

April 22, 2013

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, Maryland

Re: Centers for Medicare & Medicaid Services [CMS-0038-NC] Advancing Interoperability and Health Information Exchange (HIE) Request for Information

Submitted via: http://www.regulations.gov.

Dear Ms. Tavenner,

On behalf of AMIA (American Medical Informatics Association), I am pleased to submit these comments in response to the above-referenced request for information. AMIA is the professional home for biomedical and health informatics and is dedicated to the development and application of informatics in support of patient care, public health, teaching, research, administration, and related policy. AMIA seeks to enhance health and healthcare delivery through the transformative use of information and communications technology.

AMIA's 4,000 members advance the use of health information and communications technology in clinical care and clinical research, personal health management, public and population health, and translational science with the ultimate objective of improving health. Our members work throughout the health system in various clinical care, research, academic, government, and commercial organizations.

AMIA thanks the Centers for Medicare and Medicaid Services (CMS), and the Office of the National Coordinator for Health Information Technology (ONC) for jointly issuing this request for information (RFI) and applicable the effort to address this critical and complex topic.

General Comments

Interoperability is arguably the most important next step as we seek to advance health information technology's ability to improve health care. AMIA is encouraged that this joint RFI from CMS and ONC highlights an awareness that HIE can decrease health care costs and improve quality and a willingness to consider payment models that create incentives for HIE. Also, in our view the options listed on pp. 9-16 of the RFI indicate a willingness to think broadly about models that might be implemented to create incentives for interoperability. AMIA is encouraged that CMS is willing to consider options other than just the ones listed.

AMIA recognizes that interoperability will require a combination of (1) a business case, (2) technical interoperability capabilities, (3) appropriate organizational relationships and (4)

interoperability-enabled workflow applications. This RFI seems to be most targeted at payment levers, i.e., the business case, which is a critical link in the chain.

AMIA commends CMS and ONC for seeking to advance the interoperability of health information systems and health information exchange (HIE) by exploring the policy levers available to CMS, ONC, and HHS. Our members strongly concur that interoperability and HIE are necessary to achieve the vision of higher quality, safer health care delivery at lower cost – the triple aim. We offer the following suggestions in support of national policy based on our members' experiences at the national, state, local and regional levels to advance interoperability and HIE.

The first three questions seem to indicate that a change in national policy may eliminate an existing barrier to market competitors sharing health data to improve safety, quality, and cost of care delivery. AMIA **members do not believe** that current policy prevents health care providers from sharing electronic health data towards the aim of achieving interoperability and HIE. Rather, we believe that current policy efforts must continue to encourage and emphasize the need for trust in order to achieve data sharing. Competitors need to feel comfortable that the electronic health data they capture, store, and manage about the patients they care for will be a) protected by those with whom they share their data; b) used to improve care; c) not misused to improve a competitive position in the market; and d) to facilitate the appropriate use and re-use of data to best serve the needs of patients and populations.

In any market there is a natural distrust among competitors, and that mistrust must be addressed. For example, the Indiana Network for Patient Care (INPC) – a large HIE in central Indiana – explicitly restricts the HIE from being used to "directly compare the participants or providers themselves." AMIA members have further observed distrust about sharing data among HIEs in the same state or region. Again, the key issue is *trust* and trust is best won by establishing conditions for trusted exchange of data such as those above. AMIA has previously explored several of the complex issues related to trusted exchange of health data and principles of data stewardship and believes that additional efforts are needed in these areas. ³

AMIA believes that trust is best earned and developed at the local or regional level. AMIA further asserts that stakeholders must come together, for example via community-based HIE organizations, to develop and then enhance working relationships towards open and appropriate

¹ Sears CS, Prescott VM, McDonald CJ. The Indiana Network for Patient Care: A case study of a successful healthcare data sharing agreement. Ice Miller. 2005. Available at:

http://www.icemiller.com/pdf/2005 09 13 the indiana network for patient care a case study.pdf

² Dixon BE, Scamurra S. Is there such a thing as healthy competition? Annual HIMSS Conference & Exhibition; 2007; New Orleans, LA: HIMSS.

³ Safran C, Bloomrosen M, Hammond WE, Labkoff S, Markel-Fox S, Tang PC, Detmer DE, Expert Panel. J Am Med Inform Assoc. 2007 Jan-Feb;14(1):1-9. Epub 2006 Oct 31. Toward a national framework for the secondary use of health data: an American

Medical Informatics Association White Paper.

