PREAMBLE

Congressional Request

The Consolidated and Further Continuing Appropriations Act, 2015 was signed by the President on December 16, 2014. An explanatory statement accompanying the Act and agreed to by the House of Representatives and the Senate provides 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.

Health Information Technology Policy Committee

Since its establishment in 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 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 Congressional request, 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 went through a process to develop recommendations that included: a thorough review of past HITPC findings and recommendations, identification of gaps, conduct of two virtual hearings on financial and business barriers to interoperability, and development of final recommendations.

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. 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, and momentum is starting to build. Achieving broad adoption and use of EHRs, of course, is a prerequisite to developing electronic health information exchange. Within five years of the availability of certified EHR technology, the vast majority of hospitals and physicians had adopted certified health IT: in 2014, 97% of hospitals and three-quarters of physicians were using certified health

IT[1]. Despite the remarkable progress in EHR adoption, however, we must stay vigilant to ensure that the remaining providers and hospitals 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 Meaningful Use must also be developed if we are to ensure the free flow of information across the whole continuum of care.

To leverage the growing health information infrastructure, attention has become focused on interoperability to support coordination of care, improve population health, and enhance information access by individuals, to name a few salient objectives. Interoperability has, however, proven challenging. As 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. More specifically, while the process for implementing an EHR in a hospital or ambulatory clinic is similar whether it occurs in rural Alaska or downtown New York City, electronic health information crossing organizational and state boundaries invokes new challenges that require collaborative efforts. 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. Because most, if not all, barriers must be addressed concurrently for interoperability to be realized, it requires a tipping point be reached before effortless, free-flowing information exchange can be achieved. Additional barriers must be overcome before key data (e.g., diagnoses, medications, medication allergies) in the exchanged information (e.g., a Summary-of-Care Record) can also flow freely into receiving EHR system for easy reconciliation and use to inform care. Indeed, the greatest challenge is that there isn't just one challenge.

Given the myriad, interdependent challenges that require coordinated action on behalf of multiple stakeholders, it is becoming increasingly evident that even with the substantial work currently underway to address the challenges the pace of change is not fast enough to meet the needs of delivery system reform and to meet policy objectives of coordinated care leading to better health outcomes. Throughout the various information-gathering venues, we heard a consistent message – that stakeholders understand and appreciate the general movement towards pay-for-value, but that it will take strong and clear definition of the the business and financial incentives to significantly accelerate the pace of change. Without a strong motivation to solve all the challenges facing interoperability, two key stakeholders – providers and vendors – make the rational decision to let interoperability slip down on the priority list. Speeding the pace of

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[1] http://dashboard healthit.gov/evaluations/data-briefs/quantifying-physician-ehr-adoption.php

progress in interoperability undoubtedly requires explicit attention to drivers that create strong incentives for making interoperability an essential part of how healthcare is delivered.

In this report, we summarize relevant past HITPC recommendations that are necessary to achieve interoperability in order to clearly emphasize the diversity of challenges as well as current efforts underway to address them. We then **make four new recommendations** that specifically target financial and business barriers to interoperability that we believe will accelerate the pace of progress.

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**
- Changes in **operations workflow** among providers
- Complex challenges of **privacy and security** associated with widespread health information exchange
- Difficulty of establishing synchronous **collective action** among multiple participants
- Weak, and in some cases misaligned, **incentives**

Details of past HITPC recommendations related to interoperability are summarized in Appendix 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 Meaningful Use program has been highly successful at increasing the use of EHR systems across the country for eligible providers and hospitals.

Federal EHR certification has played a critical role in preparing the industry for interoperability. Before the introduction of federal certification, EHR systems typically used highly incompatible approaches for information exchange, often employing competing standards, resulting in a lack of interoperability. This made it next to impossible to efficiently connect the existing systems. Federal certification, though not perfect, has considerably tightened the standards used by EHR systems, and the industry is starting to see the benefits of this. For example, reporting to public health agencies has expanded enormously across the country since it was included as a Meaningful Use requirement, which has had the added benefit of motivating state public health agencies to standardize their approaches to data collection and reporting. Electronic lab results delivery and electronic prescribing are close to being "plug-and-play" interoperability functions, which has improved not only the efficiency but also the quality and safety of these vital clinical transactions. 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. Exchange of electronic, standards-based, continuity-of-care documents (CCDs) – which contain a detailed summary of a patient's clinical care – among providers using similar and disparate EHR systems has grown significantly in the last year, since the beginning of Meaningful Use Stage 2. According to DirectTrust[2], there were over 23 million Direct-based[3] transactions across EHRs in 2014[4]. Achieving semantic interoperability – having the receiving system be able 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, using application programming interfaces (APIs). There is interest across the health care industry in leveraging the same interoperability standards as used by Amazon, Facebook, Apple, and Google to promote data sharing in more of an "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.

