



March 2014

ELECTRONIC HEALTH RECORDS

HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones

GAO Highlights

Highlights of [GAO-14-242](#), a report to congressional committees

Why GAO Did This Study

The Health Information Technology for Economic and Clinical Health Act (HITECH) promotes the use of health information technology and identifies the importance of health information exchange. It provides incentive payments to promote the widespread adoption and meaningful use of EHR technology. To be a meaningful user, providers are to demonstrate, among other things, that their certified EHR technology can electronically exchange health information. GAO examined (1) the key challenges to the electronic exchange of health information, if any, that have been reported by providers and stakeholders, and HHS's ongoing efforts to address them, and (2) the extent to which HHS has planned future actions to address those key challenges. GAO reviewed HHS documentation; interviewed HHS officials; and interviewed providers—hospital officials and physicians—and relevant stakeholders about their experiences.

What GAO Recommends

GAO recommends that CMS and ONC (1) develop and prioritize specific actions that HHS will take consistent with the principles in HHS's strategy to advance health information exchange, and (2) develop milestones with time frames for the actions to better gauge progress toward advancing exchange, with appropriate adjustments over time. In commenting on the draft report, HHS, including CMS and ONC, concurred with these recommendations.

View [GAO-14-242](#). For more information, contact Linda T. Kohn at (202) 512-7114 or kohnl@gao.gov.

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HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones

What GAO Found

Providers and stakeholders GAO interviewed in four states with ongoing electronic health information exchange efforts cited key challenges to exchange, in particular, issues related to insufficient standards, concerns about how privacy rules can vary among states, difficulties in matching patients to their records, and costs associated with exchange. Officials from the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC)—agencies within the Department of Health and Human Services (HHS)—noted that they have several ongoing programs and initiatives to help address some aspects of these key challenges, but concerns in these areas continue to exist. For example, several providers GAO interviewed said that they have difficulty exchanging certain types of health information due to insufficient health data standards. Although HHS has begun to address insufficiencies in standards through its Medicare and Medicaid Electronic Health Record (EHR) programs, such as through the introduction of new 2014 standards for certified EHR technology, it is unclear whether its efforts will lead to widespread improvements in electronic health information exchange. In addition, providers GAO interviewed reported challenges covering costs associated with electronic exchange, such as upfront costs associated with purchasing and implementing EHR systems. While HHS is working to address this challenge through various efforts, including a program that helps fund health information exchange organizations—organizations that provide support to facilitate the electronic exchange of health information—some providers told GAO they do not participate in these organizations because they see limited opportunities for exchanging information through them.

HHS, including CMS and ONC, developed and issued a strategy document in August 2013 that describes how it expects to advance electronic health information exchange. The strategy identifies principles intended to guide future actions to address the key challenges that providers and stakeholders have identified. However, the HHS strategy does not specify any such actions, how any actions should be prioritized, what milestones the actions need to achieve, or when these milestones need to be accomplished. GAO's prior work, consistent with the Government Performance and Results Act Modernization Act of 2010 (GPRAMA), sets forth several key elements of strategies that can guide agencies in planning and implementing an effective government program. As noted in GAO's prior work, elements such as specific actions, priorities, and milestones are desirable for evaluating progress, achieving results in specified time frames, and ensuring effective oversight and accountability. Determining specific actions and exchange-related milestones with specified time frames can help to ensure that the agencies' principles and future actions result in timely improvements in addressing the key challenges reported by providers and stakeholders; this is particularly important because planning for Stage 3 of the EHR programs, which focuses on improving outcomes, is expected to begin as soon as 2014. This information could also help CMS and ONC prioritize their future actions based on whether health information is being exchanged effectively among providers, in order to better achieve the EHR programs' ultimate goals of improving quality, efficiency, and patient safety.

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Abbreviations

ACO	accountable care organization
AHA	American Hospital Association
CCD	continuity of care document
CHIME	College of Healthcare Information Management Executives
CMS	Centers for Medicare & Medicaid Services
EHR	electronic health record
GPRA	Government Performance and Results Act
GPRAMA	GPRA Modernization Act
HHS	Department of Health and Human Services
HIE organization	health information exchange organization
HIPAA	Health Insurance Portability and Accountability Act
HIT	health information technology
HITECH	Health Information Technology for Economic and Clinical Health Act
ONC	Office of the National Coordinator for Health Information Technology
REC	regional extension center
Recovery Act	American Recovery and Reinvestment Act of 2009
RFI	request for information
SNOMED CT	Systematized Nomenclature of Medicine Clinical Terms

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March 24, 2014

Congressional Committees

The use of health information technology (HIT), such as electronic health record (EHR) systems, has the potential to allow health care providers and others to exchange health care information electronically, which is a key way that this technology could lead to improved health care quality and reduced costs. Health information exchange is especially important because the health care system is highly fragmented, with care and services provided in multiple settings, such as physician offices and hospitals, that may not be coordinated with each other.¹ Because of this fragmentation, providers may lack ready access to critical information needed to, for example, coordinate the care of patients to ensure they make the most-informed decisions on treatment options. Lack of care coordination can lead to inappropriate or duplicative tests and procedures that increase health care spending. Estimates of this spending increase range from \$148 billion to \$226 billion per year.²

To deliver coordinated care, a physician and other members of the care team must access and share health information from multiple settings. Providers may share clinical data using manual methods such as faxing paper records, but these methods can be time consuming and costly and are often unavailable at the point of care. In addition, data shared via manual methods are generally not structured or captured electronically to be stored in EHRs. Lacking the ability to receive and store structured data in their systems, providers may not be able to easily search for the information they need or electronically transmit the information effectively to another EHR without manual efforts. Electronic health information exchange has the potential to bring patient information directly from an EHR to the provider delivering care, regardless of where the care or

¹We use the term health information exchange to refer to the sharing of health information among organizations. The term is also used elsewhere to refer to a stakeholder organization that provides services to enable the electronic sharing of health-related information among providers and other entities, such as public health departments; we refer to such an organization as a health information exchange organization (HIE organization).

²D. Berwick and A. Hackbarth, "Eliminating Waste in U.S. Health Care," *Journal of the American Medical Association*, vol. 307, no. 14 (2012).

services are delivered. Electronically exchanging information can facilitate care coordination and improve communication among providers, staff, and patients by making patient clinical information more readily available to providers. Electronically exchanging information is also important in new delivery system and payment models, such as accountable care organizations (ACO), because of the need for providers in different settings to have ready access to information needed to manage and coordinate care.³

The Health Information Technology for Economic and Clinical Health Act (HITECH), enacted as part of the American Recovery and Reinvestment Act of 2009 (Recovery Act), provided funding for various activities intended to promote the adoption and meaningful use of certified EHR technology.⁴ HITECH identified the importance of the electronic exchange of health information by requiring it as a key element in the definition of meaningful use of certified EHR technology.⁵ Specifically, in order to be a meaningful EHR user, providers are to demonstrate that their certified EHR technology is able to electronically exchange health information to improve the quality of health care, such as by promoting care coordination. As such, electronic exchange is of key importance to the Department of Health and Human Services' (HHS) Medicare and Medicaid EHR programs, which are intended to help increase the

³An ACO is a group of providers and suppliers of services, such as hospitals and physicians, that work together to coordinate care for the patients they serve.

⁴HITECH was enacted as title XIII of division A and title IV of division B of the Recovery Act. Pub. L. No. 111-5, div. A, tit. XIII, 123 Stat. 115, 226-279 and div. B, tit. IV, 123 Stat. 115, 467-496 (2009).

To be certified, EHR technology must meet certain criteria established by HHS's Office of the National Coordinator for Health Information Technology that describe minimum related performance standards and implementation specifications. Certified EHR technology helps assure purchasers and other users that an EHR offers a minimum level of technological capability, functionality, and security.