⁴ Bloomrosen M, Detmer D. Advancing the framework: use of health data--a report of a working conference of the American Medical Informatics Association. J Am Med Inform Assoc. 2008 Nov-Dec;15(6):715-22. doi: 10.1197/jamia.M2905. Epub 2008 Aug 28.

exchange of health data to improve patient care. Some of our members suggest that this type of model will provide the strongest foundation for sustainable HIE across the nation, even though the process may take many years-- perhaps five to10 years --to become fully operational. However, other members believe that current policies promoting community-based HIEs have not taken us far enough over the last several years.

We do have some concerns that, while HHS is focusing on the goal of an information-rich healthcare environment, the formats that are being established by the requirements for Meaningful Use (MU) 1 and 2 are too often "data rich but information and knowledge/insight poor." AMIA believes that the focus of CMS and ONC should not be on the volume of data exchanged but rather on the extent to which data that are collected add value.

Specifically, the RFI states, "HHS envisions an information rich, person-centered, high performance health care system where every health care provider has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes." This statement contains the underlying assumption that there is a correlation between healthcare providers having a larger quantity of clinical data about each patient, and patients having improved health. In fact, it is possible that such data overload could overwhelm providers and result in adverse consequences for patient care unless provider health IT systems have the functionalities required to effectively manage and present incoming data before the data begin to flow. AMIA asserts that incoming data must be verified as to their provenance, reconciled with existing data, and directed to appropriate staff and appropriate systems. Even with new tools to manage the processes, the additional overhead will become a significant unreimbursed expense.

We believe HHS should use the levers available to facilitate the kinds of exchange that matter most to clinicians in their efforts to maximize quality, safety and value, and that are more likely to have a positive, direct effect on health care delivery. We believe that incentives and penalties should not be directed exclusively at physicians and other clinicians and professionals involved in population health management, because they cannot directly control whether and how health information is exchanged. Incentives and penalties should be focused on other stakeholders as well, such as electronic health record (EHR) developers and third-party content/service providers, to take actions necessary to provide the functionalities, work flow support, and value necessary for the exchange processes

In sum, we believe that payment policies for HIE should be consistent with value-based payment and should focus on the delivery of services that facilitate decision-making and care coordination, and effectively measure and track clinical and population health outcomes.

Comments in Response to Specific Questions

1. What changes in payment policy would have the most impact on the electronic exchange of health information, particularly among those organizations that are market competitors?

Our members are already seeing an increase in electronic exchange of health information because of existing innovative payment models. For example, NY-Presbyterian Hospital in New

York City has seen a substantial increase in HIE-related activity in response to innovative models of payment of care and other programmatic incentives intended to improve the effectiveness and efficiency of care. The innovative payment models have come from NYS Medicaid Health Home program.⁵ Even though Medicaid patients represent a minority of the patient volume, the hospital has initiated substantial programs in response to these incentives since being designated a health home.

The HIE-related programmatic activities being implemented at NY-Presbyterian in response to this program include (1) making care plans available to contracted case managers and community based organizations (CBOs) that are involved in the program, (2) using the regional health information organization (RHIO) to which it belongs (Healthix, Inc.) as a community record so clinicians and care managers can see the patient's data from multiple institutions, and (3) receiving notifications from the RHIO about "events", for example, admissions, emergency department visits, etc., that take place at remote institutions.

Another example is a project funded under NY State Department of Health's "Health Efficiency and Affordability Law" (HEAL) program. NY-Presbyterian has a 3-year contract to improve the care of depressed diabetics using (i) certified EHRs, (ii) workflow redesign, and (iii) measurement and feedback. Part of the program involves the implementation of health information exchange activities with post-acute and long-term care facilities and community providers. This project leverages the RHIO to support the transmission of "transfer documents" at the time of admission and discharge. The RHIO also is used as a community record.

While these are unique innovations based on some long-standing partnerships in NY state, they are becoming a national model for other regions. In other words, while each state has different Medicaid health home programs, an expansion of these types of programs could be expected to lead to an increase in HIE. Another successful model is OCHIN (https://ochin.org/), which was originally developed with HRSA funding to support EHR implementation and information exchange in community health centers and other safety net providers has evolved into a multistate HIE.

