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U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: HITECH Initial Set Interim Final Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave, S.W.
Washington, DC 20201

RE: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology Interim Final Rule (RIN 0991-AB58)

Dear Sir or Madam:

I am writing on behalf of Molina Healthcare to offer comments in response to the interim final rule (IFR) that was issued in the *Federal Register* on January 13, 2010. (75 Fed. Reg. 2014). The regulations were issued as required by the Health Information Technology for Economic and Clinical Health (HITECH) Act, as included in the American Recovery and Reinvestment Act (Pub. L. No.111-5).

Molina Healthcare has 30 years of experience serving patients who have traditionally faced barriers to obtaining quality healthcare, primarily individuals covered by Medicaid, the Children's Health Insurance Program (CHIP) and other government-sponsored health insurance programs. Molina Healthcare's operations in California, Florida, Michigan, Missouri, New Mexico, Ohio, Texas, Utah, Virginia, and Washington currently serve about 1.5 million low-income vulnerable Americans who otherwise would be unable to obtain insurance coverage.

Our 19 primary care clinics in California, Washington and Virginia serve as the medical home for almost 100,000 individuals. They are located in predominately economically disadvantaged and underserved areas where care coordination is even more critical for the health and well being of individuals. Our clinics treat not only Molina members, but the uninsured as well. Our clinics are staffed by 45 physicians, physician assistants and nurse practitioners who see almost 200,000 patient encounters per year.

Molina Healthcare, Inc. is committed to advancing an interoperable system in which health information can be shared electronically in a secure and efficient manner. We, therefore, applaud initiatives to advance the use and exchange of health information and make such information more readily available for health care providers, leading to improved quality of health care services to patients.

We appreciate that the interim final rule released by the ONC sets forth an initial set of standards that will begin to define a common language to ensure accurate and secure health information exchange across different electronic health record (EHR) systems. We also recognize this is the first step in an incremental process to promote the meaningful use and adoption of EHRs. We look forward to working with you to standardize the way in which EHR information is exchanged between organizations, and to set forth criteria required for an EHR technology to be certified.

Comments

We welcome the opportunity to comment on the interim final rule and have identified several issues and recommendations that we believe should be addressed when final regulations or guidance are issued by your agency.

Generally, we are concerned about the ability of small and safety net providers to become “meaningful users” of EHRs by adopting the standards, implementation specifications, and certification criteria within the timeframes laid out in the ONC’s interim final rule as well as the Notice of Proposed Rulemaking issued by the Centers for Medicare and Medicaid Services (CMS) to address the Medicare and Medicaid EHR Incentive programs. While we appreciate the incentives offered by the federal government to providers to adopt EHRs, we are concerned these incentives may be too challenging for small and safety net providers to meet and may lead to provider non-participation in the incentive program. As a result, the federal government should give providers more flexibility in meeting the standards and criteria outlined in the interim rule.

In addition, it is critical that the rule apply common standards, implementation specifics, and certification criteria throughout the nation. Under the CMS proposed rule on “meaningful use,” the proposed regulations would allow states the flexibility to establish additional requirements for eligible providers and eligible hospitals if such an electronic infrastructure exists. As the ONC interim final rule works hand in hand with the CMS proposed rule, we believe national standards should be set to ensure that the capability to accept electronic information can be performed in a standard format and consistently, without enabling significant state or other variations. We also believe that national standards will facilitate an expeditious and efficient implementation of the EHR incentive program and are concerned that state standard development will add to the administrative costs of the program and create uncertainty among EHR vendors and delay the development of certified EHRs.

Encryption Protections for Health Information

Issue: Section 170.210 of the interim final regulation lists requirements for encryption and decryption of electronic health information. Molina fully supports regulatory requirements that are designed to protect the privacy and security of individually identifiable health information in electronic environments. We are concerned, however, that the industry may not currently have the capability to use these adopted standards, and thus it may be too soon to mandate their use.

Many of the EPs and hospitals who will be implementing the meaningful use requirements are covered entities under HIPAA. In August 2009, HHS issued guidance for HIPAA covered entities to protect health information so that it is unusable, unreadable, or indecipherable to unauthorized individuals (commonly referred to as the “data breach guidance”). Under both the HIPAA Security Rule and the August 2009 guidance, some entities may not be required to use encryption in their business operations, while other entities may be using different encryption requirements based on whether data is “at rest” or “in motion.” Thus, the HHS data breach guidance included encryption requirements for HIPAA covered entities that appear to be somewhat different from the encryption requirements listed in the ONC interim final regulations.