⁵HITECH defined a meaningful EHR user as one who, in addition to using certified technology to electronically exchange health information, demonstrates to the satisfaction of the Secretary of Health and Human Services that (1) the technology is certified and being used in a meaningful manner, and (2) the certified technology is used to submit information on clinical quality measures and other measures in a form and manner specified by the Secretary. See Pub. L. No. 111-5, § 4101(a), 123 Stat. 467-472.

meaningful use of EHR technology and which are estimated to include total spending of \$30 billion from 2011 through 2019.⁶

Research suggests that despite substantial growth in EHR adoption, electronic exchanges between providers have remained limited.⁷ HITECH requires us to report on, among other things, its effect on the adoption of EHRs by providers.⁸ We issued five reports on the EHR programs' implementation.⁹ For example, in March 2014, we reported on the extent to which providers have met measures of meaningful use, including measures that involved the electronic exchange of health information, and noted that providers may face challenges meeting some of these measures under the EHR programs. As discussed with the committees of jurisdiction, this report addresses the electronic exchange of health information and serves as one of the series of reports we conducted to respond to the mandate. Specifically, this report examines (1) the key challenges to the electronic exchange of health information, if any, that have been reported by providers and stakeholders, and HHS's ongoing efforts to address these challenges, and (2) the extent to which HHS has planned future actions to address the key challenges, if any, reported by providers and stakeholders.

To examine the key challenges to the electronic exchange of health information, if any, reported by providers and stakeholders, and HHS's

⁶Congressional Budget Office, "Health Information Technology for Economic and Clinical Health Act" (Washington, D.C.: Jan. 21, 2009).

⁷C. DesRoches et al., "Adoption of Electronic Health Records Grows Rapidly, but Fewer Than Half of US Hospitals Had at Least a Basic System in 2012," *Health Affairs*, vol. 32, no. 8 (2013); and M. Furukawa et al., "Hospital Electronic Health Information Exchange Grew Substantially In 2008-12," *Health Affairs*, vol. 32, no. 8 (2013).

⁸See Pub. L. No. 111-5, § 13424(e), 123 Stat. 278-279.

⁹GAO, *Electronic Health Records: First Year of CMS's Incentive Programs Shows Opportunities to Improve Processes to Verify Providers Met Requirements*, [GAO-12-481](#) (Washington, D.C.: Apr. 30, 2012); *Electronic Health Records: Number and Characteristics of Providers Awarded Medicare Incentive Payments for 2011*, [GAO-12-778R](#) (Washington, D.C.: July 26, 2012); *Electronic Health Records: Number and Characteristics of Providers Awarded Medicaid Incentive Payments for 2011*, [GAO-13-146R](#) (Washington, D.C.: Dec. 13, 2012); *Electronic Health Records: Number and Characteristics of Providers Awarded Medicare Incentive Payments for 2011-2012*, [GAO-14-21R](#) (Washington, D.C.: Oct. 24, 2013); and *Electronic Health Record Programs: Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care*, [GAO-14-207](#) (Washington, D.C.: Mar. 6, 2014).

ongoing efforts to address these challenges, we selected four states—Georgia, North Carolina, Minnesota, and Massachusetts—in which to interview selected providers and other relevant stakeholders to learn about the exchange of health information within their respective states.¹⁰ We initially interviewed selected providers in Georgia, and then selected the additional states of North Carolina, Minnesota, and Massachusetts because they were mentioned during interviews with stakeholders and officials from HHS as having ongoing efforts related to health information exchange.¹¹ These three states also had an existing Pioneer ACO or a Beacon Community in which providers were likely to have some experience attempting to electronically exchange health information.¹² In each of the four selected states, we asked officials from the Regional Extension Centers (REC) and health information exchange organizations (HIE organization) to tell us about the exchange activities occurring in their state and to help us identify providers—individual physicians, hospitals, and health systems—to learn about their efforts to exchange health information.¹³ We also conducted interviews with other relevant stakeholders that include the American Hospital Association (AHA), the American Medical Association, the College of Healthcare Information

¹⁰In this report the term stakeholders generally refers to officials we spoke with from professional associations, such as the American Medical Association, or officials from regional extension centers (REC), HIE organizations, or state public health departments.

RECs are organizations funded by the Office of the National Coordinator for Health Information Technology (ONC) to assist providers in the adoption, implementation, and meaningful use of EHRs. HITECH established the REC program, which awarded approximately \$721 million in grants to create these centers. Similarly, ONC has awarded \$564 million through its State Health Information Exchange Cooperative Agreement Program to states and territories to develop and advance resources to facilitate the exchange of health information among health care providers.

¹¹We selected Georgia as a pilot state to test our provider interview protocol. Because the interviews in Georgia did not result in significant changes to our interview protocol, we used the results from our Georgia interviews in addition to the results from the three states we subsequently selected.

¹²The Pioneer ACO program model is an effort by the Centers for Medicare & Medicaid Services (CMS) designed to support organizations that have experience operating as ACOs in which coordinated care is delivered to beneficiaries at a lower cost to Medicare.

The Beacon Community Program consists of 17 communities throughout the country that have received funding from ONC in an effort to demonstrate how HIT investments and meaningful use of EHRs can advance the vision of patient-centered care.

¹³A health system is an organization of people, institutions, and resources that delivers health care services.

Management Executives (CHIME), and two commonly used EHR vendors for providers that attested to meaningful use in 2012. We conducted a total of 30 interviews with providers and stakeholders. Findings based on these interviews cannot be generalized to all providers.

In addition to interviewing providers and stakeholders about electronic exchange and the challenges of such exchange, we also reviewed additional sources to supplement our interviews, such as published literature and written information provided from stakeholders such as CHIME and AHA, including their responses to HHS's March 2013 request for information (RFI) about interoperability and health information exchange.¹⁴ To provide context for the challenges reported by providers and stakeholders and to identify HHS's ongoing efforts to address them, we interviewed officials from the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) and reviewed documents related to current HHS efforts on health information exchange.

To examine the extent to which HHS has planned future actions to address the key challenges, if any, reported by providers and stakeholders, we interviewed officials from CMS and ONC who are responsible for overseeing and managing the EHR programs and other relevant programs and initiatives related to health information exchange. We asked them about the key challenges reported to us by the providers and stakeholders we interviewed as well as key challenges we identified from documents. We also reviewed documents related to ongoing and future HHS health information exchange actions, including strategy documents, policies, and presentations. In addition, we reviewed relevant requirements in our previous work on the elements of an effective strategy,¹⁵ which is consistent with the Government Performance and Results Act (GPRA) of 1993,¹⁶ as amended by the GPRA Modernization

¹⁴78 Fed. Reg. 14793 (March 7, 2013). CMS and ONC—both within HHS—released an RFI to seek 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.

Interoperability is the ability of two or more systems or components to exchange information and to use the information that has been exchanged.

¹⁵GAO, *Combating Terrorism: Evaluation of Selected Characteristics in National Strategies Related to Terrorism*, [GAO-04-408T](#) (Washington, D.C.: Feb. 3, 2004).

¹⁶Pub. L. No. 103-62, 107 Stat. 285 (1993).

Act (GPRAMA) of 2010.¹⁷ We compared HHS's documentation that delineates its planned steps for health information exchange to these requirements.

