AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
Executive Vice President, CEO

American Medical Association
515 N. State Street
Chicago, Illinois 60654

ama-assn.org

(p) 312.464.5000
(f) 312.464.4184

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Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Farzad Mostashari, MD, ScM
National Coordinator
Health Information Technology
Office of the National Coordinator
for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Advancing Interoperability and Health Information Exchange [CMS–0038–NC]

Dear Acting Administrator Tavenner and Dr. Mostashari:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments in response to the Department of Health and Human Services (HHS) Request for Information (RFI) on Advancing Interoperability and Health Information Exchange (HIE). The AMA believes that strategically advancing electronic HIE and interoperability will further our nation's goal of ensuring a high-performing health care system, and we welcome the opportunity to comment on this important work.

General Comments

Our detailed responses to the specific questions posed in the RFI are outlined below. As an overarching matter, the AMA believes that improving the Medicare fee-for-service payment system and advancing new physician-led private and public payment and delivery models, such as Accountable Care Organizations (ACOs) and the Patient-Centered Medical Home (PCMH), are critical to ensuring a sustainable health care delivery system. Real-time electronic exchange of health information and interoperability are critical components of these new models. However, they are not the only factors in this complex endeavor. From the physician perspective, there are numerous issues that hinder the development of new payment and delivery models, such as infrastructure needs (including but not limited to, HIE and data needs), the need for technical assistance to advance adoption, misaligned payment incentives, the advancement of well-tested and clinically relevant quality performance measures, and numerous and often competing state and federal regulatory requirements.

As the RFI notes, there are multiple public and private efforts under way that incorporate opportunities to advance electronic HIE. For example, the Center for Medicare & Medicaid Innovation (CMMI) has established numerous new programs and pilots to advance new payment and delivery models, including most recently the State Innovation Model Awards and the Comprehensive Primary Care Initiative. Each of these initiatives have HIE components that are dependent on physician readiness, the involvement of multiple stakeholders in the development of infrastructure, and aligned incentives to advance the use of electronic data to improve quality and care coordination. As these efforts move forward they will inform many key questions and advance HIE adoption at the physician level and multi-stakeholder level. Such testing and multi-stakeholder engagement are valuable and should not be duplicated or overburdened with additional or conflicting mandates from HHS on the electronic HIE adoption front. Instead, we encourage HHS to align, improve, and leverage existing efforts.

Comments in Response to Specific RFI 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?**

The AMA views the key purpose of payment policy changes as being to support improvements in delivery of care. For example, under the Medicare physician fee schedule, physicians are not compensated for phone calls with patients, email consultations, consultations with other physicians and health professionals, or providing support for patient self-management. Providing Medicare payments for these services would provide an enormous incentive for physicians to devote more time and resources to care coordination, and to redesigning the delivery of care to support better coordination. Care coordination is, in turn, highly dependent upon the exchange of information. For example, emergency physicians need to have access to information about all the tests and treatments patients have received before they come to the emergency department in order to make appropriate test ordering decisions and place patients in the most appropriate care setting. Information flow across ambulatory, acute, and post-acute care settings would also be helpful, and this too requires a payment policy that rewards physicians who take the time to obtain this information and use it to coordinate and improve care and lower costs.

2. **B) 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?**

While current exchange efforts are more affected by regional characteristics, competition is still the main driving force, which makes it difficult to gauge the actual impact of these identified programs.

Many recent incentive programs have helped to promote data exchange capabilities, but current efforts are insufficient. For example, the Meaningful Use (MU) program's certification requirement is helpful to the degree that it provides some basic level of assurance that physicians will be able to meet the requirements outlined by the Centers for Medicare & Medicaid Services (CMS), but it does not assure them that certified products will be able to achieve full interoperability with other products, not to mention whether a physician will find it to be a workable product for his/her particular practice. To facilitate data exchange capabilities, more focus is needed to ensure interoperability across the HIT industry, and incentive programs should be extended across the patient care continuum.

