DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Centers for Medicare & Medicaid Services

[CMS–0038–NC]

Advancing Interoperability and Health Information Exchange

AGENCY: Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice with comment; Request for Information.

SUMMARY: HHS seeks input on a series of potential policy and programmatic changes to accelerate electronic health information exchange across providers, as well as new ideas that would be both effective and feasible to implement. To further accelerate and advance interoperability and health information exchange beyond what is currently being done through ONC programs and the EHR Incentive Program, HHS is considering a number of policy levers using existing authorities and programs.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on April 22, 2013.

 ADDRESSES: You may submit comments identified by any of the following methods below (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

• Federal eRulemaking Portal: Follow the instructions for submitting comments. Attachments should be in Microsoft Word or Excel, Adobe PDF; however, we prefer Microsoft Word.

http://www.regulations.gov

• Regular, Express, or Overnight Mail: Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: Interoperability RFI, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes, but is not limited to: A person’s social security number; date of birth; driver’s license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered to be proprietary. We will post all comments received before the close of the comment period at http://www.regulations.gov.

Docket: For access to the docket to read background documents or comments received, go to http://www.regulations.gov or the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: • Kelly Cronin, Health Care Reform Coordinator; or • Steven Posnack, Director, Federal Policy Division

Office of the National Coordinator for Health Information Technology, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. Background

Since enactment of the Health Information Technology for Clinical and Economic Health Act as part of the American Recovery and Reinvestment Act, adoption and use of electronic health records in the United States has dramatically increased. Adoption of EHRs that met the criteria for a basic EHR system by office-based physicians grew by over 80% between 2009 and 2012, from 22% in 2009 to 40% in 2012.1,2 Among non-federal acute care

1 Hsiao CJ, Hing E. Use and characteristics of electronic health record systems among office-based

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hospitals, adoption of at least a basic EHR system has increased by over 260% since 2009, from 12% to 44%. Since 2009, there has been strong and steady growth in adoption of EHR technology to meet Meaningful Use objectives to improve quality, safety and efficiency. Adoption of many of the computerized functionalities associated with Meaningful Use has substantially increased among both office-based physicians as well as hospitals. For example, physician adoption of five core Meaningful Use functionalities—ranging from e-prescribing to clinical decision support—has grown by at least 66% since HITECH in 2009.

As part of stage 2 rulemaking HHS has taken major steps to expand the functionality and utility of EHRs to providers and patients. We seek to build on that work by engaging other policy areas within HHS jurisdiction to promote routine sharing of information among health care providers across settings of care to support care coordination and delivery system reform. We recognize that economic and regulatory barriers may impair the development of a patient centered, information rich, high performance health care system where a persons’ health information follows them wherever they access health care services.

The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs and Office of the National Coordinator for Health Information Technology (HIT) Certification Program are increasing standards based health information exchange (HIE) across health care providers and settings of care to support greater coordination of health care services. However, this alone will not be enough to achieve the widespread interoperability and electronic exchange of information necessary for delivery reform where information will routinely follow the patient regardless of where they receive care. With fee-for-service reimbursement and other business motivations often being the stronger influencer of provider behavior, both providers and their vendors do not yet have a business imperative to share person level health information across providers and settings of care.

For example, in 2011, 4 in 10 hospitals electronically sent laboratory and radiology data to providers outside their organization; however, only ¼ of hospitals could exchange medication lists and clinical summaries with outside providers. In addition in 2011, only 31 percent of physicians are exchanging clinical summaries with other providers. There is even more limited HIE involving post-acute and institutional long-term care providers as well as behavioral health and lab providers who may not eligible for incentive payments under the EHR incentive program. Only 6 percent of long-term acute care hospitals, 4 percent of rehabilitation hospitals, and 2 percent of psychiatric hospitals have a basic electronic health record system. Close to 1/2 of all Medicare beneficiaries discharged from acute care hospitals are discharged to post-acute care settings such as rehabilitation hospitals but there is little capacity in the system today to support HIE across these settings. Similarly consumers and patients are not actively engaged in accessing and using their personal health information and requesting that their providers do the same. Based upon the 2012 ONC Privacy & Security Survey, 19 percent of consumers reported that they were given online access to a part of their medical record by a health care provider within the last 12 months.

