

REPORT TO CONGRESS

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Challenges and Barriers to Interoperability

Prepared by:

The Health Information Technology Policy Committee (a federal advisory committee to the Office of the National Coordinator for Health IT focused on health information technology policy)

Submitted to:

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The Honorable Orrin G. Hatch, Chairman, Senate Committee on Finance

The Honorable Ron Wyden, Ranking Member, Senate Committee on Finance

The Honorable Thad Cochran, Chairman, Senate Committee on Appropriations

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The Honorable Roy Blunt, Chairman, Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

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The Honorable Harold Rogers, Chairman, House Committee on Appropriations

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I. Congressional Request

The Consolidated and Further Continuing Appropriations Act, 2015¹ was signed by the President on December 1, 2014. An explanatory statement accompanying the Act and agreed to by the House of Representatives and the Senate provided in pertinent part:

*Interoperability.--The agreement directs the Health IT Policy Committee to submit a report to the House and Senate Committees on Appropriations and the appropriate authorizing committees no later than 12 months after enactment of this act regarding the challenges and barriers to interoperability. The report should cover the technical, operational and financial barriers to interoperability, the role of certification in advancing or hindering interoperability across various providers, as well as any other barriers identified by the Policy Committee.*²

II. Health Information Technology Policy Committee

Since its establishment pursuant to Section 3002 of the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, the Health IT Policy Committee (HITPC) has made numerous policy recommendations to the National Coordinator to promote the effective use of health information technology (HIT) to improve the nation's health while reducing medical errors and reducing disparities. One of the key policy areas of focus by the HITPC has been to promote electronic exchange of health information. Consequently, the HITPC has held a number of hearings and made a number of recommendations on topics related to interoperability.

In response to the request of Congress, the HITPC established the Clinical, Technical, Organizational and Financial Barriers to Interoperability Task Force (Interoperability Task Force) to develop this report. The Interoperability Task Force began developing these recommendations through a process that included: reviewing of past HITPC findings and recommendations, identifying policy gaps that impact interoperability, conducting two virtual hearings on financial and business barriers to interoperability, leading to the development of the final recommendations in this report.

III. The Current State of Interoperability and the Importance of Addressing Financial and Business Barriers

Interoperability is defined as the ability of two or more systems to exchange information and the ability of those systems to use the information that has been exchanged without special effort. Although substantial interoperability amongst all stakeholders in American health care has not been achieved to date, there are pockets of meaningful health information exchange developing,

¹ Pub. L. 113-235.

² 160 Cong. Rec. H9047, H9839 (daily ed. Dec. 11, 2014) (explanatory statement submitted by Rep. Rogers, chairman of the House Committee on Appropriations, regarding the Consolidated and Further Continuing Appropriations Act, 2015).

and momentum is starting to build. Achieving broad adoption and use of electronic health records (EHRs), of course, is a prerequisite to enacting electronic health information exchange.

Recognizing the importance of health IT and health information exchange for transforming health and health care, and to advance this important public policy, Congress passed the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009.³ The HITECH Act stimulated demand for the adoption and use of health IT by authorizing the Medicare and Medicaid EHR Incentive Programs (also known as Meaningful Use). To date, these programs have provided more than \$31 billion⁴ in incentive payments to health care professionals and hospitals that have attested to adopting and meaningfully using electronic health records (EHRs) certified by the Office of the National Coordinator for Health Information Technology (ONC).

Now that the majority of Americans' health information are stored in EHRs, attention has become focused on interoperability to support key health objectives, such as coordinating care, improving population health, and enhancing information access by individuals. Although an increasing number of providers and developers have worked to achieve interoperability, long-standing challenges have become better understood and new challenges have been identified. While the process for implementing an EHR within a hospital or ambulatory clinic is similar whether it occurs in rural Alaska or downtown New York City, exchanging health information across organizational and state boundaries presents new challenges that require collaborative effort. For example, state-level variation in privacy laws and health insurance markets, as well as local differences in the structure of health care delivery (such as stand-alone practices versus integrated delivery networks, community hospitals versus academic medical centers, collaborative versus competitive health care communities) are all key variables that determine the pace, extent, and quality of health information exchange and interoperability in a particular market. Furthermore, most barriers must be addressed concurrently for interoperability to be realized. Consequently, it requires a tipping point to be reached across-the-board before free-flowing information exchange can be achieved. Indeed, the greatest challenge is that there is not just one challenge. As a result, the pace of progress in interoperability is not fast enough to meet the needs of delivery system reform or to meet policy objectives of coordinated care leading to better health outcomes.

Throughout our hearings, we noted a consistent message—stakeholders understand and appreciate the general movement towards pay-for-value, but that it will take strong and clear definitions of the business and financial incentives to significantly accelerate the pace of change towards that goal. Certifying or applying incentives to specific components of interoperability has not been effective at engaging and activating the required stakeholders. Because the barriers

³ Pub. L. 111-5, Division A, Title XIII, & Division B, Title IV.

⁴ See CMS, *Monthly Payment and Registration Summary Report* (Oct. 2015), <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

to interoperability are multi-faceted and involve multiple stakeholders, the incentives must be applied at the global level to motivate the required participants to act together.

We begin this report by summarizing relevant recommendations that the HITPC has made in the past that address interoperability, as well as current efforts underway in this area. We then make four new recommendations that specifically target financial and business barriers to interoperability that we believe will accelerate the pace of progress.

IV. Past HITPC Recommendations to Promote Interoperability

We frame our summary of past HITPC recommendations in the following categories of barriers to interoperability:

- Lack of universal adoption of standards-based EHR systems
- Impact on providers' day-to-day workflow
- Complex privacy and security challenges associated with widespread health information exchange
- Need for synchronous collective action among multiple stakeholders
- Weak or misaligned incentives

For additional information regarding past HITPC recommendations that are related to interoperability, please see the summary in **Appendix A**.

A. Lack of Universal Adoption of Standards-Based EHR Systems

As mentioned earlier, in any given market, health information exchange cannot happen until a critical mass of providers have installed, and are capably using, EHR systems that can exchange clinical information with other providers' systems. Fortunately, the EHR Incentive Programs have been highly successful at increasing the use of EHR systems across the country for eligible providers and hospitals. Despite the remarkable progress in EHR adoption, however, we must stay vigilant to ensure that the remaining providers and hospitals without certified EHR technology also engage and join the electronic infrastructure for health information. Additional strategies to extend the infrastructure to other providers and health stakeholders not covered by the EHR Incentive Programs, must also be developed if we are to ensure the free flow of information across the whole continuum of care.

The availability of health IT certification from the federal government has played a critical role in preparing the industry for interoperability.⁵ Before the introduction of federal certification, EHR systems typically used highly incompatible approaches for information exchange that often employed competing standards and resulted in a lack of interoperability. In this environment, it was next to impossible to efficiently connect existing systems. Since that time, federal

⁵ ONC, About the ONC Health IT Certification Program, <https://www.healthit.gov/policy-researchers-implementers/about-onc-health-it-certification-program> (last visited Dec. 8, 2015).

certification—though not perfect—has considerably tightened the standards used by EHR systems and the industry is starting to see the benefits of this standardization. For example, reporting to public health agencies has expanded enormously across the country⁶ since it was included as a requirement in the EHR Incentive Programs and state public health agencies are now motivated to standardize their approaches to data collection and reporting. Likewise, the electronic delivery of lab result and electronic prescribing are close to being interoperable “plug-and-play” functions, which has improved the efficiency, quality, and safety of these vital clinical transactions.

In contrast, EHR-to-EHR interoperability has progressed more slowly than other health information exchange domains, but this is not totally unexpected given the high fragmentation and diversity of providers and EHR vendor systems across the country. In the last year, since Stage 2 of the EHR Incentive Programs, exchange of electronic, standards-based, continuity-of-care documents⁷ among providers using similar and disparate EHR systems has grown significantly.⁸ While the number of exchanges continues to grow, achieving semantic interoperability (the ability of a receiving system to understand the meaning of the data transmitted) has been more difficult.

Perhaps the most promising development in health information technology is the evolution of interoperability standards aligned with the rest of the internet economy, such as the use of application programming interfaces (APIs). In fact, there is interest across the health care industry in leveraging the same type of API standards used by Amazon, Facebook, Apple, and Google to promote data sharing through a more “apps-based” environment. While these innovations have come to health care later than other industries, vendors are now responding to many of the same technology and market forces that have opened up information exchange across the internet.

B. Impact on Providers’ Day-to-Day Workflow

A well-known phenomenon in technological innovation is that process innovation usually lags behind technological innovation. Complex processes involving multiple handoffs between users get optimized around existing technologies and approaches over time. When new technologies are introduced, particularly those that are core to the care-delivery process, it takes time to redesign and optimize existing processes to incorporate use of the new technologies. These process barriers to technological adoption (commonly referred to as workflow barriers) are more prominent in health care than in other industries due to the complexity of the health-care domain, the lack of standardization in the steps a provider may take to treat a patient (care processes), and

⁶ CMS, *Monthly Payment and Registration Summary Report* (Oct. 2015), <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

⁷ Continuity of care documents, or CCDs, are electronic and contain a detailed summary of a patient’s clinical care.

⁸ CMS, *Monthly Payment and Registration Summary Report* (Oct. 2015), <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html>.

the fragmentation of the care delivery system. For these reasons, and since the inception of the EHR Incentive Programs, the HITPC has closely tracked the issue of workflow barriers as it relates to the adoption of EHRs and health information exchange functionality.

The industry has witnessed a significant evolution of workflow processes since Stage 1 of the EHR Incentive Programs.⁹ In Stage 1,¹⁰ providers found electronic prescribing and structured documentation of key information like vital signs, allergies, and problem lists challenging. Now, those activities are considered routine. In Stage 2,¹¹ eligible providers were introduced to the first significant EHR-to-EHR interoperability requirements and we have seen, similar to Stage 1 adoption, there were early challenges with these interoperability functions.

Numerous hearings and findings of various HITPC work groups have noted that challenges exist with the Stage 2 requirement to send a structured data summary (in the form of a Continuity of Care Document (CCD)) to the next setting of care, and have noted that these challenges often relate to workflow. We know that adapting workflows to routinely send electronic documents has proven to be a lot of work because many clinical settings were not even sending paper documents routinely prior to the Stage 2 requirement. A few years ago, as the market ecosystem for Direct-based exchange (the first exchange method certified for EHRs) launched, there was a large market timing issue – a provider could send information only to another provider who was also enabled for Direct exchange on a compatible network, and this took time to develop.

Now that the market has had over a year to mature, there has been a large spike¹² in the sending of CCDs across EHR systems via the Direct standard, as noted above. While this is a promising development, it has uncovered the next level of barriers, namely, challenges in *incorporating* CCDs that have been sent via electronic exchange. Organizations testifying at our hearings discussed the challenges they have faced in processing the documents received electronically because they were being handled through older processes that were originally designed to manage faxed and phoned information. While electronic transmission of documents sped up the processing time, the volume of information, not all of which were relevant to the recipient, proved to be challenging to manage. This presents an opportunity ripe for innovation.

Developing EHR functionality and workflow processes to help providers incorporate and highlight relevant information received from external sources is a clear opportunity for developers of EHRs to innovate. In fact, work is already underway by a national standards organization (HL7) to tighten and streamline standardized CCDs, and market feedback is also playing a role in getting providers and vendors alike to modify the information that they send to

⁹ EHR Incentive Program Payment Update (Oct. 2015), https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/HITPC_October2015_Fulldeck.pdf.

¹⁰ 77 Fed. Reg. 53978 (Sep 4, 2012).

¹¹ 77 Fed. Reg. 53969 (Sep 4, 2012).

¹² DirectTrust, *DirectTrust Grows Almost 970%, Nears 23-Million-Messages Record in 2014*, <https://www.directtrust.org/directtrust-grows-almost-970-nears-23-million-messages-record-in-2014/> (Jan. 30, 2015), <https://www.directtrust.org/directtrust-grows-almost-970-nears-23-million-messages-record-in-2014/>.

make it more useful by recipients. Stage 3 of the EHR Incentive Programs will require that providers meaningfully receive and act on CCDs from other entities, which will provide additional impetus for the development of workflow process changes that support the electronic exchange of tomorrow.

C. Complex Privacy and Security Challenges Associated with Widespread Health Information Exchange

Ensuring adequate privacy and security protections is extremely important to providers and patients as recordkeeping moves from paper-based records, to stand-alone EHRs, to interconnected EHRs. The HITPC has focused considerable attention on these areas over the past five years. Some of the major privacy and security findings that impact interoperability include the following: 1) a misunderstanding of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)¹³ and other privacy laws impede free flow of information; 2) translating privacy laws that were originally designed to address paper-based processes into the electronic world has been problematic; and 3) designing electronic systems and rules to accommodate varying state privacy and security laws has been formidable.

Electronic systems require specific configurations, such as user roles and access, which force the formalization of privacy and security policies and practices. In a paper-based world, however, such policies and practices are articulated and adhered to in a more informal fashion. While the transition to more formal privacy and security policies and practices is beneficial to the industry because it forces more attention on and more robust implementation of privacy and security measures, it also takes time to identify and fill the policy gaps that become evident in the transition from a paper-based world to an electronic world. Of even greater concern is that small mistakes in a paper-based world have relatively limited consequences, whereas small mistakes in an electronic world can have far-reaching consequences.

In addition, interpretations of HIPAA have been shown to vary widely in the market, both with respect to provider-to-provider exchange, as well as provider-to-patient exchange. There are many examples where misinterpretations of complex privacy laws inhibit providers from exchanging information that is permitted under HIPAA. Also, many providers do not fully appreciate that HITECH gives patients the right of electronic access to their EHR-stored information.

Many laws and regulations that were designed for paper-based processes and workflows are difficult to translate to today's electronic-based processes. For example, 42 CFR Part 2¹⁴ requires that any information documented in a federally-subsidized substance abuse treatment program be disclosed to other entities only with the explicit consent of the patient for each disclosure, and for each succeeding re-disclosure. Though cumbersome, this is relatively

¹³ Pub. L. 104-191.

¹⁴ 45 C.F.R. § 164.506(c).

straightforward to implement in a paper-based system where physically separate records do not easily get comingled. The advantage of electronic systems is that clinically important data can be available to those whose decisions should be informed by relevant data. However, such data sharing—the purpose of interoperability—may seem to run counter to the segregation principle required by 42 CFR Part 2. This is particularly complex in multi-use care settings where an innocuous clinical recording such as blood pressure would be considered covered by 42 CFR Part 2 consent rules if it was recorded in a substance abuse clinic visit, but would not fall under 42 CFR Part 2 if it was recorded in an emergency department visit in the same building.

A critical barrier to progress in interoperability related to privacy and security is the variation in state laws that exist in the United States today. Due to historical reasons and genuine differences in citizen attitudes and preferences across the country, state privacy laws vary, often widely, in ways that inhibit both within-state as well as cross-state information sharing. For example, some states have explicit affirmative consent requirements for sharing patient information across legal entities (e.g., Massachusetts, Rhode Island, and Utah), whereas other states rely solely on HIPAA to govern clinical information exchange (e.g., Indiana).

Furthermore, many states have specific laws related to specific conditions or information—such as sexually transmitted diseases, HIV, genetic testing, behavioral health—which have state- and even condition-specific prohibitions and consent requirements, such as consent or prohibition on sharing with certain organizations such as health insurers. Another common area of state variation is in the treatment of adolescent medical records. States differ in policies related to the age of majority, as well as a minor’s authority over disclosure—even to parents—of specific information (such as reproductive health). Such laws are often complex to interpret and implement on their own, and are exponentially more complex when attempting to address different variants across the 50 states. The need to fully understand these laws and to implement processes and technology functions to enforce them presents a hurdle to interoperability for which there is no single, nationwide solution. With time, however, we expect that technologies and processes will mature to the point that they both ease the flow of clinical information and give providers and patients greater control over how such information is used.

D. Need for Synchronous Collective Action Among Multiple Stakeholders

Effective interoperability requires agreement among all of the participants on certain “rules of the road” related to the various issues described above, as well as other issues. What are the specific types of transactions to be conducted? What standards (e.g., transport, format, and vocabulary) will be used and implemented in each system? What are the rules of access for patient information? For what purposes can exchanged data be used? What is the minimum level of security that each participant must have in place? How are patient records going to be matched across organizations? What happens if a participant violates any of the “rules of the road”? In addition, health information exchange is used for a variety of purposes across the

country, such as clinical care, accountable care, research, public health, and others. How do the rules apply to these diverse uses?

Following the patterns of other industries, health information exchange networks are emerging to implement specific technologies and policies among groups of participants with a shared common interest in specific types of health information exchange. Individual vendors and vendor consortiums are linking providers through private networks. Other multi-stakeholder networks are driven by covered entities themselves, at either a nationwide level (such as the eHealth Exchange¹⁵, which connects large providers and government agencies) or at the state level (via state health information exchanges such as the Indiana Health Information Exchange¹⁶ or via the Massachusetts Health Information HIway¹⁷ that connects health care entities on a geographic basis).

These networks, though distinct in their specific technology implementations and policies, serve a valuable purpose in connecting the hubs to each individual entity needing the information—often referred to as the “last mile” of health information exchange. As these networks grow, and more networks join them, the task of defining nationwide interoperability will become not one of defining standards and policies for activities *within* each network, but rather, defining standards and policy bridges *across* these networks for core functions that should be available to all participants, regardless of the EHR or network to which they connect. For example, wireless phone networks perform common functions across networks so that users feel that we have a single global network, yet, even in the US, some wireless systems use different standards and enable different functions within their networks than they allow outside of their networks. The same is true for ATM networks.

Setting a vision for the portfolio of HIE functions that will support nationwide interoperability and defining the standards and policies that will bridge existing and future networks are important next steps in achieving ubiquitous health information exchange. In other industries, such as banking and Wi-Fi, the private sector has coalesced to provide the necessary structure and processes to drive development, adoption, and self-regulation of industry-wide standards. In this sector, the federal government plays a unique role in health care as a large and influential market actor in health insurance (Medicare and Medicaid) and health care delivery (DoD, VA,

¹⁵The Sequoia Project, What is eHealth Exchange, <http://sequoiaproject.org/ehealth-exchange/> (last visited Dec. 8, 2015).

¹⁶ The Indiana Health Information Exchange is a non-profit organization formed by the Regenstrief Institute, private hospitals, local and state health departments, BioCrossroads and other health care and community organizations in Indiana. It operates the nation’s largest health information exchange, providing a secure and robust statewide health information technology network that connects over 90 hospitals, long-term care facilities, rehabilitation centers, community health clinics and other health care providers in Indiana. This network serves an area with a population of about six million people and over 30,000 physicians throughout the country.

¹⁷ Massachusetts launched the first CMS funded, statewide electronic health information exchange, The Massachusetts Health Information Highway (The Mass HIway). The Mass HIway is governed by a diverse Health Information Technology Council and informed by provider, consumer, legal and policy, and technology advisory groups to promote a transparent, multi-stakeholder engagement model.

IHS, etc.) and thus will have a significant role in shaping the future of nationwide health information exchange.

E. Weak or Misaligned Incentives

A key inhibitor to health information exchange has been economic incentives that, at best, have not encouraged, and at worst, have even discouraged, sharing of clinical information among providers (e.g., information blocking). Perverse incentives can have insidious effects on the motivation of stakeholders to overcome the challenges of interoperability. Traditional fee-for-service payment models (which currently still dominate most American health care markets) do not create incentives for providers to make health information exchange processes and technologies a higher priority among the many priorities that they manage on a daily basis. As a result, demands on EHR developers have historically not focused on interoperability, but rather have focused on other functions and capabilities that make sense in a fee-for-service world—such as improving documentation for billing purposes. This lack of demand for interoperability has spilled-over into slow progress in solving the related problems described above.

Through the passage of the Affordable Care Act (ACA),¹⁸ CMS has begun to establish value-based purchasing models (e.g., Pioneer Accountable Care Organizations¹⁹, Patient Health Homes²⁰, and the State Innovation Models²¹) that pay for higher quality and more efficient care, rather than paying for higher volumes of tests and procedures. HHS' recent announcement that it will convert 30% of fee-for-service payments to alternative payment models by 2016 and will increase that percentage to 50% by 2018²² has motivated private health plans to accelerate their transition to value-based models, and has spurred providers across the country to fundamentally alter their care-delivery processes and technology demands to support population health and care management across the continuum of care. Because interoperability and effective information exchange are crucial to achieving value-based care delivery under the new models, providers are increasingly focused on electronic health information exchange. While the new payment model motivates a health system to exchange data internally, additional incentives may be necessary to promote widespread health information exchange with organizations external to a provider's health system.

In large measure because of the EHR Incentive Programs and federal signals surrounding the future of health care payment, the health IT infrastructure and EHR developers are responding to growing customer demand for interoperability-based care functions by incorporating industry-

¹⁸ Pub. L. 111-148.

¹⁹ See CMS, Pioneer ACO Model, <https://innovation.cms.gov/initiatives/Pioneer-ACO-Model/> (last visited Dec. 7, 2015).

²⁰ See Medicaid, Health Homes, <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Long-Term-Services-and-Supports/Integrating-Care/Health-Homes/Health-Homes.html> (last visited Dec. 7, 2015).

²¹ See CMS, State Innovation Models Initiative: General Information, <https://innovation.cms.gov/initiatives/state-innovations/> (last visited Oct. 5, 2015).