CMS should focus more effort on finding ways to incentivize physicians of all medical specialties and other health care providers in current and new programs to create greater care coordination across the marketplace. As a starting point, the MU program must allow greater flexibility. The program's current design is too rigid and does not adequately accommodate different practice patterns, specialties, and workflows, which impedes physician participation. The AMA has raised these concerns and offered solutions in previous comment letters.[1] More work is also needed to ensure that certain physician specialties are provided incentives to utilize HIT and not face penalties, such as physicians who do not typically engage in face-to-face encounters with patients (e.g., pathologists and radiologists), who do see patients but may not provide follow-up care (e.g., anesthesiologists), who serve patients in their homes but may not have access to broad-band Internet access, and in situations where the MU requirements are simply unworkable.

We also remain extremely concerned that Stage 2 requirements will deter even those physicians who were successful attesters in Stage 1. Furthermore, not all providers are included in the MU programs. Long-term care providers, and home health providers who are significantly paper-based, are excluded. Challenges for coordinating care between behavioral health providers and others also persist. For example, the percentage of

[1] For a complete list of the AMA's comments letters on MU please go here.

psychiatrists who participate in MU is lower than other medical specialties. Also, only a small percent of psychiatrists are participating in ACOs, bundled payments, value-based purchasing, or medical homes because many of these programs are dependent in part on the participation of physician groups, while many psychiatrists are solo practitioners.

Another challenge is that the business model to achieve HIE viability remains unstable and physicians are reluctant to make costly HIT investments when it is uncertain whether their local HIE will be able to sustain itself. Some regional HIEs have already failed for lack of a sustainable business model. Also, many states have local HIE initiatives, but funding is contingent upon finite federal sources. Many states continue to face serious budget shortfalls, and it remains unclear what the longevity of these efforts will be after the Health Information Technology for Economic and Clinical Health Act funds are depleted. Unknown costs for physician participation in HIEs are also a concern. The costs for physician participation in an HIE must be low enough to spur participation, particularly since the return on investment is not expected to accrue to physicians. The payment policy changes suggested in #2 above could enhance the benefits to physicians. CMS should also consider that state-specific Medicaid programs with electronic health record (EHR) deployment are at different stages of EHR adoption and compliance, which impacts overall data exchange activities.

Another overarching concern that must be addressed from a care coordination and information exchange standpoint is the potential for creating new electronic data silos. Attention needs to be paid to ensuring the industry is not creating additional silos with separate programs.

3. A) 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?

B) 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?

As we transition from first generation ACOs that exist within a fee-for-service environment to those where high quality care delivery and payment are more closely aligned, there is the potential for HIE to occur across systems. It will be critical during this transition for CMS to encourage payment models that will fully enable HIE. Most of the bundled payment models being tested today are centered on a hospital admission or procedure. Such models are a critical part of the learning curve for many providers, but HIE is limited to a specific episode. CMS payment policies and HIE must accommodate a wide array of payment models, including medical homes, episode- or condition-based bundled, and risk-adjusted global payment bundles as a means to foster the level of HIE necessary to effectively manage patients and populations across settings. However, efforts to develop payment policies that encourage HIE should not exclude fee-for-service or other payment models that may continue to be appropriate for certain providers.

A national patient identifier is another issue that deserves further consideration as a means to encourage HIE. Arguments supporting and opposing a national patient identifier are well documented and both sides have legitimate points. The AMA has previously voiced concerns about the privacy of such identifiers. However, as we transition to more integrated and coordinated delivery systems that will succeed or fail based on HIE capabilities, CMS and the Office of the National Coordinator (ONC) should thoroughly study a national patient identifier and other ideas that could enable seamless and accurate exchange of healthcare data in a secure manner.

C) 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?

The AMA recommends the agency carefully examine data currently collected and reported through its Physician Quality Reporting System and MU Programs. Using data collected from these activities will help ensure that data collection and transmission activities are tied to certification. Ultimately, some sort of certification process must be in place regarding how data are sent, received, and integrated. It will be critical that electronic HIE land on a common data transmission format including the content standard and value set standards.

The model established around Stage 2 certification for standard test decks is a promising one. However, the processes around using these test decks have not been fully tested. The AMA recommends CMS further evaluate the use of these test decks, and incorporate any feedback and learning into its processes for encouraging more robust electronic information exchange. Moreover, to help ensure widespread adoption and implementation of EHR technology by physicians, the ONC testing standards should support efficient and aligned test procedures for verifying certification requirements.