ONC has been advancing standards based HIE through a variety of programs and initiatives including the Standards and Interoperability Framework, the State HIE Cooperative Agreement Program, the Direct Project, the Nationwide Health Information Network Exchange and the HIT Certification Program. Other HHS policies also encourage HIE through the adoption of interoperable Electronic Health Record (EHR) technology. For example we recognize that the EHR exception to the federal Physician Self-Referral law and EHR safe harbor to the federal Anti-Kickback Statute which protect the donation of certain software and related training and services when various requirements are met, have created a pathway for arrangements that promote EHR implementation and use. To further accelerate and advance interoperability and health information exchange beyond what is currently being done through ONC programs and the EHR Incentive Program, HHS is considering a number of policy levers to encourage providers to routinely exchange health information through interoperable systems in support of care coordination across health care settings. This goal potentially could be achieved through a combination of incentives, payment adjustments, and requirements that collectively result in a more coordinated, value-driven health care system over the next 1 to 3 years and beyond.

The Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively referred to as the Affordable Care Act) has created new opportunities to align current and new policies in a way that provides a compelling business and patient care case to providers to change culture and share clinical data with all providers across the spectrum as a part of their routine delivery of care and services. The Affordable Care Act initiatives including the Medicare Shared Savings Program, hospital readmission payment adjustments, Medicaid health homes, and new models being tested by the Center for Medicare and Medicaid Innovation are creating a stronger business case for many providers to exchange health information.

HHS recognizes the need to use evidence and data on provider behavior to inform ongoing policy development.
that will result in a connected, person-centric health care system where health information is routinely shared across providers and settings of care to encourage the consistent provision of high-quality care, promote efficient use of health care resources, and ensure that health outcomes are good and care is affordable. As HHS, the provider, and the health IT vendor communities gain more experience with new delivery models, meaningful use of health IT, and HIE, these insights along with up-to-date market data on provider behavior will inform the evolution of policies and programs that accelerate HIE and contribute to better quality care.

This request for information (RFI) lays out some of the potential options to accelerate the existing progress and enhance a market environment that will accelerate HIE across providers thereby improving the likelihood of successful delivery and payment reform. HHS is seeking input on the options addressed below, as well as other options that stakeholders believe would be effective and feasible.

A. Vision

We are on the dawn of a new era of health care delivery—a transformed system that is person-centered and value-based. Existing CMS programs and demonstrations, as well as new programs and initiatives authorized by the Affordable Care Act, focus on improved care coordination and new service delivery and payment models that encourage and facilitate greater coordination of care and improved quality, including accountable care organizations (ACOs), bundled payments, health and medical homes, and reductions in hospital readmission. Critical to the success of these programs and the ultimate goal of a transformed health care system is the real-time electronic exchange of health information. Experts agree that greater access to person level health information is integral to improving the quality, efficiency, and safety of health care delivery. \(^{11}\)

The lack of widespread electronic HIE is a significant barrier to achieving truly coordinated, person-centered health care. The Medicare and Medicaid EHR Incentive Programs and other value-based payment programs are significant drivers of use of interoperable health information technology and the exchange of health information. We introduced many concepts of interoperability in Stage 2 and expect that the Medicare and Medicaid EHR Incentive Programs criteria for Stage 3 of meaningful use will include requirements for advanced interoperability. As other value-based payment programs evolve, they might include a greater emphasis on HIE as either a requirement for participation, receipt of incentive payments, or avoidance of payment adjustments. However, gaps and challenges still remain to wide-spread use of interoperable systems and HIE across providers, settings of care, consumers and patients, and payers. CMS and ONC will continue to collaborate on the EHR Incentive Program and HIT Certification Program to ensure they support delivery and payment reforms. In addition, HHS intends to rely on all applicable and appropriate statutory authorities, regulations, policies, and programs to accelerate rapid adoption of health information exchange across the care continuum in support of delivery and payment reform. This combination of diverse policies and programs will ensure health information follows a person regardless of where they access health care services. 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. As the Affordable Care Act continues to be implemented, HHS will develop and evolve policies and programs to achieve this vision.

B. Policies and Questions

CMS and ONC are jointly issuing this RFI to seek input on policies and programs that would further drive HIE to support more person-centered, coordinated, value-driven care. In section II of this RFI, HHS discusses policies and programs that may further encourage HIE. They are organized by various gaps and challenges that the policies and programs are intended to address (for example, low rates of adoption and HIE among post-acute and long-term care providers). HHS is soliciting comments on these policy and programmatic options, as well as comments on other policy and programmatic options HHS could consider. In addition, the RFI includes several questions in section III on which HHS would like stakeholder input.