We conducted this performance audit from February 2013 through March 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

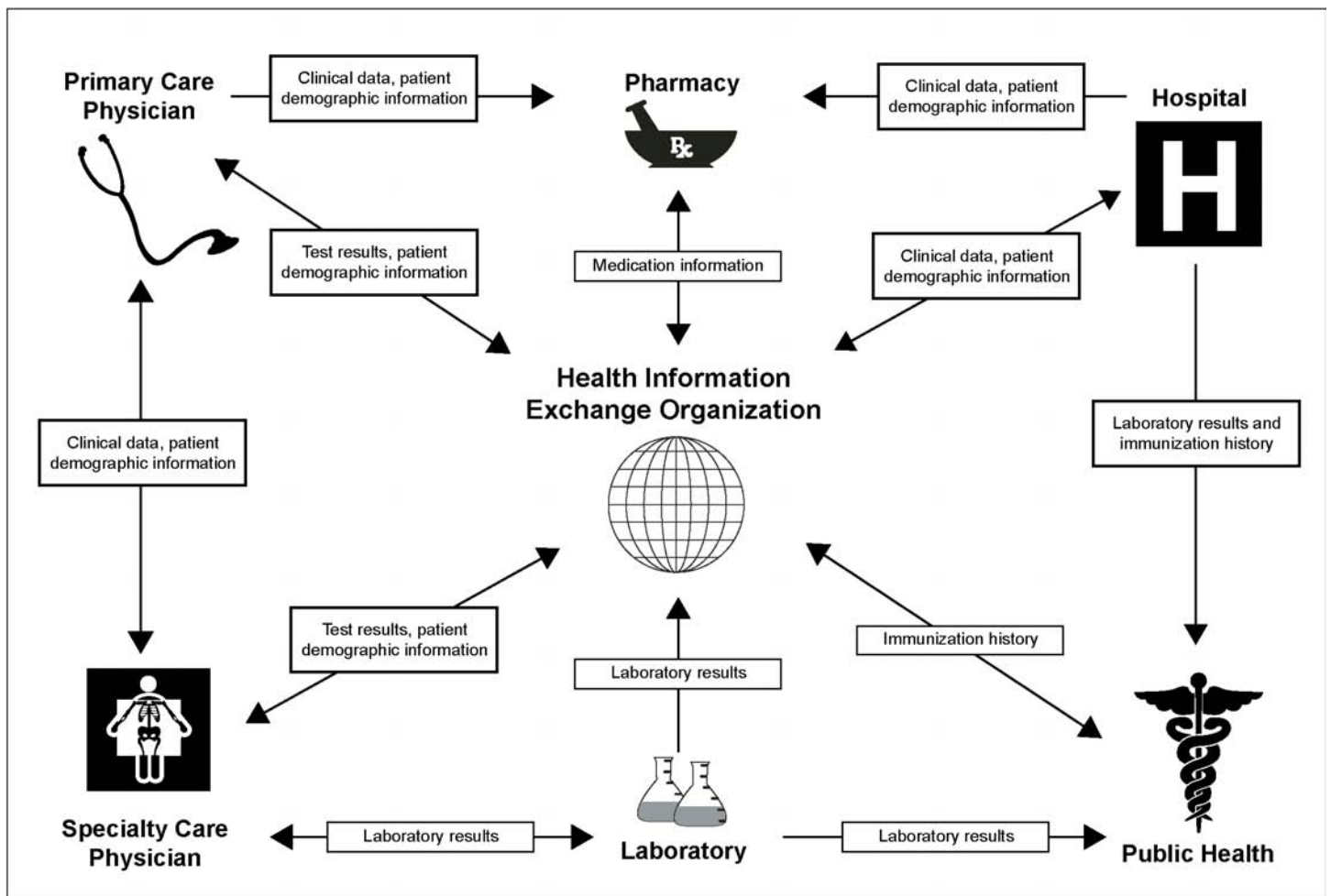
Background

Electronic Health Information Exchange

Approaches to electronic health information exchange have expanded in recent years with the increased adoption of EHRs and growth of HIE organizations. For example, some providers can electronically exchange clinical information via interoperable EHR systems. In cases in which providers wish to exchange electronic health information but do not have interoperable systems, HIE organizations can serve as key facilitators of exchange by providing for data connections among stakeholders, including laboratories, public health departments, hospitals, and physicians. Specifically, the use of EHR technology and the use of HIE organizations can allow providers to request and receive information about patients from other providers' records, such as medication lists, laboratory results, or previous diagnoses and hospitalizations. For example, when a provider requests information, the HIE organization may be able to identify the sources of the requested data and initiate the electronic transmission that delivers the data from another provider's EHR in a format that can be accepted and processed by the receiving provider's EHR. Examples of exchange activities that can occur using EHR technology directly between providers or through an HIE organization are shown in figure 1.

¹⁷Pub. L. No. 111-352, 124 Stat. 3866 (2011).

Figure 1: Examples of Health Information Exchange Using Electronic Health Record Technology



Sources: GAO analysis (data); Art Explosion (clip art).

According to an April 2012 article, exchanging EHR information with other entities can be significantly more difficult for a provider than using EHRs to manage health information within the provider’s organization only—without exchanging the information with others.¹⁸ Appendix I provides

¹⁸J. Adler-Milstein and A. Jha, “Sharing Clinical Data Electronically: A Critical Challenge for Fixing the Health Care System,” *Journal of the American Medical Association*, vol. 307, no. 16 (2012).

information about the extent to which providers are able to electronically exchange health information, as reported by providers and stakeholders we interviewed.

Medicare and Medicaid EHR Programs

HITECH provided funding for various activities, including the Medicare and Medicaid EHR programs. These programs are intended to help increase the meaningful use of EHR technology by providing incentive payments for, and later imposing penalties on, providers—that is, certain hospitals and health care professionals such as physicians—who participate in Medicare or Medicaid.¹⁹ These programs are the largest of the activities, in terms of potential federal expenditures, funded by HITECH. Within HHS, CMS and ONC have developed the programs' requirements.²⁰

CMS is responsible for administering the Medicare EHR program and overseeing and funding most of the Medicaid EHR program, which is administered by the states and U.S. insular areas.²¹ For both EHR programs, CMS established specific requirements under three progressive stages of meaningful use that providers must meet to qualify

¹⁹See Pub. L. No. 111-5, § 4101(a)-(b), 123 Stat. 467-473. In 2015 the Medicare EHR program is to begin applying a payment adjustment, referred to in this report as a penalty, for hospitals and professionals that do not meet the Medicare EHR program requirements. The Medicaid EHR program does not impose penalties on Medicaid providers that do not meet the Medicaid EHR program's requirements by a specific date; however, if Medicaid providers also treat Medicare patients, they are required to meet the Medicare EHR program's requirements from 2015 onward to avoid penalties from the Medicare EHR program.

²⁰See Medicare and Medicaid Programs: Electronic Health Record Incentive Program, 75 Fed. Reg. 44314 (July 28, 2010), codified at 42 C.F.R. pts. 412, 413, 422 and 495; Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Records Technology, 75 Fed. Reg. 44590 (July 28, 2010), codified at 45 C.F.R. pt. 170; Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2, 77 Fed. Reg. 53968 (Sept. 4, 2012), codified at 42 C.F.R. pts. 412, 413 and 495; and Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Records Technology, 2014 Edition, 77 Fed. Reg. 54163 (Sept. 4, 2012), codified at 45 C.F.R. pt. 170.

²¹CMS provides states with 100 percent of the cost of incentive payments made to Medicaid providers and 90 percent of the costs related to reasonable administrative expenses and planning activities related to the Medicaid EHR program. 42 U.S.C. § 1396b(a)(3)(F)(i) and (ii).

for incentive payments.²² As the programs progress through these stages, more requirements will be added:

- Stage 1, which began in 2011, set the basic functionalities EHRs must include, such as capturing data electronically and providing patients with electronic copies of health information.²³ CMS and ONC indicated that Stage 1 allowed providers to test the capability of their EHRs to electronically exchange health information.
- Stage 2, which began in 2014, added requirements such as increased health information exchange between providers to improve care coordination for patients. For example, Stage 2 will require hospitals and professionals to provide an electronic summary of care document for each transition of care or referral to another provider, whereas in Stage 1 this measure was optional.²⁴
- Stage 3, which is scheduled to go into effect in 2017, will continue to expand on meaningful use to improve health care outcomes and the exchange of health information, according to CMS and ONC. The requirements for this stage have not yet been developed.

ONC is responsible for identifying health data standards and technical specifications for EHR technology and establishing and overseeing the certification of EHR technology.²⁵ As part of the EHR programs, providers

²²Providers can receive incentive payments from the Medicaid EHR program in their first year of participation by reporting that they adopted, implemented, or upgraded to certified EHR technology rather than demonstrating meaningful use. In subsequent years, though, they must demonstrate meaningful use to receive incentive payments.

²³References in this report to a year in the EHR programs conform to the concept of program year, which for hospitals is based on the fiscal year and for professionals is based on the calendar year. For example, for hospitals, the 2011 program year was from October 1, 2010, to September 30, 2011, whereas for professionals, the 2011 program year was from January 1, 2011, to December 31, 2011.

²⁴Professionals do not have to satisfy this requirement if they make fewer than 100 patient transfers to another setting of care or referrals to another provider during the reporting period for the EHR programs.

²⁵In general, EHR technology is not required to be certified by ONC. However, to receive EHR program incentive payments, providers must use certified EHR technology.

Health data standards are used to facilitate health information exchange and interoperability. Such standards consist of languages and technical specifications that, when adopted by multiple entities, facilitate the exchange of health information. Health data standards include, for example, standardized language for prescriptions and for laboratory testing.

must report annually on certain mandatory meaningful use measures and on additional measures that they may choose from a menu of measures. Appendix II describes those Stage 1 and Stage 2 meaningful use measures that CMS and ONC reported as specifically relating to health information exchange.

Challenges Are Reported Related to Standards, Privacy, Patient Matching, and Costs of Electronic Exchange

Providers and stakeholders we interviewed cited key challenges to electronic health information exchange; in particular, they cited issues related to insufficient standards, concerns about how privacy rules can vary among states, difficulties in matching patients to their records, and costs associated with electronic health information exchange. CMS and ONC officials noted that they have several ongoing programs and initiatives to help address some aspects of these key challenges, but concerns in these areas continue to exist.

Reported insufficiencies in standards for electronic health information exchange. While standards for electronically exchanging information within the EHR programs exist, providers reported that standards may not be sufficient in some areas. Information that is electronically exchanged from one provider to another must adhere to the same standards in order to be interpreted and used in EHRs, thereby permitting interoperability. Several providers stated that they often have difficulty exchanging certain types of health information with other providers that have a different EHR system due to a lack of sufficient standards to support exchange.

One area for which providers told us standards were insufficient relates to standards for allergies. Specifically, one provider noted that there are not sufficient standards to define allergic reactions, and another provider explained that some EHR systems classify an allergic reaction as a side effect, while other EHR systems classify the same reaction as an allergy. Such differences can cause confusion when health information is exchanged among providers because providers who receive information may have difficulty locating or using information on allergies if their EHR systems classify the information differently than the EHR systems of the providers who sent the information. Similarly, an article from the *Journal of the American Medical Informatics Association* stated that the proper

terminology for encoding patients' allergies is complex and that some gaps still exist across existing standards.²⁶

HHS has begun to address insufficiencies in standards through the EHR programs. In order to participate in the programs, providers must use EHR technology that has been certified by HHS to meet certain criteria. Specifically, the standards and certification criteria identify certain vocabularies and structured formats that must be included in certified EHR technology that providers use when exchanging health information.²⁷ HHS has issued a new edition of the standards and certification criteria that takes effect in 2014. Providers are required to use EHR technology certified to these standards beginning in 2014, regardless of whether they participated in the EHR programs in earlier years. Compared to the previous 2011 edition, the 2014 edition includes more certification criteria and specifies certain standards to support exchange, such as standards for the transmission of health information and a summary of care record standard that providers must use to participate in the EHR programs. For example, the standards require certified EHR technology to be able to transmit patient care summaries using a structured format, referred to as a continuity of care document (CCD), which allows providers to record health information using the same template.²⁸ In addition, in order to standardize the transmittal of health information, ONC has developed the Direct Protocol, which defines a standard format that providers can use to send secure health messages

²⁶F. R. Goss et al., "Evaluating Standard Terminologies for Encoding Allergy Information," *Journal of the American Medical Informatics Association*, no. 20 (2013): 969-979. The article noted that while gaps still exist across standards related to allergies, some existing standards cover most allergy-related information.

²⁷Providers who participated in the EHR programs from fiscal year 2011 through fiscal year 2013 could use certified EHR technology that conformed to the 2011 edition of the standards and certification criteria. All providers that participate in the EHR Programs in fiscal year 2014 must conform to the 2014 edition of the standards and certification criteria. ONC is expected to develop another set of standards and certification criteria that certified EHR technology would be required to conform to beginning in 2016.

²⁸The CCD was created to foster interoperability of clinical data by allowing physicians to send electronic medical information to other providers. CCDs provide information such as pertinent clinical, demographic, and administrative data for a specific patient. In Stage 2, CCDs are created using consolidated clinical document architecture, which is a base standard that provides a common architecture, coding, semantic framework, and markup language for the creation of electronic clinical documents that facilitates the exchange of health information.

from one entity to another.²⁹ HHS expects that providers using the 2014 edition will have greater ability to exchange information.³⁰

Although progress has been made, as represented by the 2014 edition of the standards and certification criteria, concerns regarding standards remain. First, while the 2014 edition certification standards may lead to a greater ability to exchange information and HHS has tested the implementation of the standards among certain providers, HHS officials told us that the extent to which the standards will lead to widespread improvements in electronic health information exchange will remain unclear until a larger number of providers begin using technology that is certified to the standards. Second, some concerns regarding standards were not addressed through the 2014 edition, and several providers we interviewed said there is a need for standards that would allow all certified EHR technology to be interoperable so all types of health information could be electronically exchanged across providers. In addition, the AHA, in its response to HHS's March 2013 RFI, stated that the 2014 edition does not require certified EHRs to support a standard to facilitate more advanced exchange than is supported by the Direct Protocol. The AHA noted that it is appropriate to require certified EHRs to support both the Direct Protocol and other standards that would allow for more robust exchange so providers can choose which standard is appropriate for their needs when exchanging health information. Third, some providers suggested that there is a need for standards that enable providers to electronically exchange more detailed clinical information, such as patient narratives, than what is included in a CCD.³¹ Fourth, one provider we interviewed noted that standards regarding allergies were insufficient and

²⁹The Direct Protocol is part of ONC's Direct Project and serves as a standard format to transmit and share clinical information necessary to satisfy some Stage 1 and Stage 2 meaningful use requirements. For example, a primary care physician who refers a patient to a specialist can use the Direct Protocol to provide a clinical summary of that patient to the specialist and receive, in return, a summary of the consultation.

³⁰CMS and ONC announced in December 2013 that the agencies plan to propose a 2015 edition of the standards and certification criteria that would be voluntary for providers participating in the EHR programs. According to the agencies, this edition would respond to stakeholder feedback on the 2014 edition, and it would continue to advance health information exchange.

³¹Patient encounters are commonly recorded in free-form text narratives, or as unstructured clinical data. While free-form patient narratives give the provider flexibility to note observations that are not supported by structured data, they are not easily searchable and aggregated and can be more difficult to analyze.

that RxNorm and the Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) should be expanded for nonmedication allergies and allergic reactions.³² Fifth, several providers and stakeholders commented that the Direct Protocol allows for limited exchange, such as exchanging a secure email message, rather than enabling certain other functionalities, such as the ability to query another EHR system.³³

Reported variation in state privacy rules and lack of clarity about requirements. Some providers noted that exchanging health information with providers in other states can be difficult due to their limited understanding of variations in privacy rules from state to state. Some providers also noted that exchange can be especially difficult in cases when providers are located close to state borders and therefore serve patients from another state. Providers that are covered by the Health Insurance Portability and Accountability Act (HIPAA) of 1996 must adhere to federal privacy rules and can also be subject to state privacy rules.³⁴ These state rules can be more stringent than HIPAA requirements or standards.

³²RxNorm, developed by HHS's National Library of Medicine, provides normalized names for clinical drugs and links its names to many of the drug vocabularies commonly used in pharmacy management and drug interaction software. SNOMED CT is a set of clinical terminology owned and maintained by the International Health Terminology Standards Development Organisation. RxNorm and SNOMED CT are examples of standards that are required by the 2014 edition of the standards and certification criteria.

³³HHS officials stated that the Direct Protocol could be used to enable more sophisticated means of exchange, such as alerts to providers when patients are admitted to a hospital. However, the availability of these features varies by EHR vendor and geographic location.

³⁴HIPAA's Administrative Simplification Provisions required the establishment of, among other things, national privacy standards. Pub. L. No. 104-191, Title II, Subtitle F, 110 Stat. 1936, 2021 (codified at 42 U.S.C. §§ 1320d-1320d-8). These provisions also expressly provided that such national standards would not preempt state laws that impose requirements, standards, or implementation specifications that are more stringent than those imposed under federal regulation. Pub. L. No. 104-191, Title II, Subtitle F, 110 Stat. 1936, 2021, see 42 U.S.C. §§ 1320d-2 notes. HIPAA regulates covered entities' (including most health care providers') use and disclosure of personal health information. The Privacy Rule generally permits the use or disclosure of an individual's protected health information without the individual's written authorization for purposes of treatment, payment and health care operations. Under the Privacy Rule, more stringent state laws that are not preempted by federal law include those that prohibit or restrict a use or disclosure in circumstances under which such use or disclosure would be permitted under HIPAA. See 45 C.F.R. 160.202.

To address privacy issues related to electronic health information exchange, ONC officials have several ongoing efforts. For example, ONC has issued high-level guidance for providers on how to ensure the privacy and security of health information covering a wide range of topics related to meaningful use and the HIPAA Privacy and Security Rules, among other things. Regarding state privacy laws, this guidance suggests that providers seek information from state agencies, RECs, and professional associations to understand how state laws affect the sharing of patient health information. In addition, ONC began the Data Segmentation for Privacy Initiative to develop and pilot test standards for managing patient consents and data segmentation.³⁵ As part of this initiative, ONC released an implementation guide for consent management and data segmentation in the summer of 2012, and the agency is currently pilot testing this guide. In addition, ONC's state HIE organization program is currently receiving reports from states on how they are implementing their state's privacy rules. Officials expect to receive the information from states by March 2014. ONC officials are hopeful that these efforts will help address privacy concerns and, as a result, facilitate exchange efforts for providers.

Although ONC is working on privacy issues, some providers we spoke with reported that lack of clarity in state privacy laws is one reason that they have experienced difficulty exchanging health information with providers in other states. They found it difficult to ensure they were compliant with state laws when exchanging certain personal health information with providers in another state. For example, some providers in Minnesota and Massachusetts noted that some state laws have stringent requirements related to sharing health information related to mental health, or human immunodeficiency virus or other sexually transmitted infections. In addition, some providers told us that different providers in their state have different interpretations regarding how frequently they must obtain consent from the patient, as required under the state privacy rule, for the exchange of patients' health information. For example, some providers may interpret the state privacy rule to mean that every time a patient's health information is exchanged with another provider they have to obtain consent. Other providers in the same state may interpret the state privacy rule to mean that they have to obtain consent only once.

³⁵Data segmentation is a process that enables the sharing of some but not all health information. According to researchers, data segmentation could enable patient control over the sharing or withholding of health information.

In addition to the privacy challenges identified by providers, stakeholders responding to HHS's March 2013 RFI also identified privacy as a challenge related to health information exchange, and noted that additional training for providers on varying state privacy laws is needed to address this challenge. Stakeholders also suggested that HHS could focus more resources on consent policies and recommended that HHS undertake additional work to facilitate (1) electronically obtaining patient consent for disclosing health information, and (2) communicating that consent along with the related health information.

Reported difficulty of accurately matching patients to their health records. Some providers we interviewed reported that they do not have an accurate and efficient way to match patients to their records when exchanging health information. Multiple providers and stakeholders cited situations in which several of their patients are listed with the same name and birth year, and live in the same area. Two of these providers reported that patients can be matched to the wrong set of records, and that providers often need to manually match records, which is time-consuming. Some stakeholders also noted similar problems, including safety concerns from incorrect patient matching.

HHS programs or initiatives to address patient matching issues related to health information exchange include both a patient matching project and efforts by two federal advisory committees. According to ONC officials, planning for the Patient Matching Initiative was begun by the State Health Information Exchange Cooperative Agreement Program in July 2013, and the project launched publicly in September 2013. The goals of the initiative are to (1) improve patient matching based on an assessment of current approaches used by selected stakeholders, (2) identify key attributes and algorithms for matching patients to their records, and (3) define processes or best practices to support the identified key attributes. The first phase of the initiative was completed in February 2014 with the release of a report containing patient matching recommendations for possible inclusion in Stage 3 of the EHR programs and the 2015 edition of the standards and certification criteria.³⁶ The two federal advisory committees established under HITECH, the HIT Policy Committee and the HIT Standards Committee, made recommendations to

³⁶Audacious Inquiry, LLC, *Patient Identification and Matching Final Report*, a report prepared at the request of the Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Feb. 7, 2014.

HHS in 2011 that relate to patient matching.³⁷ The HIT Policy Committee recommended standardized formats for demographic data fields, internally evaluating matching accuracy, accountability, developing, promoting and disseminating best practices, and supporting the role of the patient. The HIT Standards Committee made four recommendations on patient matching covering patient attributes that could be used, data quality issues, formats for data elements, and the data that could be returned from a match request. According to ONC officials, as of July 2013 ONC had efforts under way to respond to these recommendations, under the Patient Matching Initiative, in coordination with the committees. For example, to address one recommendation related to developing, promoting, and disseminating best practices, ONC officials said that they plan to determine which approaches to patient matching work best and develop guidance to help organizations implement such steps.

Although HHS has ongoing efforts to address the patient matching challenge, several providers and stakeholders commented that more work needs to be done on this issue. Some providers we interviewed use different methodologies, such as algorithms that make use of multiple patient attributes for identifying patients. However, providers told us that they still have challenges matching patients to their records. Several providers and stakeholders have stated that there should be a national patient identifier for matching patients to their records.³⁸ Some stakeholders who responded to HHS's March 2013 RFI stated that HHS has an opportunity to reduce the potential risks of engaging in exchange by focusing more resources on patient matching.

³⁷U.S. Department of Health and Human Services, Health IT Policy Committee letter to the National Coordinator for Health Information Technology, February 8, 2011, accessed September 10, 2013, http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__policy_recommendations/1815. U.S. Department of Health and Human Services, Health IT Standards Committee letter to the National Coordinator for Health Information Technology, August 17, 2011, accessed December 31, 2013, <http://www.healthit.gov/policy-researchers-implementers/health-it-standards-committee-recommendations-national-coordinator-h>.

³⁸HHS has stated that it is prohibited from implementing a national patient identifier and referred to the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999. The act prohibits HHS from using any funds to promulgate or adopt any final standard providing for, or providing for the assignment of, a unique health identifier for an individual until legislation is enacted specifically approving the standard. See Pub. L. No. 105-277, § 516, 112 Stat. 2681, 2681-386 (1998).

Reported challenges with cost of exchanging health information.

Providers we interviewed reported challenges covering costs associated with health information exchange, including upfront costs associated with purchasing and implementing EHR systems, fees for participation in state or local HIE organizations, and per-transaction fees for exchanging health information charged by some vendors or HIE organizations. Several providers said that they must invest in additional capabilities such as establishing interfaces for exchange with laboratories or other entities such as HIE organizations. For example, many providers told us that the cost of developing, implementing, and maintaining interfaces with others to exchange health information is a significant barrier. One provider and several officials estimated various amounts between \$50,000 and \$80,000 that providers spend to establish data exchange interfaces. Other stakeholders we interviewed or who responded to HHS's March 2013 RFI also identified costs associated with participation in HIE organizations and maintaining EHR systems as a challenge for providers.

To address costs of exchanging health information, ONC's State Health Information Exchange Cooperative Agreement Program has provided funding to HIE organizations.³⁹ Agency officials stated that by funding HIE organizations, a relatively low cost option can be made available for providers to use to exchange health information. However, ONC officials said that this program is scheduled to end in March 2014.⁴⁰ In addition, several providers we interviewed told us that for them the benefits to them of joining an HIE organization often do not exceed the costs, in some cases because few providers have joined their state or regional HIE organizations, resulting in limited opportunities to exchange health information. Some providers told us they do not participate in HIE organizations because they exchange information in other ways that they believe are more efficient, such as exchanging directly with other providers that use the same EHR system from the same vendor. One

³⁹ONC's State Health Information Exchange Cooperative Agreement Program has provided funding for 56 states, eligible territories, and qualified State Designated Entities since March 2010.

ONC officials also stated that the Direct Protocol is a low-cost option for exchanging health information, and therefore may help providers reduce the cost of exchanging health information.

⁴⁰Two states, Florida and Ohio, requested to end their funding support from ONC's State Health Information Exchange Cooperative Agreement Program in fall 2013, according to ONC officials.

study noted that most health care providers, including over 65 percent of hospitals and 90 percent of physician practices, were not participating in HIE organizations.⁴¹

HHS payments to providers under the EHR programs can help support the cost of exchange, but providers can participate in the programs without routinely exchanging information electronically that could lead to improved care. While some of the meaningful use requirements for Stage 1 and Stage 2 help to facilitate the exchange of health information, they require exchange only under certain circumstances. (See app. II for more information.) For example, one part of the requirement to provide a summary care document for each transition of care or referral in Stage 2 compels providers to complete either (1) one successful electronic exchange of a summary of care record with a recipient using technology designed by an EHR developer other than the sender's, or (2) one successful test with CMS's test EHR during the reporting period.⁴² One stakeholder we spoke with explained that for this part of the requirement some providers just complete one successful test with CMS's test EHR and do not routinely demonstrate exchanging health information electronically with other EHR systems. HHS officials stated that Stage 2 is an incremental step toward advancing exchange, and that providers generally do not yet have the technology to enable greater exchange.

⁴¹J. Adler-Milstein, D. W. Bates, and A. K. Jha, "Operational Health Information Exchanges Show Substantial Growth, but Long-Term Funding Remains a Concern," *Health Affairs*, vol. 32, no. 8 (2013).

⁴²The requirement to provide a summary of care document for each transition of care or referral in Stage 2 also requires eligible professionals and hospitals to provide summary of care documents for more than 10 percent of transitions of care and referrals either (1) electronically transmitted using certified EHR technology or (2) through an exchange with an organization that is a Nationwide Health Information Network Exchange participant or in a way that is consistent with the Nationwide Health Information Network. The Nationwide Health Information Network was a program funded by ONC that transitioned to the eHealth Exchange, a group of federal agencies and nonfederal organizations whose mission, among other things, is to improve public health reporting through secure, trusted, and interoperable health information exchange.

CMS and ONC have identified a minimum set of technical capabilities that are required for an EHR to be considered a test EHR. Eligible professionals and hospitals that select to attest to this requirement will be randomly matched with a designated test EHR that is designed by an EHR developer other than the sender's.

HHS Developed an Electronic Health Information Exchange Strategy That Includes Principles to Address Key Challenges but Lacks Specific Prioritized Actions and Milestones

HHS, including CMS and ONC, developed and issued a strategy document in August 2013 that describes how it expects to advance electronic health information exchange, with principles to guide future actions in three broad areas—accelerating health information exchange, advancing standards and interoperability, and patient engagement.⁴³ Examples of principles in the strategy include (1) working with multiple stakeholders to develop standards and facilitating the adoption and use of standards among federal agencies; (2) supporting the privacy, security, and integrity of patient health information across health information exchange activities; (3) seeking to enable a patient’s health information to be available wherever the patient accesses care, to support patient-centered care delivery; and (4) supporting exchange through state-led efforts to reduce costs to providers. (See app. III for a complete list of principles.) According to the strategy, these principles have the potential to address the key health information challenges identified by providers and stakeholders we interviewed, which relate to standards, patients’ privacy, matching patients with data, and costs.

While HHS officials intend these principles to lead to future actions that have the potential to address key challenges, the HHS strategy does not specify any such actions, how any actions should be prioritized, what milestones the actions need to achieve, or when milestones need to be accomplished. Our previous work, consistent with GPRAMA, sets forth several key elements of strategies that can guide agencies in planning and implementing an effective government program.⁴⁴ As noted in our prior work, elements such as specific actions, priorities, and milestones are desirable for evaluating progress, achieving results in specific time frames, and ensuring effective oversight and accountability. These elements can also be used to gauge progress when implementing

⁴³For more information, see the Department of Health and Human Services, the Office of the National Coordinator for Health Information Technology, and the Centers for Medicare & Medicaid Services, *Principles and Strategy for Accelerating Health Information Exchange (HIE)*, (Aug. 7, 2013).

⁴⁴[GAO-04-408T](#).

See Pub L. No. 103-62, 107 Stat. 285 (1993) (GPRA), as amended by Pub. L. No. 111-352, 124 Stat. 3866 (2011) (GPRAMA). GPRA requires, among other things, that federal agencies develop strategic plans that include agencywide goals and strategies for achieving those goals. We have reported that these requirements also can serve as leading practices for planning at lower levels within federal agencies, such as individual programs or initiatives.

programs and to determine whether adjustments need to be made in order to maintain progress within given time frames.⁴⁵ Below are examples of how the lack of these elements affects the HHS strategy.

- **Specific Actions.** While the strategy mentions that HHS seeks to enable a patient's health information to be available wherever the patient accesses care, it does not indicate specific actions that HHS will take to implement that principle or how those actions would overcome exchange-related challenges. Including specific actions could enhance the strategy's usefulness for helping to make program management decisions.
- **Prioritized Actions.** While the HHS strategy states that HHS will continue to evaluate short- and long-term steps to advance exchange, it does not clearly delineate how future actions related to the principles should be prioritized. Prioritizing actions can help HHS ensure that the most appropriate activities are completed first, to more efficiently achieve the goal of advancing exchange.
- **Milestones.** The HHS strategy does not provide milestones with specific time frames to help the agencies gauge their progress in advancing exchange. Exchange-related milestones with specified time frames could be particularly useful because they could provide a framework for determining whether any actions HHS intends to take could help lead to progress in addressing the challenges providers face related to exchange. Milestones with time frames could also set realistic expectations so stakeholders can anticipate when they can expect to see actions to advance exchange.

CMS and ONC officials acknowledged the importance of providers being able to exchange health information effectively by Stage 3 of the EHR programs to allow for improved outcomes such as quality, efficiency, and patient safety. Determining specific, prioritized actions and exchange-related milestones with specified time frames can help to ensure that the agencies' principles and future actions result in timely improvements in addressing the key exchange-related challenges reported by providers and stakeholders, which are particularly important because planning for Stage 3 is expected to begin as soon as 2014. This information could also

⁴⁵GAO, *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers*, [GAO/GGD/AIMD-99-69](#) (Washington, D.C.: Feb. 26, 1999), and GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, [GAO/GGD-96-118](#) (Washington, D.C.: June 1996).

help HHS prioritize its future actions based on whether health information is being exchanged effectively among providers, in order to better achieve the EHR programs' ultimate goals of improving quality, efficiency, and patient safety.

Conclusions

HHS and providers have made some progress toward addressing challenges reported by providers and others related to the electronic exchange of health information, but these challenges are complex and difficult to address and are likely to continue to persist. Some of HHS's most important efforts, such as designing the 2014 edition of the standards and certification criteria to include an increased exchange capability in EHR systems, may lead to greater exchange over the next year. In addition, exchange may increase as providers modify their systems to meet more stringent exchange-related requirements in Stage 2 of the EHR programs. However, a number of remaining challenges make these outcomes uncertain.

HHS has both ongoing programs and future plans to address concerns about exchange, but it is not always clear how HHS will effectively prioritize and implement its potential responses to the challenges of exchange. Specifically, the HHS strategy to advance electronic health information exchange does not identify specific actions that CMS and ONC expect will lead to increased exchange, prioritize these actions, or include milestones for gauging progress over time. Guidance on planning and implementing effective strategies highlights the importance of key elements, such as specific, prioritized actions and milestones for gauging progress. These elements could help the agencies make future adjustments based on the effectiveness of their efforts. Exchange is especially important because of its potential to help improve coordination of care within the fragmented health care system. According to CMS and ONC officials, ensuring progress in providers' ability to electronically exchange information is critical for the effective implementation of the EHR programs. Without a sufficient focus on exchange—including specific, prioritized actions with milestones and time frames—CMS and ONC run the risk that the desired outcomes of the EHR programs of improved quality, efficiency, and patient safety will be compromised.

Recommendations for Executive Action

To address challenges that affect the ability of providers to electronically exchange health information, we recommend that the Secretary of Health and Human Services direct CMS and ONC to take the following two actions:

- develop and prioritize specific actions that HHS will take consistent with the principles in HHS's strategy to advance health information exchange; and
- develop milestones with time frames for the actions to better gauge progress toward advancing exchange, with appropriate adjustments over time.

Agency Comments

We provided a draft of this report to HHS for comment. HHS provided written comments, which are reprinted in appendix IV. HHS concurred with our recommendations. For the first recommendation, HHS (including CMS and ONC) stated that it has begun to develop and prioritize specific action items, consistent with the principles in its strategy to advance health information exchange, and that it has begun to take action on some of the prioritized items. For the second recommendation, HHS (including CMS and ONC) stated that it has begun developing milestones with time frames for the actions to better gauge progress toward advancing exchange. In general, HHS's comments also reiterated that the electronic exchange of health information is a key element of meaningful use and ultimately will be critical for the success of health care delivery system reforms under the Patient Protection and Affordable Care Act. HHS also stated that it has begun to take definitive steps to accelerate exchange through policy guidance, grant funding to states, and development of standards and certification, such as collaborating with private sector organizations that develop health IT standards to fill key gaps in standards to better support information exchange during transitions in care and when coordinating care across providers. Additionally, HHS provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Health and Human Services, the Administrator of CMS, the National Coordinator for Health Information Technology, and other interested parties. In addition, the report will be available at no charge on GAO's website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-7114 or at kohnl@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix V.



Linda T. Kohn
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Appendix I: Information Reported by Providers on the Electronic Exchange of Health Information and Its Related Benefits

This appendix provides additional information reported from providers we spoke with about health information exchange and its related benefits. We conducted a total of 25 interviews with providers and stakeholders, such as regional extension centers (REC) and health information exchange organizations (HIE organization), in four states—Georgia, Massachusetts, Minnesota, and North Carolina. We interviewed staff from at least two hospitals or health systems and at least one physician office or group practice in each state. We selected the four states because they were mentioned during interviews with officials from HHS and relevant stakeholders as having ongoing efforts related to health information exchange. We asked interviewees about what types of patient health information providers are currently able to electronically exchange, the methods used to exchange such information, and the benefits providers have realized or foresee from such exchange.

Providers we interviewed reported that the most critical types of health information that they need to be able to electronically exchange include patient allergy information, medication lists, and problem lists. However, providers generally reported being able to electronically exchange only specific types of health information at this time, including lab orders and results, immunization and prescription information, and certain clinical documents. For example,

- Almost all the providers we interviewed reported some exchange of lab information. In most cases, such exchanges involved both the submission of lab orders and the receipt of lab results via interfaces designed for exchange between providers and labs or through their electronic health record (EHR) system. While these exchanges were reported to generally occur between providers and laboratories outside their organizations, two providers noted that such capabilities were still limited to sharing lab information with others in the same health system.
- Some providers also reported electronically exchanging some information with state public health departments, generally immunization data and notification of certain infectious diseases. They said that these electronic exchanges were generally limited to submissions to the departments and did not include receipt of data from these departments.
- Several of the providers we interviewed said they engaged in e-prescribing activities, which in some instances included both the submission of electronic prescriptions to pharmacies and the receipt of medication information from pharmacies. However, some providers

noted that such exchanges could take place only if the pharmacy had a compatible e-prescribing system that could electronically receive prescription information from the provider's EHR system. In the absence of compatible systems, faxes were used.

- Several providers we interviewed also noted that they could exchange continuity of care documents (CCD) with other providers in their organization, although the exchange of this type of information varied among the providers we interviewed.¹ Several providers said they could exchange CCDs within their health system, whereas other providers said they could exchange this information only with providers using the same EHR vendor.

Providers in all four states and stakeholders that we interviewed reported that, at this time, methods used to electronically exchange health information are limited to use within health systems, use between certain EHR systems, or use of the Direct Protocol.² For example,

- In Georgia, REC officials and the four providers we spoke with told us that electronic exchange is generally occurring only within health systems and among those affiliated providers that work in the health systems. Some providers noted that they could electronically exchange lab orders and results outside their organizations, but one provider noted that even this information was still exchanged electronically only within its hospital.
- Providers in Minnesota, Massachusetts, and North Carolina reported that they used the same EHR system from the same vendor and were able to electronically exchange all patient clinical information with any other entity using that vendor via an interoperability feature.³

¹The Continuity of Care Document (CCD) was created to foster interoperability of clinical data by allowing physicians to send electronic medical information to other providers. The purpose of the CCD is to allow the transmission of information without loss of clinical meaning. CCDs provide information such as pertinent clinical, demographic, and administrative data for a specific patient.

²The Direct Protocol is part of the Office of the National Coordinator for Health Information Technology's (ONC) Direct Project and serves as a standard format to transmit and share clinical information necessary to satisfy some Stage 1 and Stage 2 meaningful use requirements for the EHR programs. For example, a primary care physician who refers a patient to a specialist can use the Direct Protocol to provide a clinical summary of that patient to the specialist and receive, in return, a summary of the consultation.

³Interoperability is the ability of two or more systems or components to exchange information and use the information that has been exchanged.

According to these providers, this interoperability feature provides a mechanism for them to electronically exchange all types of clinical information about their patients.

- A community-based hospital in Minnesota reported using a different EHR system than was used by the other, larger health systems in the community it shared information with. This provider reported relying on the Direct Protocol to electronically exchange some limited health information with other providers in the region. A provider in Massachusetts noted that it was building web-based “view portals” to allow other providers outside its health system to view health information electronically in order to help coordinate patient care.

Providers that participated in an HIE organization reported being able to electronically exchange health information with other providers. Others have opted to electronically exchange information using their EHR technology rather than an HIE organization, even if one was available.

- In Massachusetts, some providers told us that they are able to directly connect to the state’s HIE organization in order to electronically exchange health information, such as CCDs. However, not all providers in the state are electronically exchanging information at this time. A Massachusetts law calls for the creation and maintenance of a state HIE organization that allows providers in all health care settings to exchange patient health information with other providers by the end of 2016.⁴
- Some providers we spoke with in Minnesota said they had no plans to join any of the HIE organizations available in the state at this time due to the limited benefits they would realize from participating, and would instead continue to rely on their EHR technology to electronically exchange health information with other providers that use the same vendor. Some providers noted that without a sufficient number of other providers participating in an HIE organization, it would be of limited value.
- Several Georgia and North Carolina providers reported that the availability of an HIE organization could help facilitate electronic exchange among providers. Entities in both states are establishing regional HIE organizations that will ultimately connect to one another via a statewide HIE organization. Providers in both states said they

⁴See 2012 Mass. Acts. ch. 224 (August 6, 2012).

expected that the HIE organizations, once established, would facilitate broader electronic exchange of health information throughout the state.

Although providers we interviewed described certain circumstances when they could electronically exchange health information, they indicated that they would like to expand the electronic exchange of health information and cited a variety of benefits related to such electronic exchange. For example, some providers noted that electronic exchange can

- provide access to critical information needed when administering medical care, thus improving care quality and reducing duplicative testing;
- improve access to information related to a patient's health history, including medication histories and previous diagnoses;
- result in more timely access to information, which is particularly helpful in emergency departments; and
- reduce labor-intensive efforts to send and receive health information in paper form, such as a printed document, or conduct public health reporting activities.

Appendix II: Stage 1 and Stage 2 Meaningful Use Measures Related to Electronic Health Information Exchange

This appendix provides information on the Stage 1 and Stage 2 meaningful use measures related to electronic health information exchange, according to officials from the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC). According to these officials, Stage 2, which began in 2014, provides additional requirements related to the exchange of health information. For example, some meaningful use measures related to health information exchange that providers could select from a menu of optional measures in Stage 1 are mandatory for Stage 2. In addition, some Stage 2 measures are new. For example, the measure “provide structured electronic lab results to ambulatory providers” is a new measure for hospitals in Stage 2. See table 1 for more information.