²² HHS recently announced an aggressive timeline for shifting Medicare reimbursement from volume to value. HHS, *Better, Smarter, Healthier: In Historic Announcement, HHS Sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value*, (Jan 26, 2015), <http://www.hhs.gov/news/press/2015pres/01/20150126a.html>.

based open standards, adding functionality for team-based care, and building or participating in health information exchange networks. However, there is growing impatience about whether the pace of progress on interoperability is sufficient to support the pace of payment reform.

After considering the past recommendations of the HITPC, which we still believe are valid and valuable, the task force examined business and financial barriers to more rapid progress. As described above, these barriers have not received sufficient attention and are perhaps the most powerful lever as they are likely to spur progress in all the domains required for interoperability to occur.

V. Context for New Recommendations: Financial, Business, and Cultural Barriers

The Interoperability Task Force identified four recommendations that could begin to be acted upon in the next six months and that could set in motion changes that could significantly speed progress towards widespread interoperability by targeting financial and business barriers. None of the recommendations are likely to change the facts on the ground overnight, but instead will target misaligned incentives and strengthen the business case for key stakeholders—especially providers and EHR vendors—such that they would engage in business practices that result in routine interoperable data exchange with needed partners. Three important points set the context for our recommendations.

First, interoperability appears deceptively simple. Although the definition is short and the target end-state is defined, there is little agreement on the “right” approach. Further, these decisions require multiple stakeholders to act in a coordinated manner. No single provider, vendor, or policymaker can take unilateral action that would enable widespread interoperability in the near-term. However, there are actors who are relatively more powerful and whose actions could have a disproportionate positive impact on the pace of progress. The federal government is one of these essential actors.

Second, as stated before, the long-standing fee-for-service reimbursement model creates a perverse incentive to ignore information from other sources. With an increasing shift from fee-for-service reimbursement to value-based reimbursement, incentives for interoperability are beginning to shift from perverse to aligned.

Third, while the overall incentives to achieve interoperability have begun to shift with changing reimbursement models, not all providers and vendors will or do feel this shift to the same degree. There are still many areas where misaligned incentives continue to dominate. The US health care delivery system continues to have a culture that lacks a team-based approach and too often treats data as a competitive advantage (in some cases leading to passive or active data blocking) rather than as a basis for coordinated care. As the percentage of reimbursement under alternative

payment models increases, the demand for broad interoperability will increase. Developers who fail to adequately support interoperability will be under pressure to serve their customers operating under alternative payment models.

While we lack quantitative data about the extent of the problem, reports of information blocking have raised significant concern. In the end, it will be essential to change the culture of health care to one that incentivizes information sharing. The key is to accelerate the transition from fragmented fee-for-service care to one that supports coordinated, individual- and family-centered, high value care, and to provide the tools, resources, and incentives to perform effectively in an interdependent, complex ecosystem.

The following new recommendations were developed by the Interoperability Task Force of the HITPC to build upon work that ONC has undertaken to identify solutions to some of the barriers identified within this report, most notably, ONC's updated version of the Shared Nationwide Interoperability Roadmap (Interoperability Roadmap).²³ These recommendations are designed to accelerate the pace of change toward meaningful interoperability that is driven by business and financial incentives.

A. Develop and Use Health Information Exchange-Sensitive (HIE-Sensitive) Measures for Consumers, Providers, and Payers

Recommendation 1: Develop and implement meaningful measures of HIE-sensitive health outcomes and resource use for public reporting and payment

HIE-sensitive measures are those which require health information to be exchanged and effectively used in order for the applicant to earn high scores. In order to enhance the strength of incentives that drive interoperability, a set of specific measures should be developed that focus on the delivery of coordinated care, facilitated by shared information across the entire health team (including the individuals and families) and throughout the continuum of care settings. An example of an HIE-sensitive measure would look at medically unnecessary duplicate testing. Payers could provide incentive clout by declining to reimburse for medically unnecessary duplicate testing. Performing well on HIE-sensitive measures of care coordination would require a shared care plan and shared access to all orders and results for an individual patient by all members of the health team.

Identifying existing, or developing new, measures (including patient-reported outcome measures) that can be applied to provider organizations and are sensitive to interoperability would serve as a powerful basis for strengthening incentives in two ways. First, those who pay

²³ONC, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap Draft Version 1.0* (2015) (hereinafter "Roadmap"), available at <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>.

for care can incorporate them in new payment models, and second, they can be used in public reporting that would create more transparency regarding which specific provider organizations deliver better coordinated care. The latter will empower consumers to select providers who perform better on measures that are directly relevant to their care. Thus, it is critical that these measures are “measures that matter” to consumers and payers. Providers also are likely to see direct value in these measures if they allow them to easily track performance, and inform performance improvement efforts along dimensions relevant to ACO and other value-based reimbursement models.

Today’s measures are largely process measures under the control of an individual organization. Agreement on a set of high-value HIE-sensitive measures would require coordinated actions among key stakeholders, which we discuss further in the fourth recommendation in this report.

Most of the measures in use today focus on specific diseases or conditions. Development of such measures were often funded by specialty societies or associations. There has been limited prior work to define cross-cutting, HIE-sensitive outcome measures which capture whether care is well-coordinated and affordable. This is an area in which federal funding for measure development, testing, and validation would be particularly helpful since the current pipeline of such measures is scant. The federal government has the largest market share and strongest business case for such measures, and should invest in their development and implementation so that other payers may follow suit in the rest of the market.

B. Develop and Use Meaningful Measures of Developer Performance

Recommendation 2: Develop and implement HIE-sensitive vendor performance measures for certification and public reporting

While use of HIE-sensitive quality and value measures for provider organizations may serve as an indirect incentive for vendors to improve their systems, we believe that direct measures of HIE-sensitive vendor performance will bolster market forces behind vendor business practices that promote interoperability. Today, purchasers of EHR systems lack such measures to inform purchasing decisions or to use as a lever to put pressure on vendors to improve. Although vendors have strong incentives to pass the interoperability requirements for EHR certification, this process is “one-time” and occurs in a lab. It has not been shown to translate into interoperability that is affordable or easy to implement in the field. While certification could be improved (in particular, to focus on certifying capabilities to get data in and out of EHR systems) and expanded to include more robust post-market surveillance, it is probably more effective and efficient to use transparent measures as the primary driver of meaningful interoperability. Such measures would not only be valuable to providers, but also would be valuable to policymakers who are seeking more inputs to surveillance for certification and regulation.

As with the first recommendation, a coordinated, multi-stakeholder effort to define such measures is required, and to-date no entity has stepped forward to fund this area of measure development. Thus, federal resources would help speed progress towards a single set of measures that could be reported on across vendors and shared transparently to drive vendors to more heavily invest in interoperability capabilities.

Selecting measures that reflect actual use (and value) by frontline users is critical. Just measuring technical capabilities that are demonstrated under controlled conditions should be avoided in favor of measures that demonstrate how access to external data contributes to decisions in daily care delivery. Below is an example of a set of measures which, when used as a complete package, would not only measure the exchange of data, but would measure the impact of data exchange on clinical decision making:

1. Number of data exchanges from external sources, which could include other providers, community social-service organizations, consumers, payers, etc. (denominator that measures ability to exchange data with another electronic system such as an EHR, HIE or consumer application (app));
2. Percentage of external data elements viewed (numerator that measures perceived value of the external data);
3. Percentage of external data elements incorporated/reconciled with internal records (represents meaningful data); and
4. Percentage of time viewing of external data changed current activity (e.g., appeared in clinical decision support, led to change in order being written), which demonstrates impact of external data.

C. Accelerate Payment Incentives for Interoperability

Recommendation 3: Set specific HIE-sensitive payment incentives that incorporate specific performance measure criteria and a timeline for implementation that establishes clear objectives of what must be accomplished under alternative payment models

While high-value interoperability measures targeting both providers and vendors can help motivate progress towards interoperability, our hearings and our review of previous testimony, public comment, and other evidence indicate that progress will be dramatically accelerated if such measures are directly tied to reimbursement. The early experience to-date of relying on certification criteria to drive interoperability has not led to sufficient progress in the field. Today, the lack of palpable financial incentives for interoperability favors the status quo. Pressing internal priorities compete for attention and resources are needed to achieve interoperability, especially when specific actions to enact interoperability are complex and time-consuming. This results in slow progress. Moving interoperability up the priority list will likely take financial incentives that are more targeted than a broad shift from fee-for-service to pay-for-

value. To have the desired effect, the incentives must be strong and specific, with clearly defined measures and a deliberate implementation timeline and effective dates.

Payers have existing mechanisms through which to incentivize providers to meet HIE-sensitive outcome measures, and Medicare is the logical payer to lead such efforts (particularly as CMS operationalizes new payment requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)²⁴). We note that these measures do not require defining interoperability as a new domain of performance incentives as they could easily be incorporated into incentive programs that target dimensions of provider performance that are HIE-sensitive, such as care that is coordinated, high-value, and safe, as well as integrated across the health and social services continuum. For example, a payment policy that denies claims for medically unnecessary duplicate testing for high-cost imaging would require coordination, or at least awareness, of orders and results by all providers involved in the care of an individual patient. Providing a roadmap for specific HIE-sensitive performance measures for future payment incentives, with enough lead time, will motivate and catalyze specific actions to speed the pace of achieving effective health information exchange that facilitates high priority use cases.

Recognizing that health information exchange, by definition, requires multiple parties to engage in collective, synchronous actions to complete the electronic exchange successfully, actions that constitute “information blocking” would preclude both parties from achieving interoperability. As CMS defines new payment incentives to reward value-based purchasing using HIE-sensitive outcome measures, it should incorporate mechanisms that identify and discourage information blocking activities that interfere with providers who rely on information exchange to deliver high quality, coordinated care.

²⁴ ²⁴ Public Law 114-10.

D. Initiate Sustained Multi-Stakeholder Action

Recommendation 4: Convene a working Summit of major stakeholders co-led by the federal government (e.g., ONC, CMS) and the private sector to act on the ONC Interoperability Roadmap to accelerate the pace of progress towards interoperability

Successfully achieving the recommendations described above requires coordinated actions on a wide range of complex issues by multiple stakeholder groups. For example, efforts to define HIE-sensitive measures for providers or vendors will also mean tackling upstream issues related to patient identity matching and “rules of the road” for collective action. The Interoperability Roadmap developed by ONC, with robust participation from the public, provides a blueprint for tackling these issues and should serve as the framework for guiding such efforts. In addition, as described above, without collective action to agree on critical HIE-sensitive measures, it is unlikely that measures will be widely adopted and, as a result, will have little ability to strengthen market forces driving interoperability.

Although there have been calls for action related to interoperability in the past, most have been limited to specific stakeholders (e.g., vendors, standards organizations). A number of things have evolved in the environment that makes the timing riper for accelerated change. First, as a result of the EHR Incentive Programs, the majority of health information on individuals resides in electronic health record systems. Second, the Secretary of HHS established clear milestones for delivery system reform, and for the accompanying reform of payment models. Third, we believe that in order to achieve meaningful interoperability, collective, synchronous action must be undertaken by multiple stakeholders across the whole continuum, from professional education and training programs to health care organizations, consumers and payers, both public and private.

Our recommendation for a public-private, multi-stakeholder working Summit is intended to kickoff operational actions necessary to implement the ONC Interoperability Roadmap -- and our policy recommendations on interoperability. Convening a high-level working Summit leading to industry commitment, requires both the convening power and leadership of the federal government to spur collective action, and the enduring private-sector business interests to sustain the effort.

The output of the Summit would be an action plan with milestones and assigned accountabilities for achieving the milestones in the context of this larger interoperability initiative. We expect the compelling call-to-action would engage the stakeholders to continue their activities after the Summit as a way of meeting the payer-driven incentives that reward HIE-sensitive measures of coordinated care. As the federal advisory committee to ONC on health IT policy, the HITPC could hold quarterly progress briefings on the multi-stakeholder activities to help ensure coordination and accountability of the efforts to accelerate progress towards widespread interoperability.

VI. Conclusion

In contrast to the commitment of internal resources required to implement an EHR within an organization, exchanging health information between organizations requires multiple systems and parties to cooperate – at the same time. The EHR Incentive Programs have successfully stimulated the widespread adoption and use of EHRs to manage health information. This accomplishment reflects enormous effort by individual healthcare organizations throughout the country, both small and large. The next major challenge is to safely and efficiently exchange critical information needed to coordinate care amongst all the members of an individual’s health team (including patients and families). Meeting this challenge requires the interoperability of health IT systems, including EHRs, and presents different challenges than those previously encountered when implementing a standalone system for a single organization.

No single component-based recommendation by itself will be enough to achieve interoperability. Beyond technical barriers, there are business barriers, complex privacy laws, workflow challenges, and misaligned incentives that conspire to slow progress. Any one of these barriers could—and do—prevent the successful transfer of information from one place to another. Recommending a patchwork of individual steps to address interoperability will not work as well as motivating the entire ecosystem to work on the multi-dimensional challenges of achieving interoperability.

Over the past few years, the Health IT Policy Committee has made several recommendations that address specific aspects of health information exchange and interoperability. To accelerate the pace of progress towards interoperability, however, almost every stakeholder in United States healthcare must participate. Indeed, all stakeholders would benefit. We believe it will take concerted effort to align all the forces for change in a single direction.

In this report, we make four new recommendations which address the lack of a singular focus on overcoming the multi-dimensional barriers to interoperability. In order to motivate and align the efforts needed to bring about widespread interoperability, we believe there must be specific global criteria or measures to drive the collaboration needed to achieve meaningful exchange. Therefore, this report includes a recommendation to define and incorporate specific HIE-sensitive outcome measures into payment models with a defined timeline that will promote collective actions that overcome the multi-faceted barriers we have described. Focusing on HIE-sensitive outcome measures will encourage and reward innovation with fewer unintended consequences than relying on certification of technology alone.

In addition, we recommend convening a summit of major stakeholders to create a shared, coordinated action plan with assigned accountabilities, building on the ONC Interoperability Roadmap. Without broad-based coordinated efforts, it is unlikely that widespread interoperability will be achieved fast enough to deliver the health care that Americans expect and deserve.

The Health IT Policy Committee appreciates the opportunity to provide this report on the technical, operational, and financial barriers to interoperability. We look forward to continued work with Congress and the Office of the National Coordinator for Health Information Technology on matters related to health IT advancement.

Appendix A

Summary of Past Health IT Policy Committee Recommendations

Lack of Universal Adoption of Standards-Based EHR Systems

- HHS should consider opportunities for certifying technology to facilitate value-based purchasing activities that go beyond the MU foundation.²⁵
- HHS should work to simplify and harmonize requirements across advanced payment models for public and private payers.²⁶
- The health IT certification program should consider a requirement by which vendors would demonstrate that they can easily integrate with other applications.²⁷
- Facilitate consensus around shared approaches to standards-based electronic shared care planning across the continuum of care to promote wider adoption of these tools.²⁸
- Drive progress on standardization and capture of social determinants of health data elements that are critical to accountable care and other delivery models.²⁹
- Promote greater standardization for social determinants of health data, including data reported by individuals, families and caregivers, and related performance measures.³⁰
- Promote greater standardization and usefulness of human services and clinical data across systems utilized by all health and service professionals, caregivers, individuals and their families.³¹
- Pursue greater specificity in federal interoperability standards around transactional data. Look for opportunities to increase specificity around transactional data such as discrete HL7 data feeds for admissions, discharges and transfers, notifications, labs, prescriptions, etc., as well as further specification of structured data within the CCDA.³²
- Explore better individual identity-matching strategies to facilitate aggregation of data across clinical and non-clinical settings and other high-priority use cases.³³
- Strengthen data portability elements in certification criteria to ensure systems have demonstrated that they can receive and process data, not only send data. Expand testing procedures for certified EHR technology that require products to demonstrate the

²⁵ Health IT Policy Committee, Recommendations to the National Coordinator for Health IT (Oct. 14, 2014), https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf.

²⁶ Health IT Policy Committee: Recommendations to the National Coordinator for Health IT, https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf. (last visited Nov. 10, 2015).

Id.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ Health IT Policy Committee: Health IT Policy Committee, Recommendations to the National Coordinator for Health IT (Aug. 11, 2015), https://www.healthit.gov/sites/faca/files/HITPC_AHM_Hearing_Transmittal_08-11-2015_0.pdf.

³¹ *Id.*

³² Health IT Policy Committee, Recommendations to the National Coordinator for Health IT (Oct. 14, 2014), https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf.

³³ *Id.*

technical ability to not only send discrete data points in a recognized, structured, and consumable manner, but also receive and make data computable within a receiving application.³⁴

- Limit the scope of certification to those functions critical to interoperability and outcomes improvement.³⁵ Suggested priority areas include interoperability, clinical quality measurement, and privacy and security.
- Nationwide shared services. Developing standards for, and ensuring deployment of, universally necessary shared services that are highly sought after and thus would facilitate DSN alignment, such as public use licensed vocabularies, and perhaps nationwide health care provider and entity directories, etc.³⁶
- When considering whether to pursue any new certification initiative, consider the below Five Factor Framework, asking whether the proposed certification initiative would:³⁷
 1. Advance a National Priority or Legislative Mandate: Is there a compelling reason, such as a National Quality Strategy Priority, that the proposed ONC certification program would advance?
 2. Align with existing federal/state programs: Would the proposed ONC certification program align with federal/state programs?
 3. Use the existing technology pipeline: Are there industry-developed health IT standards and/or functionalities in existence that would support the proposed ONC certification program?
 4. Build on existing stakeholder support: Does stakeholder buy-in exist to support the proposed ONC certification program?
 5. Appropriately balance the costs and benefits of a certification program: Is certification the best available option? Considerations should include financial and non-financial costs and benefits.

Complex Privacy and Security Challenges Associated with Widespread Health Information Exchange

- Explore regulatory options and other mechanisms to encourage appropriate sharing of information protected under 42 CFR Part 2 across participants in an accountable care organization.³⁸

³⁴ *Id.*

³⁵ Health IT Policy Committee, Final HITPC Recommendations on Health IT Certification for LTPAC and BH Settings, https://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.

³⁶ Health IT Policy Committee, JASON Report Task Force: Final Report (Oct. 15, 2014),

https://www.healthit.gov/sites/faca/files/Joint_HIPC_HITSC_JTF_Final%20Report_2014-10-15.pdf.

³⁷ Health IT Policy Committee, Final HITPC Recommendations on Health IT Certification for LTPAC and BH Settings, https://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf.

³⁸ Health IT Policy Committee, Recommendations to the National Coordinator for Health IT (Oct. 14, 2014), https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf.

- Provide clarifying guidance and disseminate best practices about privacy considerations associated with sharing of individual data among HIPAA covered entities and other community organizations.³⁹
- Promote Fair Information Practice Principles (FIPPs)-based protections for data outside of HIPAA:
- Voluntarily adopt self-governance codes of conduct. In order to credibly meet the requirements of both protecting sensitive personal information and enabling its appropriate use. Codes must include transparency, individual access, accountability, and use limitations.
- U.S. Department of Health and Human Services (HHS), Federal Trade Commission (FTC), and other relevant federal agencies should guide such efforts to more quickly establish dependable “rules of the road” and to ensure their enforceability in order to build trust in the use of health big data.⁴⁰

Need for Synchronous Collective Action among Multiple Stakeholders

- Any increase in regulatory authority should be carefully considered through evaluation of reasonable and meaningful benchmarks, and specifically calibrated to address remaining barriers that the market has failed to overcome.⁴¹
- Some suggested priority areas for certification included interoperability, clinical quality measurement, and privacy and security. To be effective, overarching governance and public-private collaboration would be needed.⁴²

Weak or Misaligned Incentives

- Increase public transparency around hospital and health system performance on measures related to health information exchange through public reporting websites.⁴³
- Coordinate across HHS to expand support for the development of state-level all-payer claims databases to support accountable care arrangements (inclusive of Medicare & Medicaid).⁴⁴
- Integrate clinical data with claims, cost, and price data across participating payers and providers to support less burdensome reporting of quality metrics, helping providers to improve quality and reduce costs, and improve specificity of predictive modeling.⁴⁵

³⁹ Health IT Policy Committee, Recommendations to the National Coordinator for Health IT (Aug. 11, 2015), https://www.healthit.gov/sites/faca/files/HITPC_AHM_Hearing_Transmittal_08-11-2015_0.pdf.

⁴⁰ Health IT Policy Committee Privacy and Security Workgroup, Health Big Data Report Recommendations (Aug. 2015), https://www.healthit.gov/sites/faca/files/HITPC_Health_Big_Data_Report_FINAL.pdf.

⁴¹ Health IT Policy Committee, JASON Report Task Force: Final Report (Oct. 15, 2014), https://www.healthit.gov/sites/faca/files/Joint_HIPC_HITSC_JTF_Final%20Report_2014-10-15.pdf.

⁴² Health IT Policy Committee, Certification Hearing May 7, 2014 (June 24, 2014), https://www.healthit.gov/sites/faca/files/Certification_Hearing_2014-06-24.pdf.

⁴³ Health IT Policy Committee, Recommendations to the National Coordinator for Health IT (Oct. 14, 2014), https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf.

⁴⁴ Health IT Policy Committee: Recommendations to the National Coordinator for Health IT, https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf. (last visited Nov. 10, 2015).*Id.*

- Advance progress by articulating a strategy for how the federal government will engage with the various entities capable of receiving and aggregating data at the local, regional, and state level.⁴⁶

⁴⁵Health IT Policy Committee: Recommendations to the National Coordinator for Health IT, https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf. (last visited Nov. 10, 2015).*Id.*

⁴⁶*Id.*