4. A) 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?

Physicians who treat homebound patients are stymied by their inability to get predictable connectivity and variable bandwidth limitations because of the lack of enforceable standards. Thus, when caring for the patient in the home, home care physicians have limited access to such things as lab tests and portable x-rays. Homebound patients also need direct patient contact with their clinicians on an initial and continuing basis, otherwise the potential for cost savings and quality improvements will suffer no matter what technology is used. For instance, just using telemonitoring to home health nursing services has failed to show savings, but using telesensor data streaming directly to the medical team including the prescribing clinicians has yet to be studied.

When it comes to behavioral health (and all health care for that matter), we believe strongly that clear policies are needed surrounding the medical liability of a physician who uses an electronic HIE. Liability protection for physicians participating in HIEs and HIE participation in and of itself does not establish a standard of care. Physicians should not be held liable for any data breaches that occur within an HIE once the physician has released the data to the HIE.

B) How should these programs and policies be developed and/or implemented to maximize the impact on care coordination and quality improvement?

First, we strongly urge CMS and ONC to convey to the Office for Civil Rights (OCR) the need to finalize reasonable guidance associated with accounting for disclosures. If the final rule is adopted as proposed or is adopted without substantial revisions, then the impacts will reverberate across the health care industry and will significantly dampen not only HIE efforts but overall use of electronic systems and HIT.[2] This not only will impact physician providers, but also long-term care, home health, and behavioral health providers.

CMS should also explore ways to include all providers in HIT and care coordination initiatives to facilitate overall interoperability. Also, this may create the needed pressure to develop more robust IT products used by the aforementioned providers since most of their work is done in a largely paper-based environment.

Additionally, education and training still are required with respect to Health Insurance Portability and Accountability Act (HIPAA) privacy and security, and should be increased and more comprehensive. Providers, especially physicians, must have the right tools (privacy, security, consent management) to exchange

[2] The AMA's recommendations on this rule can be found here.

data effectively and confidently. For example, it is clear from our conversations with physicians who have been audited under the MU program, and from speaking with CMS staff, that there is a tremendous amount of confusion around the requirement to perform a risk analysis.
We request that CMS continue to identify ways that quality measures for multiple programs can be better aligned, so physicians have more time to engage in direct patient care. We have worked with CMS to better align the quality measures physicians participating in these programs must report. Currently, there remains some overlap among the programs in the measures that must be reported, and duplicative reporting detracts from the time physicians can spend directly treating and caring for their patients.

Additionally, we ask that CMS, ONC, and OCR work together with physicians, patients, and the rest of the health care community to address how extra-sensitive information should be handled within an EHR (i.e. data segmentation, privacy controls). We also believe that more needs to be done to address how state privacy laws that could serve as additional barriers to HIE are better integrated and synchronized.

5. How could CMS and states use existing authorities to better support electronic and interoperable HIE among Medicare and Medicaid providers, including post-acute, long-term care, and behavioral health providers?

There are a number of ways CMS and states could use existing authorities to better support electronic, interoperable HIE between Medicare and Medicaid providers. For instance, CMS could expand the use of grant programs such as the Innovation grants, which are available to state Medicaid, to facilitate HIE deployment and active use. Consideration should be given to expanding funding for the Regional Extension Centers which were created to support primary care physician participation in the MU program and whose funding is winding down, to support HIT adoption with other providers (including additional types of physician specialties). CMS could also explore showcasing states that are leveraging technology infrastructure across multiple initiatives including HIE and patient health insurance exchanges (HIXs).

6. A) How can CMS leverage regulatory requirements for acceptable quality in the operation of health care entities, such as conditions of participation for hospitals or requirements for SNFs, NFs, and home health to support and accelerate electronic, interoperable health information exchange?

We agree that coordination of care across institutional and non-institutional settings of care, as well as timely, electronic exchange of health information to support patient admission, discharge, and transfer is a desirable goal. However, CMS should not attempt to reach this goal by requiring new clinical standards in the form of conditions of participation (CoPs) or requirements. Furthermore, many of the entities at issue are at vastly different stages of HIT implementation and integration; the infrastructure and interoperability required for CMS to contemplate making HIE in this context a requirement is just not present at this time. Rather than trying to spur HIE in this context through additional requirements in the CoPs or elsewhere, CMS should work to provide positive financial incentives for entities to adopt and engage in HIE.