There are numerous other examples where electronic exchange of health information under existing policy is occurring, including states such as Indiana, Ohio, and Kansas. The Indiana Health Information Exchange (IHIE) and Cincinnati-based HealthBridge exchanges have existed since the mid-1990s, well before even current policies such as HITECH existed. These exchanges are pushing and querying data of various sorts for a variety of clinical and public health use cases. The Kansas Health Information Network (KHIN) recently reported adoption of both DIRECT-based and query-based technologies enabling nearly 4000 messages to be exchanged across 194 facilities. Because these and other HIEs are operating and expanding under current policies to encourage HIE, it remains unclear what additional policies are necessary to encourage market competitors to share information.

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⁵ (http://www.health.ny.gov/health_care/medicaid/program/medicaid_health_homes/.

2. Which of the following programs are having the greatest impact on encouraging electronic health information exchange: Hospital readmission payment adjustments, value-based purchasing, bundled payments, ACOs, Medicare Advantage, Medicare and Medicaid EHR Incentive Programs (Meaningful Use), or medical/health homes? Are there any aspects of the design or implementation of these programs that are limiting their potential impact on encouraging care coordination and quality improvement across settings of care and among organizations that are market competitors?

Existing policies in the Patient Protection and Affordable Care Act are naturally advancing the need for market competitors to come together, build relationships, and begin exchanging data. In a recent analysis of emergency department visits, for example, researchers at the Regenstrief Institute found that nearly all emergency departments in Indiana shared patients with nearly every other emergency department in the state. The research implies that as many as 40% of patients will receive a significant portion of their care outside any given accountable care organization (ACO).

AMIA strongly believes that public policies should continue to support encourage data sharing. . Future policy should continue to support and encourage affordable, high quality of care for patients because delivering better, coordinated care requires interoperability and HIE.

3. To what extent do current CMS payment policies encourage or impede electronic information exchange across health care provider organizations, particularly those that may be market competitors? Furthermore, what CMS and ONC programs and policies would specifically address the cultural and economic disincentives for HIE that result in "data lock-in" or restricting consumer and provider choice in services and providers? Are there specific ways in which providers and vendors could be encouraged to send, receive, and integrate health information from other treating providers outside of their practice or system?

AMIA believes that CMS and ONC should consider refinements to stage 2 MU objectives regarding transitions of care. Meaningful use requirements have expanded what was usually a carefully crafted page and a half of relevant information to 7 or more pages of information. We are concerned that too much of this information is not helpful to the receiving clinician, who is forced to scan through the unstructured document to try to determine what matters (diagnosis and thought processes) and what has changed (medications, test results, treatment plans). AMIA urges HHS to develop incentives that encourage exchange with conciseness, precision, and high usability for clinical recipients.

AMIA believes that HHS policies should seek to minimize the number of connections and protocols that eligible hospitals and providers will need to establish and manage. Currently, many EHR vendors are charging each hospital or provider thousands of dollars to establish a connection to each external organization or system. Similarly, vendors are charging hospitals and

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⁶ Finnell JT, Overhage JM, Grannis S. All Health Care is Not Local: An Evaluation of the Distribution of Emergency Department Care Delivered in Indiana. AMIA Annu Symp Proc. 2011;2011:409-16.

providers for each type of document they wish to exchange through an HIE. Vendors are further signaling that there will be ongoing maintenance charges for each connection type for each practice. There is nothing to be gained from HHS policies that encourage exchange if the exchange partners do not have cost-effective and readily available connections. Therefore, AMIA believes that HHS should examine what it can do to encourage bundled pricing for services which will support the variety of HIE connections and document types emerging. AMIA believes that there are several opportunities for valuable exchange that could be encouraged though HHS policies. These include:

- o Directories of provider contact information complete and up to date.
- o Reliable and accurate patient identification and matching.
- o Rapid notification of patient care activities such as emergency department arrivals, and admission and discharge notifications to Primary Care Providers.
- o Cross-system management of patient consent.
- o Support for quality measures that track patients across care settings.
- o Data cleaning and standardization services.
- o Management of longitudinal care records.
- o Data analytics, alerts and public reporting services.
- 4. What CMS and ONC policies and programs would most impact post acute, long term care providers (institutional and HCBS) and behavioral health providers' (for example, mental health and substance use disorders) exchange of health information, including electronic HIE, with other treating providers? How should these programs and policies be developed and/or implemented to maximize the impact on care coordination and quality improvement?