Changes in operations workflow among providers

A well-known phenomenon in technological innovation is that process innovation usually lags technology innovation. Complex processes involving multiple handoffs get optimized around certain technologies and approaches over time, and injecting a new technology into the mix takes time to accommodate, particularly for processes that involve significant safety risks. These barriers to adoption are more prominent in healthcare than in other industries due to the lack of standardization in care processes, the fragmentation of the care delivery system, and the individual and complex nature of health status and disease.

Since the inception of the Meaningful Use (MU) program, the HITPC has closely tracked the issue of workflow barriers to adoption of EHRs and health information exchange functions. The industry has witnessed significant evolution in clinical processes since MU Stage 1, when providers found challenging what we now consider to be routine processes, such as electronic prescribing and structured documentation of certain information such as vital signs and allergies and problems. And with the start of MU Stage 2, which began in January 2014 for physicians and which introduced the first significant EHR-to-EHR interoperability requirements, we have seen similar early challenges with interoperability functions. Numerous hearings and findings of various HITPC work groups have noted the challenges with MU Stage 2 Summary of Care requirements, which require the sending of structured summary data (in the form of a Continuity of Care Document – CCD) to the next setting of care. Adapting workflows to routinely send

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[2] DirectTrust is a collaborative non-profit association of 150 health IT and health care provider organizations to support secure, interoperable health information exchange via the Direct message protocols.

[3] Direct exchange transactions, transactions between addresses within the DirectTrust network that includes 35,000 health care organizations and more than 660,000 individual accounts nationwide.

[4] https://www.directtrust.org/directtrust-grows-almost-970-nears-23-million-messages-record-in-2014/

such electronic documents has proven to be a lot of work because many clinical settings were not sending such documentation routinely to begin with, and even where they were, it was via fax or paper. A few years ago, as the market ecosystem for Direct-based exchange was being 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 spike in the sending of CCDs across EHR systems via the Direct standard, as noted earlier. And while this is a promising development, it has uncovered the next level barrier, namely, challenges in *incorporating* CCDs that have been sent via electronic exchange. A number of hearings this year described the challenges that organizations have experienced in receiving and efficiently and safely managing a large uptick in electronic documents pouring into processes designed to manage faxed and phoned information. As noted earlier, variations in the content of CCDs has also limited the rate of adoption, as providers receiving information must learn how to parse what are sometimes lengthy documents to distill the core information that they need. 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 make it more useful by recipients. MU Stage 3 will require that providers meaningfully receive and act on CCDs from other entities, which will provide additional impetus for the process changes needed to move from the current processes to the electronically connected processes of tomorrow.

Complex Challenges of Privacy and Security 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 5 years. Some of the major findings on issues that have presented barriers to interoperability are: 1) incomplete understanding of HIPAA and other existing privacy laws; 2) challenges translating laws designed for paper-based processes to an electronic world; and 3) variation in state privacy and security laws.

Electronic systems require specific configurations, such as user roles and access, which force formalization of privacy and security policies and practices that, in a paper-based world, are more informally articulated and adhered to. While this 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 enumerate and fill the policy gaps from a paper-based world that are exposed and logged in an electronic world. Of even greater concern and cause for trepidation 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.

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. For example, many providers interpret the HIPAA Notice of Privacy Practices to be a consent for exchanging information, which it is not. There are many examples where misinterpretations of complex privacy laws inhibit providers from exchanging information as freely as HIPAA allows. Also, many providers do not understand the details associated with the HITECH-enhanced right to electronic access, where patients can request and receive their records electronically, as long as providers hold electronic data.

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 2 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 redisclosure. Though cumbersome, this is relatively 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 exists in the US today. Due to historical reasons and genuine differences in citizens' 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, 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 per-disclosure 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 minor's authority over disclosure of specific information, such as reproductive health, even to parents. Such laws are often complex to interpret and implement on their own, and exponentially more complex when taken together. The need to fully understand these laws and 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.

Difficulty of Establishing Synchronous Collective Action Among Multiple Participants

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 (transport, format, vocabulary) will be used and implemented in each system? What are the rules of access for patient information? What purposes can exchanged data be used for? 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 etc. How do the rules apply to the 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, like the eHealth Exchange which connects large providers and government agencies, or state level, via state health information exchanges such as the Indiana Health Information Exchange or the Massachusetts Health Information HIway, which connect health care entities on a geographic basis.