B) How could requirements for acceptable quality that involve health information exchange be phased in overtime?

The purpose of an HIE is to advance better and affordable care by providing access to a patient's medical information. CMS could approach participation in many ways, including as a set of data elements as well as clinical documents (e.g., lab result file, image or care plan) that need to be transmitted and made available to HIE users (including potentially patients). As such, there would need to be a validation process of these data elements and documents to ensure their accuracy. This could be done via a certification process for participants in an HIE. CMS should also consider alignment to the MU and other programs where electronic data is exchanged. This would include leveraging the requirements for the aforementioned Medicare programs for HIEs.

Similar to MU, CMS could start with a minimum set of elements and documents and incrementally increase the data that are exchanged and are required for the calculation and reporting of clinical quality measures (CQMs) over time. The agency could also scale up the number of participants over time (e.g., start with skilled nursing facilities and hospitals and then move to ambulatory practices). To be clear, though, while current reporting criteria and certification requirement for CQMs are imperfect, they are a starting point, and it is important to let the marketplace work. Otherwise, we risk having different vendors saturating the market, and this could lead to an unclear and confusing understanding of what data are important, and further, market demand will be stymied and uptake minimal.

C) How might compliance with any such regulatory requirements be best assessed and enforced, especially since specialized HIT knowledge may be required to make such assessments?

It is important to recognize that electronic HIE requires HIT knowledge. If CMS wants this area to advance, the health care community will need to learn new skills to support it. These new skills and care processes will require intensive resources—both staff and financial. Compliance for HIE should be approached through a scaled approach, similar to that adopted for the MU program.

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?

Provider directories (the "electronic" white pages) are a central tenent of HIE. The AMA believes that a good approach to advancing the development of provider directories, in addition to the existing private and public provider directory efforts that are already underway in different areas across the country, would be for CMS to provide access to existing sources of provider information such as the MU attestation database. Consideration should be given to working with Healtheways (formerly NwHIN), an existing private and public consortium for promoting the expansion and use of HIE across the country.

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?

The AMA believes that it is critical to adopt the standard and operating rules for facilitating claims attachments as required by the Affordable Care Act (ACA) Section 1104, which will facilitate the movement of health information across health care settings. We believe it will bring significant value and efficiency to the prior authorization (PA) process as physicians are increasingly being required to obtain PAs and supply attachments for all types of health care services, including medical, pharmacy, laboratory, radiology, and durable medical equipment services. We urge CMS to adopt the ASC X12 275, Additional Information to Support a Health Care Claim or Encounter (hereinafter referred to as the 275) as the named standard.

The AMA also calls for HHS to expand use of the existing named HIPAA standard from just being used by payers to communicate with providers about the status of their claim (known as the X12 277), to also serve as an acknowledgement by a payer that they have received a claim and to request additional information needed from a provider. Together, the robust use of 277 transactions could remove the largely manual, time consuming, and expensive process for physicians when responding to payers' varying attachment requests.[3]

[3] For more details on the AMA's proposal for the use of the 275 and 277 transactions, please see our testimony to National Committee on Vital Health Statistics here.

We fully recognize that the long-term goal of automating the information exchange processes in health care and achieving true administrative simplification rely largely on the incorporation of structured, coded data into streamlined electronic transactions. We recognize, though, that there is much more work to be done with regard to the implementation of both technology and health care standard transactions and operating rules by all stakeholders in the health care delivery process. This work, while progressing quickly, is still expected to take years to complete. The fact remains that with all the HIT adoption success of late, health care payers and providers still rely heavily on the exchange of information that is based upon rich text narrative, unstructured data or data that require being structured according to payer rules driven by limitations of legacy processing infrastructures and plan design.

We also believe the ACA provision contained in Section 10109 concerning establishing a payer certification program is critical. A payer certification program must ensure transactions meet not only the syntactical requirement, but the business need as well to ensure administrative simplification is realized.[4] HIPAA validators certify compliance using only the syntactical requirements, but payers need to be encouraged to meet the business needs in order to reduce calls and increase administrative savings. Complete business testing includes end to end testing of the entire transaction process.

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?

The AMA fully supports patient engagement in their health, as this is a basic tenet of the doctor-patient relationship. We recognize that as health care becomes more digitized and patient data are exchanged, issues around access, use, and ownership must be addressed. The AMA House of Delegates has instructed us to study issues related to clinical data access, use, and ownership within HIEs, and to study issues related to how best to protect the legitimate interests of patients and physicians regarding clinical data that are sent to and received from an HIE, particularly in regard to payers and their access to and use of clinical data obtainable via an HIE, and develop policies and standards regarding HIE data, with attention to:

- Who owns the clinical data that are passed to and from an HIE;
- What types of parties have a legitimate interest in obtaining clinical data from HIEs, and for what purposes;
- Who may determine what data are made available to whom;
- What constraints should properly be placed on the use of clinical data in an HIE;
- Ensuring that at a very minimum, no payer would be allowed to obtain identifiable clinical data on individuals who are not currently insured members of a health plan belonging to that payer, with the possible exception of informed consent having been signed by a patient as part of an application for acceptance of that patient by a specified health plan, if such underwriting were once again allowed by law;
- How policies and standards for data sharing and access should differentiate between individually identifiable patient data, and de-identified or aggregated patient data;
- Standards for de-identified and aggregated data to protect against reverse engineering to re-identify clinical data, especially where data relate to rare diseases or comes from rural areas;
- Policies for data sharing and access that specifically address data use for mandated reporting, "care management," research, and proprietary purposes;
- Informed consent for sharing of data: what such informed consent should include and who should be tasked to obtain it; and

[4] Syntactical compliance requires a number be placed in a field designated for a number and an alpha character be placed in a field designated for an alpha character.

- Possible model state legislation to define accountability for clinical data use in an HIE and to ensure that those policies that are essential to protect patients and physicians can be legally enforceable; and privacy issues including genetic testing, mental health disorders, and substance use disorders.

Our recommendations on these matters will be considered at our Annual Meeting in June, after which we will be in a better position to discuss our policies.

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

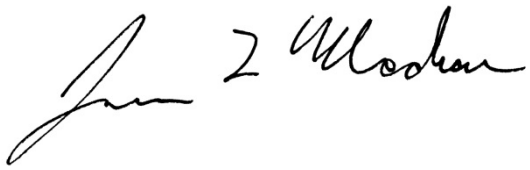
The AMA continues to believe that the MU requirements must be more flexible, including those that involve lab requirements. The incorporation of clinical lab results into EHRs as structured data is dependent on the EHR vendor and the laboratory, not just the physician's use of the EHR. HIT interoperability and standards efforts have continued to evolve, and industry adoption is steadily increasing. However, customized interfaces between an EHR and lab systems (which are predominantly hospital-based) do not exist on a widespread basis today, and even when they are technically feasible, they are difficult and costly for physician practices to implement, test, and maintain.

In many cases expensive customized EHR interfaces are still needed to support EHR integration with HIEs. Moreover, small or rural practices may never achieve a sufficiently high priority (from the lab's perspective) to get an electronic interface. We have heard from physicians that this is an issue in their practices today; even if they have made a formal request for an interface, they languish for long, and sometimes indefinite, periods of time waiting for their request to be prioritized. There have also been reports from physicians on the difficulties in matching patients within the lab compendium, resulting in problems with erroneous transactions and erroneous results reporting to incorrect patients.

Without the interface, physicians are excessively burdened with keying information into their EHRs in order to meet the MU requirements, or faced with the possibility of having to purchase a costly interface. Physicians and their staffs should not be expected to key in lab results simply because there is no ability for the lab to send these results directly to the EHR. It is incumbent upon ONC to ensure the interoperability of EHR systems and advocate for the inclusion of expectations of laboratory service providers to follow a single standard that EHR vendors can adopt so that laboratory result interfaces can be easily created by EHR vendors and offered at little to no additional cost to physicians and other EPs who use their products. CMS and ONC should consider funding for these interfaces to further promote HIE in the lab space.

The AMA appreciates the opportunity to comment on these important matters. Should you have any questions please direct them to Mari Savickis, Assistant Director of Federal Affairs at 202-789-7414 or mari.savickis@ama-assn.org.

Sincerely,



James L. Madara, MD