Further, as a Medicaid managed care plan, we are concerned about the impact on and the readiness of state Medicaid programs in moving to these new standards. States have been challenged in preparing to implement electronic systems because of significant cost and time constraints. The cost of implementing these systems in a compressed timeframe may severely limit a state’s Medicaid program, particularly during times in which state Medicaid budgets are stretched to the brink or being dramatically cut. Accordingly, states need additional time to upgrade current systems and business processes to handle the complex changes as required. Therefore, we remain concerned that many state Medicaid programs as well as providers will not be prepared under the EHR implementation timeline established by CMS and ONC.

We recognize that the encryption, de-encryption, and hashing requirements were included in the initial meaningful use stages to help promote the industry’s use of such technologies and methods. However, we are concerned that the listed standards may conflict with existing federal guidance and current industry practices, and may also have the unintended consequence of impeding the legitimate and necessary exchange of health information.

Recommendation: ONC should evaluate whether the technologies and methods required in regulation §170.210 for encryption, decryption, and hashing are currently being used within the health care industry by EPs, hospitals, and other health care entities (e.g., other HIPAA covered entities). If not, ONC should consider delaying the encryption, de-encryption, and hashing requirements and address them in future regulations after additional information is obtained from the industry and the public about the effective use of these technologies and methods.

Criteria for “Complete EHRs” or an “EHR Module”

Issue: The IFR sets out general certification criteria and would require “Complete EHRs” or “EHR modules” to have the capability of and functionality for checking insurance eligibility and submitting health care claims to public and private payers. Without these technical capabilities and functionalities, a complete EHR or EHR module would not meet the defined certification criteria.

Molina Healthcare supports establishing certification criteria that require EHRs to have the capability of and functionality for checking insurance eligibility and submitting health care claims or equivalent encounter information to public and private payers. Fostering the use of

these electronic processes for such commonly-used transactions within the health care industry will help to reduce administrative costs for eligible professionals (EPs) and hospitals while providing greater transparency and quality of services for patients. However, we question whether these two transactions should be required as part of the EHR or the EHR module, particularly since a variety of tools exist for eligible for EPs and hospitals to conduct these transactions electronically (e.g., practice management systems, multi-payer web portals, etc.). In addition, it is unclear whether a professional or hospital that uses such systems or tools would be deemed part of an “EHR module,” since the capability to conduct the required administrative transactions exists external to the EHR.

Recommendation: We recommend that final regulations or future guidance allow EPs and hospitals flexibility in meeting these requirements (e.g., by using clearinghouses, web portals, etc.). As such, ONC should clarify that an EP or hospital that uses systems or tools to conduct certain administrative transactions (e.g., eligibility and claims submission) that are external to an EHR could meet the definition of an “EHR module” and be deemed in compliance with the general certification criteria for conducting the specified administrative transactions.

If this recommendation is not adopted, as an alternative, we recommend that ONC should: (1) consider delaying the certification requirements related to conducting the listed administrative transactions until Stage Two; and (2) evaluate whether an EP’s or hospital’s existing private certification, such as a certification under the Council for Affordable Quality Healthcare (CAQH) Committee on Operating Rules for Information Exchange (CORE) project, would deem an EP or hospital in compliance with the certification requirement to conduct eligibility transactions.

Electronic Prescribing Standards

Issue: The IFR sets out the content exchange standards for the transmission of prescription or prescription-related information. Molina support the adoption of the Medicare Part D standards to support electronic prescribing in the initial stage of implementing the meaningful use requirements. However, these standards are comprised of numerous transactions, and some of them are not currently implemented on a widespread basis. We believe some of the most vital information that can be shared between providers and pharmacies is whether an electronically sent prescription has been successfully filled and obtained by or for the individual. Thus, we support ONC adopting specific standards in regulations that would require the generation and transmission of this information.

Recommendation: ONC should either modify the interim final regulations or develop future regulations to adopt specific transactions for prescription fill status notifications. Specifically, the regulations should required EHRs to support the NCPDP SCRIPT standard Fill Status Notification (RXFILL) transaction as a necessary component of meaningful use requirements.