In Indiana, the Indiana Network for Patient Care (INPC) has been working with post acute, long term care (LTPAC) providers for almost three years. The INPC has found that connecting these providers to the HIE has been difficult, because often the providers lack either an electronic infrastructure (e.g., an EHR system) or technical personnel with the right skill sets for HIE. These providers have data of interest to other providers currently participating in HIE, and LTPAC providers would strongly benefit from receiving data available in an HIE. However, policies that require or incentivize HIE may be putting the cart before the horse. These providers require resources (financial and human) and time to first implement a robust electronic infrastructure – modern EHR systems, interface engines – before they can begin to meaningfully participate in HIE. Rushing LTPAC providers into HIE before they have basic electronic components may encourage these providers to choose simple, "lite" applications that will enable them to view available HIE data but won't allow them to send data into the HIE. Furthermore, "lite" applications may not support workflow redesign, which our members view as a critical component not only for adoption but also long term cost savings in health delivery processes.

AMIA encourages CMS and ONC to consider enhancing current program requirements to help assure robust health information technology and systems that support patient, provider and payer needs. Some of AMIA's members suggest that CMS and ONC expand current MU incentive programs to entities not currently included, such as post-acute and long term care providers and facilities, dialysis facilities, as well as home health and laboratories.

Any standards that are promoted for the representation of data from LTPAC and specialty environments should be aligned with the ONC Standards and Interoperability(S&I) Framework.

7. How could the EHR Incentives Program advance provider directories that would support exchange of health information between Eligible Professionals participating in the program. For example, could the attestation process capture provider identifiers that could be accessed to enable exchange among participating EPs?

AMIA suggests that ongoing efforts should be focused on leveraging existing directory services and organizations that have existing mechanisms for registering and maintaining a directory that includes a broad array of providers. Private sector as well as federal programs such as Council for Affordable Quality Healthcare (CAQH) Universal Provider Directory or the CMS National Plan & Provider Enumeration System (NPPES) system already has such directories and operations in place. These directories could easily be extended to include additional provider identifier information that can help facilitate exchange.

Secondly, ONC and CMS should leverage directory standards work currently underway under the Standards and Interoperability (S&I) Framework; little if any additional work would be required to finalize an already agreed upon entity and provider directory standard (assuming that such standards are balloted via an SDO). Additionally, this standard allows for a distributed or federated directory structure that allows for the service providers themselves to create and maintain a provider directory at a more local level.

Lastly, we recommend that ONC and CMS find ways to encourage compliance with any directory standards among those vendors and other service providers that will be enabling these services. Including this directory standard as part of the Certified EHR requirement is one recommended solution.

Based on the current experiences of exchange such as the Indiana Network for Patient Care (INPC), we note that it will be very difficult for the EHR Incentives Program to create a sustainable model for provider directories in support of HIE. The reality is that provider directories are incredibly challenging to develop and maintain. The INPC provider directory maintains listings for 19,000 of the state's 23,000 physicians. The provider registry requires multiple FTEs to keep its contents up-to-date given that providers move in and out of the health care system every month. Some retire, new ones are created or credentialed; and others simply re-affiliate with a different set of peers or hospitals. There are also errors that must be corrected. Capturing data during an annual attestation process would not support the development and maintenance of the high quality provider directory. The information captured would likely be out-of-date for more than 10% of providers by the time it was published and made available to state-based HIEs. Furthermore, reconciling a national list with more granular state-based data sources could require more effort than the current task of simply staying on top of local changes. Therefore, we perceive little advantage to national-level data collection for a provider directory which will primarily be used at local and regional levels to facilitate HIE.

8. How can the new authorities under the Affordable Care Act for CMS test, evaluate, and scale innovative payment and service delivery models best accelerate standards based electronic HIE across treating providers?

We suggest that HHS include a requirement that qualified health plans in insurance exchanges be able to allow the beneficiary to have electronic access to their clinical information. Access should align with Certified EHR technology standards that enable a patient to View, Download, Transmit and support of consumer support and recommended efforts (e.g., Blue Button).

9. What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program to maximize beneficiary access to their health information and engagement in their care?

AMIA believes that Meaningful Use stage 2 objectives that focus on patient engagement have not fully had an opportunity to demonstrate their effectiveness. View, Download, or Transmit and Patient Communications MU objectives are important drivers that AMIA believes will result in some level of patient engagement. We caution HHS to allow sufficient deployment and use as well as appropriate evaluation to determine if, how, or to what degree these current (MU) policies are effective. At a minimum, this readies providers with standards based capabilities to enable patient access to their health information when it is requested. Further, AMIA suggests that the impact of MU2 is not yet known, should be evaluated and subsequent activities should build experiences and evaluations of MU stages 1 and 2.