II. Policies and Programs Under Consideration by CMS and ONC

A. Low Rates of EHR Adoption and Health Information Exchange Among Post-Acute and Long-Term Care Providers

There are a variety of options HHS might pursue to encourage HIE among post-acute and long-term care providers. Some of these options are described below.

- CMS has existing authority to allow states flexibility to implement innovative delivery and payment models for Medicare and Medicaid beneficiaries which could accelerate HIE as a part of improving care coordination across acute, post-acute and long-term care providers, reducing avoidable readmissions and improving health outcomes. For example, under section 1145 of the Social Security Act (the Act), added by section 2703 of the Affordable Care Act, states can establish Medicaid health homes for certain beneficiaries by amending their state plans to include the new benefit. Use of HIT is required to the extent “feasible and appropriate” to link services.
- Section 1115 of the Act gives the HHS Secretary authority to approve experimental, pilot, or demonstration projects that promote the objectives of Medicaid and Childrens Health Insurance Program (CHIP). These demonstrations give states additional flexibility to design and improve their programs, demonstrate and evaluate policy approaches such as providing services not typically covered by Medicaid or using innovative service delivery systems that improve care, increase efficiency, and reduce costs. Some states use this authority to advance and support their ability to incentivize health outcomes improvement and rely less on traditional forms of payment that reward high volume of discrete services. Furthermore, some of these models build on the concepts in the Medicare Shared Savings Program and encourage disparate providers to create formal arrangements establishing responsibility for managing all Medicaid services and total cost of care for an assigned population, including behavioral health and long-term care. HIE could be an important component of programs like these or other programs that rely on care coordination across settings of care. Special terms and conditions (STCs) for these demonstration projects can require the use of HIE in delivery system and payment reform efforts, to coordinate and manage services, and monitor quality of care. For example, in Oregon’s recent section 1115(a) demonstration

Incentive Program. Certain state infrastructure as a part of the developing and sustaining HIE expenditures when care is continually provided to individuals who would otherwise require the level of care provided in certain institutions. Section 1915(i) of the Act permits states to provide these services to certain eligible individuals without considering whether such individuals would otherwise require an institutional level of care. Section 1915(k) permits states to provide home and community-based attendant services to certain eligible individuals that may include skills training for daily life activities and back-up systems to ensure continuity of care and provides an increase in the federal financial participation rate for these services. Under these authorities, states can offer an array of specified home and community based services as well as other services requested by the state and approved by the Secretary that serve the purposes of the benefit. These services are important adjuncts to the care people receive from other areas of the health care system. Encouraging the appropriate exchange of health and other information across all providers involved in caring for these individuals is necessary to support effective care coordination and cost-effective care delivery. Furthermore, tracking their use of the health care system through health information technology will be critically important to development of new models of care delivery. Exchange of health information as beneficiaries transition to home or between providers (including acute, specialty, and primary care) could significantly improve continuity and the quality of their health care and result in reduced expenditures when care is continually managed in community settings.

In addition, CMS issued a State Medicaid Director (SMD) letter regarding a cost allocation policy for developing and sustaining HIE infrastructure as a part of the administration of the Medicaid EHR Incentive Program. Certain state expenditures related to the development and sustaining of HIE may be eligible for 90 percent Federal financial participation (FFP) under this program, however, CMS approval of funding for HIE infrastructure costs requires assurances that other payers and providers will bear an appropriate share of the costs, risks and governance. States could propose to implement HIE infrastructure enhancements that enable the creation and exchange of health information across settings of care, including post-acute and long-term care providers with the Medicaid program.

CMS’ Conditions of Participation or Coverage are designed to ensure that providers and suppliers maintain health care quality and safety. CMS and State staff oversee compliance with Medicare health and safety standards in hospitals, laboratories, nursing homes, home health agencies, hospices, rural health clinics, ambulatory surgical centers, organ transplant centers, and End Stage Renal Disease facilities. CMS has a role in advancing clinical standards in settings with a technologic health IT capacity and the implementation of delivery and payment reforms in the Affordable Care Act that increasingly rely on coordination of care across institutional and non-institutional settings of care. CMS could require new clinical standards in the form of conditions of participation or requirements to ensure timely, electronic exchange of health information to support patient admissions, discharge, and transfers as well as care planning to ensure care continuity as patients receive care across inpatient, post-acute and long-term care providers.

