collaborate on the identification and annual reporting of key measures that assess national progress on interoperability and information sharing to support bringing information to the point of care and providing individuals access to their own health information. They should convene efforts to define and launch the execution of private sector actions that will accelerate progress on measures.

Conclusion

The United States healthcare system is poised to transform in ways that will bring information to individuals and those who deliver care to drive improvements in the health of individuals and the quality, safety, and cost of care. Interoperability and information sharing play a key role in achieving this goal. Together, public- and private-sector leaders can take actions to accelerate interoperability to improve health, improve care, and improve the lives of all Americans.

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Anthem

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athenahealth

Beth Israel Deaconess Medical Center

BioReference Laboratories

BlueCross BlueShield of Tennessee

Bristol-Myers Squibb

Cardinal Health

CareJourney

CARIN Alliance

Center for Medical Interoperability

Centers for Medicare and Medicaid Services

Cerner

Change Healthcare

ChenMed

Children's Hospital of Philadelphia

CHIME

City of Hope

Cleveland Clinic

Clinovations

Comfort Keepers

CommonWell Health Alliance

ConnectiveRx

Cotiviti

Eli Lilly

Epic

Fairview Health Services

Franciscan Missionaries of Our Lady Health System

Geisinger Health System

Genosity

Hearst Health

HCA Healthcare

HIMSS North America

Intermountain Healthcare

IQVIA

Johnson & Johnson

Kaiser Permanente

Leidos

LEO Pharma

LTPAC Health IT Collaborative

Mallinckrodt

Marshfield Clinic Health System

Massachusetts eHealth Collaborative

Maxim Healthcare Services

Mayo Clinic

McKesson

Medidata Solutions

Medtronic

MedStar Health

MemorialCare Health System

Merck

National Association for the Support of Long Term Care

National Health Council

National MS Society

New England Healthcare Exchange Network

NewYork-Presbyterian Hospital

NorthShore University HealthSystem

Novartis

Office of the National Coordinator for Health Information Technology

Roivant Sciences and Datavant

Pfizer

Premier healthcare alliance

SCAN Health Plan

Senior Helpers

Stryker

Surescripts

Teladoc

Tenet Health

Texas Health Resources

The Pew Charitable Trusts

The Sequoia Project

UCB

University of California, San Francisco

University of Texas at Austin

Vizient

ZS Associates

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