AMIA encourages CMS and ONC to pursue additional options regarding how to appropriately address issues and concerns relating to authentication of patient identity. Health information exchange relies upon the ability to accurately and confidently identify and match patients with their clinical information. Some of AMIA's members believe that the ACA mandate for Unique Health Plan Identifiers coupled with mandates for individual insurance may result in a unique identifier comprised of the Health Plan ID and the individual benefit account number (similar to bank routing number and account number). ONC and CMS should encourage policies that will enable portability of individual insurance account numbers between and among Unique Health Plan ID members.

AMIA anticipates that organizations such as the Patient-Centered Outcomes Research Institute (PCORI) will play a significant role in helping addressing improvement of patient care and access to health information by broadly disseminating its research findings. PCORI seeks to address barriers to information dissemination by incorporating diverse clinical settings and participants in its work and studying challenges to information access. Among PCORI's five priorities is *communication and dissemination research*, which is to be achieved via comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision-making between patients and their providers. PCORI's research agenda notes, "All funder studies will have a strong orientation to the patient perspective, which included an emphasis on evidence that enhances communication at the point of care, including self-care. PCORI-funded studies will have patients

involved in the development of the research, its governance and oversight, and its dissemination strategy."

AMIA believes that CMS and ONC can more effectively address patient access and use of electronic health information by collaborating with PCORI and other organizations conducting similar research to identify opportunities for improvement and best practices. AMIA and its members stand ready to provide technical assistance and/or to apply findings from appropriate and relevant research.

10. What specific HHS policy changes would significantly increase standards based electronic exchange of laboratory results?

In the context of laboratory data exchange, AMIA's understands that there is a CLIA policy that requires labs to verify the display of the data in whatever system will show the data. This slows down HIE because the lab has to verify the display. Thus AMIA believes that it is important to consider revisions to the Clinical Laboratory Improvement Amendments (CLIA) that would require laboratories to transmit laboratory results using standardized terminologies such as LOINC and SNOMED. These terminologies are required for EHR certification testing under current meaningful use (MU) regulations. Adoption of LOINC by hospitals and other downstream recipients of local, idiosyncratic laboratory test codes requires mapping to LOINC. Yet mapping to LOINC is expensive and challenging.⁷⁸

Meaningful use incentives do not provide nearly enough encouragement for providers to map all existing laboratory codes to LOINC, which means that up to a third of tests required for public health reporting may go unmapped. Furthermore, it encourages institutions to only map the minimum necessary to qualify for meaningful use incentive payments. A recent analysis revealed that laboratory data from various meaningful use certified EHRs in 2011 failed to provide a LOINC code in the majority of case reports to public health. Thus, although these systems are capable of sending LOINC and SNOMED codes, it seems that this is not regularly occurring. This results in significant challenges and makes semantic interoperability nearly impossible at the community level. AMIA believes that one way to ensure that standard codes are used by hospitals and providers in their electronic messages to HIEs, the Social Security Administration (SSA), the Veterans Health Administration (VHA), and other federal agencies, is for the standardized codes to be included in the electronic messages sent by the labs where the test was performed.

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⁷ Vreeman DJ. Maintaining mappings from source systems in a local health information infrastructure. AMIA Annu Symp Proc. 2006:1131.

⁸ Vreeman DJ, Stark M, Tomashefski GL, Phillips DR, Dexter PR. Embracing change in a health information exchange. AMIA Annu Symp Proc. 2008:768-72.

⁹ Gamache RE, Dixon BE, Grannis S, Vreeman DJ. Impact of selective mapping strategies on automated laboratory result notification to public health authorities. AMIA Annu Symp Proc. 2012;2012:228-36.

¹⁰ Dixon BE, Siegel JA, Oemig TV, Grannis SJ, editors. Towards Interoperability for Public Health Surveillance: Experiences from Two States. International Society for Disease Surveillance 11th Annual Conference; 2012 Dec 4-5; San Diego, CA.

Concluding Comments

AMIA appreciates the opportunity to submit these comments. Again, we thank ONC and CMS for issuing this joint request for information. Please feel free to contact me or Meryl Bloomrosen, AMIA's Vice President for Public Policy at any time for further discussion of the issues raised here.

Sincerely,

Kevin Fickenscher, MD

AMIA President and CEO