B. Low Rates of HIE Across Settings of Care and Providers

There are several potential ways in which HHS might accelerate HIE across providers including ambulatory care, post-acute and long-term care, behavioral health, and lab providers. Four examples of options are briefly summarized below:

- HHS can collaborate in the development of new e-specified measures of care coordination that encourage electronic sharing of summary records following transitions in care. This could be incorporated into and aligned across multiple programs including the EHR Incentive Program, and other CMS quality reporting programs.
- The Medicare Shared Savings Program establishes requirements for participating ACOs. CMS might consider new ways to require or encourage Medicare ACOs to exchange health information as a part of coordination of care across aligned providers or patient engagement strategies. Currently, meaningful use of EHRs is treated as a measure of quality, which is used to determine ACO eligibility for the shared savings and/or shared losses.
- Under the Affordable Care Act, CMS has the authority to test innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or CHIP expenditures while maintaining or improving the quality of care for beneficiaries. Several new models are underway that encourage the use of HIE in support of care coordination such as the Bundled Payments for Care Improvement Initiative, Comprehensive Primary Care Initiative, the Pioneer ACO model and the State Innovation Model Initiative. For future and new models, CMS could request applicants to explain how they are using interoperable technology to advance HIE strategies in support of care coordination and quality improvement. Their HIE capacity could be factored into model participation decisions, as well as requirements over the model testing period, similar to meaningful use requirements under the Pioneer ACO model.
- Under the Affordable Care Act authority, CMS is testing models to better align the financing of Medicare and Medicaid and integrate care delivery for people who are enrolled in both Medicare and Medicaid, also known as dual eligibles. Under the Capitated Financial Alignment model, CMS will contract with states and health plans, and the health plans will receive a prospective, blended payment to provide comprehensive, coordinated care. CMS could address requirements, expectations, and/or the role of HIE in these new arrangements, which have the potential to use HIE to deliver a higher degree of coordinated care for this fragile and costly population whose members often see numerous types of providers and require a high degree of care.

C. Low Rates of Consumer and Patient Engagement

CMS wants to encourage beneficiary engagement in their care through improved beneficiary access to their personal health information and better electronic communication between beneficiaries and their health care team. There are several ways CMS could encourage beneficiary access to their information through the use of new measures or patient-reported care experiences, new technology tools, and
new financial models. These options are described below.

- The Medicare Advantage Program could encourage improved beneficiary access to their personal health information by incorporating new measures in the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) survey. The Medicare CAHPS® surveys are a set of surveys sponsored by CMS that collect consumer evaluations of health care experiences that are not currently assessed by other means. Questions could be expanded to include topics such as the extent to which patients believe they are able to participate collaboratively in decisions about their health, and the extent to which information technology supports their ability to share and communicate with providers and other members of their health care team, and manage their care between various providers.

- CMS could promote the use of Blue Button. The Blue Button provides easy electronic access to personal health information for consumers. To strengthen its success, ONC released guidelines for data holders and application developers that support the growth of an ecosystem of tools to help consumers manage their health. The Blue Button Plus guidelines include specifications for a structured data format (consistent with Meaningful Use Stage 2), and enable updates of the information contained in individual consumer’s health records to be sent automatically to the applications of their choice. To date, tools built on Blue Button Plus specifications could be made available to all CMS beneficiaries, and widely promoted by healthcare providers and via avenues such as the Medicare Handbook, Medicare.gov, and Medicare Advantage plans.

- As stated previously, under the Affordable Care Act, CMS has the authority to test innovative payment and service delivery models that have the potential to reduce program expenditures while maintaining or improving the quality of care for beneficiaries. In future and new models, CMS could encourage applicants to experiment with providing incentives for consumers to more actively participate in their health and health care—including through shared-decision making—supported by the collection, use, and sharing of electronic health information.

- Modifications to Clinical Laboratory Improvement Amendments of 1988 regulations and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule could enable patients’ direct access to their lab results from laboratories. CMS and the HHS Office for Civil Rights (OCR) received public comments on this potential modification through a notice for proposed rulemaking (76 FR 56712).

III. Questions for Public Comment

CMS and ONC are soliciting public comments on the following 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?

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?

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?

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?

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?

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 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 be best assessed and enforced, especially since specialized HIT knowledge may be required to make such assessments?

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?

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?

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?

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


Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 27, 2013.

Farzad Mostashari,
National Coordinator.

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BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI)