April 19, 2013

Marilyn Tavenner  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Ave, S.W., Room 445-G  
Washington, DC 20201

Farzad Mostashari, M.D.  
National Coordinator for Health Information Technology  
Department of Health and Human Services  
200 Independence Ave, S.W., Suite 729D  
Washington, DC 20201

Re: CMS-0038-NC Advancing Interoperability and Health Information Exchange

Dear Ms. Tavenner and Dr. Mostashari:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the request for information (RFI) on advancing interoperability and health information exchange published by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) in the March 7 Federal Register.

America’s hospitals are moving toward an e-enabled health care system where all hospitals meaningfully use electronic health records (EHRs) and share information to improve patient care and safety and achieve national goals for improved health. They share the administration’s vision of a health care system where widespread use of interoperable EHRs supports improved clinical care, better coordination of care, fully informed and engaged patients, and improved public health. To achieve this goal, relevant health information must follow the patient across settings of care. Hospitals also work every day to ensure adequate privacy and security for patients and their personal health information.

The AHA greatly appreciates the intention behind the RFI and is committed to the development of a health care system where the best information is available to support the best possible care and engage patients. However, by asking a series of questions about regulatory levers, the RFI wrongly suggests that additional regulatory requirements are necessary to advance interoperability and the electronic exchange of health information.
Rather than engaging in additional regulation, the AHA recommends that CMS fully implement the multiple payment and delivery programs already underway that provide incentives for information exchange to support better care coordination and greater efficiency in care delivery, while carefully monitoring their results. Concurrently, we urge ONC to re-double its efforts to remove barriers to interoperability and support the development of a robust infrastructure for health information exchange.

Below we provide over-arching comments on these recommendations, while the attachment includes our responses to selected specific RFI questions.

**PAYMENT AND DELIVERY REFORM INITIATIVES ARE ADVANCING THE BUSINESS CASE FOR HEALTH INFORMATION EXCHANGE**

Electronic information exchange is one tool among many that providers use to achieve the goals of improved health and the best possible health care. Payment policy should incentivize those end goals, not specific means to achieve them. New payment mechanisms such as value-based purchasing, accountable care organizations (ACOs) and bundled payment models incentivize better care coordination and reduced fragmentation of care. The AHA supports these new payment and delivery models, and hospitals around the country are engaged in their implementation. We do not believe it is productive to add specific information exchange requirements to these projects, as the mechanisms of exchange may vary by project, and the specification of requirements could result in unintended consequences, including limiting innovation and posing a reporting burden.

A key principle behind these new payment and delivery models is to incentivize the right outcomes, while allowing flexibility in determining how they are achieved. These new models are encouraging the movement of data from individual silos that support individual transactions and clinical encounters toward integration of information to support collaboration among a health care team, while allowing local considerations to shape the care delivery approaches taken. Already, we are beginning to see positive outcomes, such as a significant reduction in hospital readmission rates for Medicare beneficiaries in 2012, and several years of historically low hospital costs per Medicare beneficiary, followed by an actual decline in 2012.

Adding specific health information exchange requirements risks significant unintended consequences, including forcing use of tools that are not suited to local conditions, duplicating approaches to sharing data and increasing reporting burden. Indeed, 32 participants in the Pioneer ACO program sent a letter to CMS on Feb. 25, 2013, noting the challenges associated with gathering data to calculate the quality measures they already are reporting. Adding additional metrics could pose significant additional barriers to success.
WIDESPREAD ADOPTION OF CERTIFIED EHRs AND PARTICIPATION IN INCENTIVE PROGRAMS WILL ACCELERATE DEMAND FOR HEALTH INFORMATION EXCHANGE

The AHA recommends that CMS and ONC focus on successful implementation of the health information exchange requirements in Stage 1 and Stage 2 of the EHR incentive programs before placing any additional requirements on providers. The health care field is in mid-stream deployment of certified EHRs to support Stage 1 of “meaningful use.” To date, about 45 percent of all hospitals have adopted at least a basic EHR. Most hospitals are either still implementing meaningful use for the first time, or have only recently attested to Stage 1. While Stage 1 focuses on moving toward electronic capture and use of health information to inform care, many Stage 2 requirements involve information exchange, including:

- Sending structured summary documents when patients transition from one setting of care to another, including requirements for electronic transmission;
- Maintaining patient portals with large volumes of patient data accessible over the internet and transmitted to a third party using secure email at the patient’s request; and
- Conducting ongoing reporting of three types of public health data to public health departments.

Achieving Stage 2 of meaningful use will require tremendous changes to provider information systems, including adoption and use of many new standards for recording and sharing data, and will take place over the next two to three years. Providers are reliant on their vendors to build and deploy certified EHRs that meet the Stage 2 regulatory requirements, including the new functionality for health information exchange.

The AHA was encouraged by Acting Administrator Tavenner’s recent comments at the HIMSS annual meeting committing CMS to supporting provider implementation of certified EHRs and a successful transition to Stage 2, and fully supporting policies that emphasize achieving the regulatory requirements already in place, rather than adding new ones. We look forward to partnering with CMS on educational efforts and other activities focused on implementation of the many regulatory requirements already in place, but urge CMS to refrain from adding additional regulations.

FOCUS ON REMOVING BARRIERS TO INTEROPERABILITY AND SUPPORTING A ROBUST INFRASTRUCTURE FOR HEALTH INFORMATION EXCHANGE

The AHA urges ONC to focus on removing the barriers to data exchange and sharing best practices in order to support the acceleration of the payment and service delivery redesign initiatives currently underway. The health care system increasingly needs data that moves fluidly from the place of capture to where it is needed. However, significant technical, policy and cost barriers to such exchange still exist. **We recommend that ONC focus its efforts on reducing those barriers and sharing knowledge to increase the likelihood that electronic**
exchange is a feasible means to achieve broader care goals. ONC should focus on the following activities to support the infrastructure that providers need to efficiently and effectively share health information:

- Ensure that EHRs support information exchange;
- Foster effective and affordable exchange networks;
- Establish provider directories;
- Support successful adoption and use of standards by providers;
- Address the patient-matching problem; and
- Reduce policy barriers to exchange, such as consent and privacy rules that vary by state.

Ensure that EHRs Support Information Exchange. As hospitals strive to meet Stage 2 requirements, they will require EHRs that will support information exchange effectively and efficiently. ONC should take steps to ensure that certified systems meet that need. For example, semantic interoperability is necessary to make the shared information understandable and actionable by those who receive a care summary or query data for use. Thus, efficiently sending and receiving interoperable information (with a standard message format, and through secure document exchange) should be strengthened as a metric in the certification of EHRs.

In addition, connecting health records across platforms and systems faces several obstacles, including getting health information exchanges (HIEs) to use similar standards for how and when information is exchanged. Almost all state-level HIEs now have the capability to exchange health information using Direct Protocol secure messaging, but it is unclear how this will scale to support the levels of exchange anticipated in Stage 2 of the “meaningful use” EHR Incentive Program. Direct is new and relatively untested. Therefore, we urge ONC to publish the results of its pilot on Direct, particularly as it relates to expanding use of Direct from a core set of vendors involved in creating Direct to use by all providers across the country. We also support additional work by ONC to ensure that the care summary documents generated by different vendors and sent using Direct can be easily accessed by the recipient, incorporated into the recipient’s information system, and used to support care. True interoperability also will require smooth integration of data from medical devices into the EHR.

Furthermore, the current “2014 Edition” certification requirements make support of more robust data exchange standards optional. Widespread health information exchange will likely require the more robust exchange standards. Therefore, the AHA believes ONC should revise these requirements to make the Simple Object Access Protocol (SOAP)-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 standard, currently used by the federal Nationwide Health Information Exchange Network, a requirement for all certified EHRs. The Direct standard supports limited exchange of documents via secure email, while the SOAP-based standards allow for more robust exchange of computable data. The AHA believes it is
appropriate to require vendors to support both standards in order to give providers the ability to choose which standard is appropriate in a given circumstance. It is certainly possible that a single hospital could use both standards, depending on the capacity of receiving entities. We encourage ONC to take steps to ensure that certified EHRs support robust exchange standards, perhaps including additional rulemaking for the “2014 Edition.” ONC also should use all means available to encourage vendors to support information exchange – both sending and receiving data without undue added costs for interfaces or “steering” of providers to information exchange that is limited to the customers of a single vendor.

Foster Effective and Affordable Exchange Networks. Although progress has been made in some places, many AHA members report that they continue to be hindered by a lack of affordable health information exchange networks in their communities. In some areas, multiple exchange efforts are under way, causing confusion and possible waste due to duplication of efforts. In addition, there continues to be a lack of consistency in the policies and technologies across HIEs. ONC should provide a status report on the state-designated HIEs it has funded, including practical information such as their operational status, the kinds of information that can be shared, and the current fee structures. ONC also should support development of test beds for HIEs to test their capacity to share data according to the exchange standards in the “2014 Edition” certification rule.

The Department of Health and Human Services (HHS) also should support state departments of public health in developing the capacity to receive electronic data in standardized formats. We urge CMS to develop the website the agency outlined in the Stage 2 regulations that will provide information on the ability of each immunization registry and state or local department of public health to receive the public health measures required for meaningful use. No additional public health reporting should be required of providers until all registries and public health departments can receive all of the Stage 2 data on an ongoing basis.

Establish Provider Directories. A major stumbling block to information exchange, including the transition of care requirements under meaningful use Stage 2, is the lack of provider directories that allow providers and patients to determine where to send information. Given that CMS maintains the National Provider Identifier, we recommend that HHS explore ways to support the state-designated HIEs and other entities that could establish provider directories.

Support Successful Adoption and Use of Standards. The Stage 2 meaningful use requirements mandate an unprecedented level of standards adoption and use. Standards adoption is necessary, and the movement toward standards adoption and greater interoperability will facilitate the ease of sharing health information so that clinicians and patients have the information they need to provide treatment and promote health, in the form and at the time they need it. The success of a standard, however, is shown through its actual use and usefulness to those providing care. HHS should re-double its efforts to educate providers on the new standards embedded in meaningful use and how they are best used. Support for implementation through development of educational materials, funding for technical assistance ongoing national provider calls, and monitoring of progress will be crucial to success. The new standard for specifying patient problem list – SNOMED – is of particular concern because it is not
widely used and duplicates the clinical concept behind ICD-10 – patient diagnosis. HHS is requiring providers to simultaneously adopt both SNOMED and ICD-10.

Consistent use of standards is challenging; it requires providers to change information technology systems, change how care is provided, and conduct extensive – and ongoing – training of staff. All of this happens in a fast-paced, rapidly changing health care system where there is a strong emphasis on reducing costs. Based on experience to date in Stage 1 of meaningful use, more work needs to be done. Steps taken by the National Library of Medicine in providing a Value Set Authority Center for some of the required vocabulary standards is a good start. However, an effective transition to standards adoption needs to be supported by educational resources that are easy to find and understand. The educational efforts CMS has undertaken to support the overlapping transition to ICD-10 serve as an example. Similarly, the funding ONC and the Centers for Disease Control and Prevention (CDC) have provided to support the transition to the use of the required laboratory vocabulary standard for reporting electronic lab results to public health – LOINC – has been greatly appreciated by the 912 hospitals involved in Laboratory Interoperability Cooperative project.

Additional technical assistance projects to support adoption of new standards, and particularly the SNOMED standard that identifies clinical elements for the problem list, would help ensure a successful transition to Stage 2. The AHA is very concerned that few health care providers use SNOMED, and the nation has few technical experts to support the transition. Nevertheless, HHS requires providers use SNOMED to document the patient problem list in order to meet Stage 2, beginning Oct. 1, 2013. HHS also is requiring providers to adopt a second standard, ICD-10, to support the same clinical concept – problem diagnosis – for billing and other administrative transactions beginning Oct. 1, 2014. Currently, there is no full, verified cross-walk between the ICD-10 diagnosis and procedure codes and SNOMED. Given that the federal government is requiring providers to adopt both of these standards, we believe it is crucial that HHS support development of a single, tested and verified cross-walk between them. SNOMED also will need to be named as an approved code set for administrative transactions in order for covered entities to prepare for its use. This would create a target for vendors to develop products.

Further Education and Knowledge Sharing. ONC has funded many projects related to electronic information exchange. These projects were undertaken to build the infrastructure for exchange or provide an understanding of how information exchange can support improvements in health and health care. Before any new requirements are made of providers, ONC should publish the results of independent evaluations of these activities and undertake systematic educational efforts to widely share the outcomes and lessons learned from those endeavors. These include:

- State-designated entities for health information exchange ($564 million);
- Beacon Communities grants that support demonstrations of how health information exchange can lead to better health and health care ($265 million for 17 awardees);
SHARP grants to fund research that addresses well-documented problems that impede health IT adoption and information exchange ($60 million for four awardees, ranging between $10 and $18 million each); and

Regional Extension Centers (RECs) that support providers in achieving, among other things, the exchange requirements of meaningful use ($677 million for 70 RECs, ranging between $1 million and $30 million each).

Address the Patient-Matching Problem. A key barrier to efficient health information exchange is the lack of a single, national approach for matching patients to their records. This issue must be resolved if the nation hopes to accelerate information exchange on the regional and national level. Currently, hospitals and health systems are forced to expend significant resources on expensive, proprietary solutions to develop master patient indexes that apply only to that particular hospital or health system’s patients. The inability to match patients across silos raises safety concerns from mismatches – incorrectly matching patients, or missing a match that should have been made. HHS should explore whether the systems being developed to identify individuals for the state-level or state-federal partner health insurance exchanges being built under the Patient Protection and Affordable Care Act also can be used to support patient identification for the purposes of sharing health information.

Reduce Policy Barriers to Exchange. Additional work is needed to overcome policy barriers, such as variations in privacy laws across state lines, as well as to balance the restrictions on information sharing within the Health Insurance Portability and Accountability Act (HIPAA) rules with the goals of broader health information exchange. Treatment of sensitive information, such as mental health information or HIV status, is particularly challenging. Issues such as when and how patients must provide consent for information to be shared and ways to ensure that a treatment relationship exists before information is shared also continue to stand as barriers.

Thank you for the opportunity to provide input on this important topic. If you have any questions or need additional information, please contact me or Chantal Worzala, director of policy, at 202-626-2313 or cworzala@aha.org.

Sincerely,

/s/

Ashley Thompson
Vice President and Deputy Director, Policy

Attachment
## Attachment: Detailed Responses to Selected Questions

<table>
<thead>
<tr>
<th>RFI Question</th>
<th>AHA Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>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?</strong></td>
<td>The AHA does not believe that payment policy should be used for the goal of promoting information exchange. Rather, information exchange is a tool to achieve broader health care goals. Payment policy should focus on incentivizing broader outcomes, such as better coordination of care, and not individual tools.</td>
</tr>
<tr>
<td><strong>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?</strong></td>
<td>The AHA supports new models of payment and service delivery that support better care coordination and efficient use of resources. Achieving these goals will likely require use of health information exchange. However, many different approaches are being deployed, and different providers may find one or another approach is better suited to their size, patient population or range of clinical services. Therefore, the AHA discourages HHS from favoring one approach over another based on its impact on electronic exchange of health information. The overarching goals will be better served by activities to ensure that the available technology and information exchange infrastructure support multiple use cases at affordable prices. The success of all of these approaches will be dependent on the extent to which specific vendor products and the information exchange infrastructure support individual provider and patient needs.</td>
</tr>
<tr>
<td><strong>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</strong></td>
<td>As noted in our letter, existing new care delivery models and the requirements of meaningful use already promote information exchange. These policies need time to be implemented, and should be supported by a range of activities to build and support the infrastructure for exchange. Our letter provides examples of federal policies and actions that would remove barriers and build the infrastructure for health information exchange.</td>
</tr>
<tr>
<td>RFI Question</td>
<td>AHA Response</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>send, receive, and integrate health information from other treating providers outside of their practice or system?</strong></td>
<td>The AHA supports programs and <em>positive</em> incentives to support adoption of EHRs and other tools in post-acute, long-term care and behavioral health settings. In particular, approaches are needed to address market gaps for these and other low-volume settings so that information can cover the entire continuum of care. Products developed for acute and ambulatory care are often incompatible with these settings due to incongruent scopes of service and/or the lack of scalability for small settings. In addition, it would be helpful for ONC to support development of standards and technologies to build summary documents from existing post-acute and long-term care patient information structures, such as the OASIS dataset captured by Skilled Nursing Facilities and the Minimum Data Set captured by home health agencies. Limited certification could also apply to EHRs developed for these settings, focused on sending and receiving documents for transitions of care. Some work on technical requirements for sharing information with post-acute and long-term care settings is already underway in the Standards and Interoperability Framework Longitudinal Coordination of Care Work Group. Additional federal support would be helpful to test the feasibility of the standards developed and demonstrate solutions that work.</td>
</tr>
<tr>
<td><strong>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 CMS-0038-NC 17 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?</strong></td>
<td>Medicaid programs are a significant source of information about patients in post-acute, long-term care and behavioral health settings. State Medicaid programs should engage in health information exchange efforts, and CMS should provide administrative funds to support that work.</td>
</tr>
<tr>
<td><strong>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?</strong></td>
<td>Conditions of Participation (COPs) set forth basic requirements for Medicare participation related to a hospital’s structure, operations and delivery of care. Any change in the hospital CoPs would need to be proposed and considered through notice and comment rulemaking in accordance with the <em>Administrative Procedures Act</em>, and be</td>
</tr>
<tr>
<td><strong>6. 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</strong></td>
<td></td>
</tr>
<tr>
<td><strong>RFI Question</strong></td>
<td><strong>AHA Response</strong></td>
</tr>
<tr>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>home health to support and accelerate electronic, interoperable health information exchange? How could requirements for acceptable quality that involve health information exchange be phased in overtime? How might compliance with any such regulatory requirements is best assessed and enforced, especially since specialized HIT knowledge may be required to make such assessments?</td>
<td>supported by scientific evidence on why a specific requirement is essential. Adding a requirement specific to health information exchange would also require assurance that all providers have access to affordable, efficient exchange mechanisms – a level of health information exchange infrastructure that has yet to be established. Our letter provides examples of federal policies and actions that would remove barriers and further build the infrastructure for health information exchange. Furthermore, hospitals appreciate the value in sharing data across settings, and existing incentives and regulatory requirements already encourage this kind of information sharing, making a CoP in this area unnecessary. Use of health information exchange will accelerate as the exchange infrastructure is established and becomes more accessible and workable for providers.</td>
</tr>
</tbody>
</table>

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? | HHS should review options for supporting provider directories, either centrally or through the state-designated HIEs. CMS maintains the National Provider Identifier, which could be one source of information. CMS would need to assess carefully whether the limited administrative data captured during meaningful use attestation is sufficient for this purpose, given that it may point to an organization, not a clinician, and includes only those providers that are both eligible for meaningful use and able to successfully attest. Significant provider populations will likely be left out of a directory based on that data source. |

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 AHA does not believe that innovation grants should be used for the goal of promoting information exchange. Rather, information exchange is a tool to achieve broader health care goals. The innovation grants should focus on incentivizing broader outcomes, such as better coordination of care, and not individual tools. See the body of the letter for a range of activities HHS could undertake to build and support the infrastructure for exchange. |

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 | Stage 2 of meaningful use includes extensive requirements for hospitals and other providers to access their health information electronically and benefit from educational materials prompted by the EHR. Rather than pursuing additional policy changes, HHS should support implementation of patient access to their health information through view, download, and transmit requirements, while ensuring security of protected health information. |
<table>
<thead>
<tr>
<th>RFI Question</th>
<th>AHA Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>beneficiary access to their health information and engagement in their care?</td>
<td>Evaluation of the success of Stage 2 should occur before any additional policies are proposed.</td>
</tr>
<tr>
<td>10. What specific HHS policy changes would significantly increase standards based electronic exchange of laboratory results?</td>
<td>Stage 2 of meaningful use includes extensive requirements for hospitals to conduct standards-based exchange of laboratory results. Rather than pursuing additional policy changes, HHS should focus its efforts on supporting implementation of these requirements, including follow-on work to the Laboratory Interoperability Cooperative, while ensuring security of protected health information. Evaluation of the success of Stage 2 should occur before any additional policies are proposed. HHS also should finalize its proposed rules allowing patients direct access to their laboratory results (Medicare, Medicaid, and CLIA Programs; Patient Access to Laboratory Test Reports; CMS-2319-P).</td>
</tr>
</tbody>
</table>