Adopted Implementation Specifications

Issue: In regulation §170.205(d) the Secretary has adopted content and exchange standards for electronic transactions to verify an individual's eligibility to receive covered health care services. These standards include the adoption of the CAQH CORE Phase One Operating Rules. Molina supports the adoption of the CAQH CORE Phase One Operating rules as implementation specifications. We believe that a consistent set of operating rules will better define the technical and operational components inherent in electronic transactions standards and we suggest that ONC consider the additional phases of the CAQH CORE Operating Rules for implementing the meaningful use regulations.

We believe the requirement to include adoption of the CORE Operating Rules, along with the future requirements for the Health Insurance Portability and Accountability Act (HIPAA) version 5010 electronic transactions standards may hasten the adoption of electronic transactions, and thus reduce the costs in the current system related to variations in administrative data content and electronic revenue cycles. While the HIPAA electronic transactions requirements have helped to streamline some administrative efficiencies in the health care system, using the CORE rules may help to build on the HIPAA mandated processes by expanding and defining the meaningful information that can be required as part of these transactions in the health care industry.

Recommendation: **There is a need within the health care industry for practical and consistent rules to enhance the use of the electronic transactions standards. ONC should consider rules such as the CAQH CORE Operating Rules as a model for future stages of the meaningful use requirements.**

A National, Cohesive Approach for Adopting and Implementing Health IT

Issue: We appreciate HHS' recognition of existing regulatory requirements (e.g., implementing the International Classification of Diseases (ICD) 10th Revision, Related Health Problems [referred to as ICD-10-CM], the ICD, 10th Revision, Procedure Coding System [referred to as the ICD-10-PCS], and the HIPAA electronic transactions and code sets requirements) and how these requirements can affect implementation and staging of the interim final meaningful use requirements. We encourage the agency to keep abreast of how these initiatives progress and to issue guidance as necessary to prevent unnecessary delays, or to allow for additional time for affected entities to comply with the regulatory requirements, if applicable.

For example, we remain concerned about the readiness of state Medicaid programs in moving to new electronic health record systems. With the adoption of the administrative simplification code sets to electronic transactions in 2002-03, states were challenged in preparing to implement electronic systems because of significant cost and time constraints. Medicaid programs have been similarly challenged to meet the ICD-10 implementation. It is critical ONC remain cognizant of the states' continued efforts with preparing and implementing electronic systems and readjust any requirements as necessary.

Many entities within the health care industry (e.g., HIPAA covered entities) are accustomed to implementing federal and state statutory and regulatory requirements. Often, implementation of the mandated requirements is based on one entity's analysis of what is being required, development of strategic plans and timelines, and budgeting of financial and administrative resources. As we have learned, one entity's success is often contingent on another entity's cooperation and progress (e.g., with implementing the same or similar electronic processes, systems, electronic transactions, with testing electronic processing between entities, with updating and finalizing contracts, etc.).

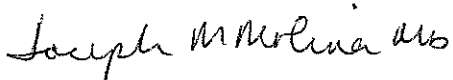
We believe HITECH's EHR incentive program presents a good opportunity for ONC to harmonize the different technical standards, and to ensure that various electronic standards used within the health care industry (e.g., meaningful use requirements, HIPAA electronic transactions standards, etc.) are not duplicative, stay streamlined and effective, and are used in ways that help reduce administrative costs for affected entities. In addition, we believe security standards must also be harmonized as the emerging patchwork of state security standards could impede the progress of setting up electronic health record systems.

Recommendation: We encourage HHS to: (1) keep abreast of how the meaningful use and other related regulatory requirements and technical initiatives progress; and (2) issue guidance as necessary to prevent any unnecessary delays, or allow for additional time for entities to come into compliance with the requirements, if applicable.

In addition, we suggest that HHS or ONC develop a clear roadmap with an associated timetable listing what infrastructure must be in place to implement the technical and regulatory requirements. This should include using a process that harmonizes electronic transaction standards currently used within the health care industry including leveraging the work performed to date by the Healthcare Information Technology Standards Panel (HITSP).

We appreciate the opportunity to provide comments on these important issues.

Sincerely,

A handwritten signature in cursive script that reads "Joseph M. Molina MD".

Joseph M. Molina, MD