These networks, though distinct in their specific technology implementations and policies, serve a valuable purpose in reaching 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 which EHR or network they are connected to. 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 wifi, the private sector has coalesced to provide the necessary structure and processes to drive development, adoption, and self-regulation of industry-wide standards. 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, IHS, etc.) and thus will have a significant role in shaping the future of nationwide health information exchange.

Weak, and in Some Cases 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 healthcare 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 EHRs has historically not focused on interoperability, but rather 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 has spilled-over into slow progress in solving the related problems described above.

Through the passage of the Affordable Care Act (ACA) CMS has begun to establish value-based purchasing models (e.g., Pioneer Accountable Care Organizations, Patient Health Homes, and the State Innovation Models) that pay for higher quality and more efficient care, rather than higher volume of tests and procedures. HHS' recent announcement that it will convert 30% of fee-for-service payments to alternative payment models by 2016, rising to 50% by 2018, 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. Interoperability and effective information exchange are crucial to achieving value-based care delivery. 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 the health system.

In large measure because of Meaningful Use 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-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.

Context for New Recommendations: Financial, Business and Cultural Barriers

The task force identified four recommendations that could be acted upon in the next six month, setting 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 target misaligned incentives and strengthening 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 is deceptively simple. Although there is a short definition and widely agreed upon target end-state, the simple definition masks a complex set of decisions, on which there is little agreement on the "right" approach, and these decisions require multiple stakeholders to act in a coordinated manner. No single provider or vendor or policymaker can take unilateral action that would enable widespread interoperability in the near-term. However, that 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. The critical next step is to ensure that incentives become better aligned, and ultimately become universal such that interoperability is perceived to be an **essential** component of delivering high quality, value-based health care nationwide.

Third, while the overall incentives to achieve interoperability have begun to shift with changing reimbursement, 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. America's health delivery system continues to have a culture that lacks a team-based approach and too often treats data as a competitive advantage, resulting in passive or active data blocking, instead of a shared asset for better care. As the percentage of reimbursement under alternative payment models increases, the demand for broad interoperability will increase. Similarly, developers who fail to adequately support interoperability will be under pressure to improve to serve their customers operating under alternative payment models. While we lack quantitative data to know for certain the extent of the problem of information blocking, 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 and improve value and support team-based care with individuals and families at the center.

The key is to help the market move from its slow initial pace to an accelerated one that supports coordinated, individual- and family-centered, high value care, and to do so in a way that gives providers the tools, resources and incentives to perform effectively in an interdependent, complex ecosystem.

The following recommendations were developed by the Interoperability Task Force 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[5] (Interoperability Roadmap). These recommendations are designed to accelerate the pace of change towards meaningful interoperability, driven by business and financial incentives.

Develop and Use Meaningful Measures for Consumers and Payers

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

In order to enhance the strength of incentives that drive interoperability, a set of specific measures should be developed that focusses on delivery of coordinated care, facilitated by shared information across the entire health team (including the individuals and families), and across the continuum of care settings. An example of an HIE-sensitive policy would be if payers decline 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 on an individual patient by all members of the health team.

Identifying existing, or developing new, measures (including patient-reported measures) that can be applied to provider organizations and are sensitive to interoperable HIE would serve as a powerful basis for strengthening incentives in two ways. First, those who pay for care can incorporate them in new payment models, and second, they can be used as the basis for public reporting, creating more transparency on which specific provider organizations are achieving high performance. The latter will empower consumers to select providers who perform better on measures that are directly relevant to their care in ways that address a key concern for them – lack of coordinated care. Thus, it is critical that these measures are "measures that matter" in particular to payers and consumers. Providers are also 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, measures that exist are less effective in driving change towards coordinated, high-value care because they are largely process measures under the control of an individual organization.

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[5] https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf

Agreement on a set of high-value HIE-sensitive measures would require coordinated action among key stakeholders – which we develop further in recommendation 4.

There has been limited prior work to define 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.

Develop and Use Meaningful Measures of Developer Performance

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

While developing HIE-sensitive quality and value measures that can be applied to 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, those purchasing EHR systems lack such measures to inform purchasing decisions or to use as a lever to put pressure on vendors to improve. While 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 likely more effective and efficient to use measurement and transparency as the primary driver for impactful use. Such measures would not only be valuable to providers but also to policymakers who are seeking for more inputs to surveillance for certification and regulation.

As with the prior 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 measure its impact on clinical decision making:

1. Number of exchanges of data from external sources, which could include other providers, consumers, payers, etc. (denominator that measures ability to exchange data with another electronic system such as an EHR, HIE or consumer 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)

Accelerate Payment Incentives for Interoperability

Recommendation 3: Set specific HIE-sensitive payment incentives – that incorporate specific performance measure criteria – and timeline for implementation that establish 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 review of previous testimony, public comment and other evidence indicates that progress will be dramatically accelerated if such measures are directly tied to reimbursement. The early experience to-date relying on certification criteria to drive interoperability has not led to sufficient progress in the field. Today, lack of palpable financial incentives for interoperability favors the status quo. Pressing internal priorities compete for attention and resources 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 – clearly defined measures with 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 they operationalize new payment requirements under MACRA). These measures do not require defining interoperability as a new domain of performance incentives; 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.

Initiate Sustained Multi-Stakeholder Action

Recommendation 4: Convene a major-stakeholder Summit co-led by federal government (e.g., ONC, CMS) and private sector to act on the ONC Roadmap to accelerate the pace of change toward 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 need to tackle 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 Meaningful Use program, the majority of health information on individuals resides in electronic health record systems. Second, the Secretary has established clear milestones for delivery system reform, and the accompanying payment model reforms. 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 healthcare 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 participate in quarterly progress reports that help ensure coordination and accountability of the public-private efforts organized at the working Summit to accelerate progress towards widespread interoperability. Without these coordinated efforts, it is unlikely that the collective action to enable interoperability called for in the Roadmap will occur fast enough.

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[6].
- HHS should work to simplify and harmonize requirements across advanced payment models for public and private payers[7].
- The health IT certification program should consider a requirement by which vendors would demonstrate that they can easily integrate with other applications[8].
- Facilitate consensus around shared approaches to standards-based electronic shared care planning across the continuum of care to promote wider adoption of these tools[9].
- Drive progress on standardization and capture of social determinants of health data elements that are critical to accountable care and other delivery models[10].
- Promote greater standardization for social determinants of health data, including data reported by individuals, families and caregivers, and related performance measures[11].
- 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[12].
- 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[13].
- Explore better individual identity-matching strategies to facilitate aggregation of data across clinical and non-clinical settings and other high-priority use cases[14].
- 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 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[15].

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[6] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[7] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[8] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[9] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[10] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[11] https://www.healthit.gov/sites/faca/files/HITPC_AHM_Hearing_Transmittal_08-11-2015_0.pdf
[12] https://www.healthit.gov/sites/faca/files/HITPC_AHM_Hearing_Transmittal_08-11-2015_0.pdf
[13] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[14] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[15] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf

- Limit the scope of certification to those functions critical to interoperability and outcomes improvement[16]. 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 healthcare provider and entity directories, etc.[17].
- When considering whether to pursue any new certification initiative, consider the below Five Factor Framework, asking whether the proposed certification initiative would[18]:
    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 challenges of privacy and security 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.[19]
- Provide clarifying guidance and disseminate best practices about privacy considerations associated with sharing of individual data among HIPAA covered entities and other community organizations[20].
- 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

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[16] https://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf
[17] https://www.healthit.gov/sites/faca/files/Joint_HIPC_HITSC_JTF_Final%20Report_2014-10-15.pdf
[18] https://www.healthit.gov/facas/sites/faca/files/HITPC_LTPAC_BH_Certification_Recommendations_FINAL.pdf
[19] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[20] https://www.healthit.gov/sites/faca/files/HITPC_AHM_Hearing_Transmittal_08-11-2015_0.pdf

  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[21].

Difficulty of establishing synchronous collective action among multiple participants

- 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[22].
- 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[23].

Weak, and in some cases misaligned, incentives

- Increase public transparency around hospital and health system performance on measures related to health information exchange through public reporting websites[24].
- 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)[25]
- 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[26].
- 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[27].

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[21] https://www.healthit.gov/sites/faca/files/HITPC_Health_Big_Data_Report_FINAL.pdf
[22] https://www.healthit.gov/sites/faca/files/Joint_HIPC_HITSC_JTF_Final%20Report_2014-10-15.pdf
[23] https://www.healthit.gov/sites/faca/files/Certification_Hearing_2014-06-24.pdf
[24] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[25] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[26] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf
[27] https://www.healthit.gov/sites/faca/files/HITPC_ACWG_RecommendationsTransmittalLetter.pdf