Appendix II: Stage 1 and Stage 2 Meaningful Use Measures Related to Electronic Health Information Exchange

Table 1: Meaningful Use Measures Related to Electronic Health Information Exchange According to the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC), Stage 1 and Stage 2

Meaningful use measure related to electronic health information exchange	Hospitals		Professionals	
	Stage 1	Stage 2	Stage 1	Stage 2
Generate and transmit permissible prescriptions electronically: For hospitals for Stage 2, generate, transmit, and check each prescription for the existence of a relevant drug formulary for more than 10 percent of hospital discharge prescriptions; for professionals, generate and transmit more than 40 percent (for Stage 1) or more than 50 percent (for Stage 2) of permissible prescriptions electronically and for Stage 2 also check each prescription for the existence of a relevant formulary		○	●	●
Provide patients with their health information electronically: For Stage 1: provide information (for hospitals and professionals, provide diagnostic test results, problem list, medication lists, and medication allergies, and for hospitals also provide discharge summary and procedures) within 3 business days to more than 50 percent of patients who requested to receive that information electronically. For Stage 2: provide more than 50 percent of patients online access to their health information within 36 hours of discharge (for hospitals) or 4 days (for professionals); more than 5 percent of patients view, download, or transmit their health information to a third party	● ^a	●	● ^a	●
For hospitals, provide patients with electronic copy of discharge instructions at the time of discharge, upon request; for professionals, provide patients with clinical summaries for each office visit: For hospitals, provide information for more than 50 percent of patients who requested that information; for professionals, provide information for more than 50 percent of visits within 3 business days for Stage 1 or 1 business day for Stage 2	●	b	● ^c	●
Exchange key clinical information electronically: Perform at least one test of electronic health record technology's capacity to exchange key clinical information	● ^d		● ^d	
Incorporate clinical lab-test results into electronic health records as structured data: Incorporate into the electronic health record technology more than 40 percent (for Stage 1) or 55 percent (for Stage 2) of the clinical lab test results ordered whose results are positive, negative, or in numerical format	○ ^e	● ^e	○ ^e	● ^e
Perform medication reconciliation for patients received from another setting of care or provider of care: Perform for more than 50 percent of transitions of care	○ ^c	● ^c	○ ^c	● ^c
Provide summary of care document for each transition of care or referral: For Stage 1 and Stage 2, provide for more than 50 percent of transitions of care and referrals; for Stage 2 also (a) provide for more than 10 percent of transitions of care and referrals either electronically transmitted using certified electronic health record technology or through an exchange with a Nationwide Health Information Network Exchange participant or in a way that is consistent with the Nationwide Health Information Network ¹ and (b) conduct one or more successful electronic exchanges of a summary of care document with a recipient with electronic health record technology designed by a different developer than the sender's or conduct one or more successful tests with the CMS-designated test electronic health record	○	●	○	●
Submit electronic data to immunization registries or immunization information systems: For Stage 1, perform at least one test of electronic health record technology's capacity to submit data to immunization registries and, if test is successful, institute regular reporting; for Stage 2, demonstrate successful ongoing submission of data to immunization registries	○	●	○	●

Appendix II: Stage 1 and Stage 2 Meaningful Use Measures Related to Electronic Health Information Exchange

Meaningful use measure related to electronic health information exchange	Hospitals		Professionals	
	Stage 1	Stage 2	Stage 1	Stage 2
Submit electronic syndromic surveillance data to public health agencies: For Stage 1, perform at least one test of electronic health record technology's capacity to submit data to public health agencies and, if test is successful, institute regular reporting; for Stage 2, demonstrate successful ongoing submission of data to public health agencies	○	●	○	○
Submit electronic data on reportable lab results to public health agencies: For Stage 1, perform at least one test of electronic health record technology's capacity to submit data (as required by state or local law) to public health agencies and, if test is successful, institute regular reporting; for Stage 2, demonstrate successful ongoing submission of data (as required by state or local law) to public health agencies	○	●		
Use secure electronic messaging to communicate with patients: More than 5 percent of patients sent the professional a secure message				●
Provide patients with timely electronic access to their health information: Provide electronic access to health information (including lab results, problem list, medication lists, and allergies) to at least 10 percent of patients within 4 business days			○ ^g	○ ^b
Ensure that imaging results and accompanying information are accessible through certified electronic health record technology: Make more than 10 percent of all tests with one or more images accessible through certified electronic health record technology		○		○
Demonstrate capability to identify and report cancer cases to public health central cancer registry: Demonstrate successful ongoing submission of cancer case information from certified electronic health record technology to a public health central cancer registry				○
Demonstrate capability to identify and report specific cases to a specialized registry: Demonstrate successful ongoing submission of specific case information from certified electronic health record technology to a specialized registry other than a cancer registry				○
Provide structured electronic lab results to ambulatory providers: Send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders		○		

Source: GAO analysis of guidance from the Centers for Medicare & Medicaid Services (CMS) and of information obtained from officials from CMS and the Office of the National Coordinator for Health Information Technology (ONC).

Note: Mandatory measures are indicated by a filled circle (●), and optional measures are indicated by an open circle (○).

^aBeginning in 2014, the Stage 2 criteria apply for Stage 1 with the exception that there is no requirement that patients view, download, or transmit their health information.

^bFor Stage 2, this measure was incorporated into the "provide patients with their health information electronically" measure.

^cONC did not indicate that this measure is related to health information exchange.

^dThis requirement was eliminated from the Stage 1 requirements beginning in 2013.

^eWhile CMS officials did not indicate that this measure is related to the actual transfer of health information between entities, they did explain that this measure helps enable exchange by allowing information to be structured in such a way that when it is transferred it is usable by the recipient. CMS officials also stated that various other meaningful use measures (not included in this table) fulfill this purpose.

**Appendix II: Stage 1 and Stage 2 Meaningful
Use Measures Related to Electronic Health
Information Exchange**

^fThe Nationwide Health Information Network, funded by ONC, provides a set of standards, services, and policies that enable the secure exchange of health information over the Internet.

^gThis requirement was eliminated from the Stage 1 requirements beginning in 2014.

Appendix III: CMS and ONC Principles to Facilitate Health Information Exchange

This appendix provides information on the principles that the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) plan to use to guide their future actions to facilitate health information exchange. These principles are outlined in a strategy that the agencies released in August 2013 to describe how they expect the principles to lead to future actions that have the potential to address the key challenges providers and stakeholders have identified relative to electronic health information exchange in four areas—standards, patients’ privacy, matching patients with data, and costs.¹ The strategy includes principles under three broad categories—accelerating health information exchange, advancing standards and interoperability, and patient engagement. See table 2 for more information.

¹For more information, see Office of the National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services, *Principles and Strategy for Accelerating Health Information Exchange (HIE)*. August 7, 2013.

Appendix III: CMS and ONC Principles to Facilitate Health Information Exchange

Table 2: The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) Principles Related to Health Information Exchange

CMS and ONC Categories	CMS and ONC Principles
Accelerating Health Information Exchange	<p>Seek to ensure that all new regulations and guidance on existing programs enable a patient’s health information to follow them wherever they access care to support patient-centered care delivery.</p> <p>Implement policies that encourage health information exchange incrementally and could evolve from incentive and reward structures to ultimately considering health information exchange a standard business practice for providers.</p> <p>Enable health information exchange where possible in support of state-led delivery and payment reform through federal and state partnerships.</p> <p>Encourage interoperability across states’ electronic information infrastructures, including Medicaid and State Survey Agencies and other Department of Health and Human Services (HHS)–funded enterprise systems.</p> <p>Collaborate with other departments in the federal government to facilitate the adoption and use of HHS health information technology (HIT) standards and interoperability requirements by those departments and their constituents.</p> <p>Educate consumers from diverse cultural and socioeconomic backgrounds on health information exchange and what it means for them.</p> <p>Support the privacy, security, and integrity of patient health information across all of its health information exchange acceleration activities.</p>
Advancing Standards and Interoperability	<p>Advance multi-stakeholder development of standards through the Standards and Interoperability Framework and coordination with standards development organizations such as Health Level 7 International^a</p> <p>Accelerate interoperability through adoption of HIT standards through a variety of policies and programs, informed by advice from the HIT Policy Committee, the HIT Standards Committee, and the National Committee on Vital and Health Statistics.</p> <p>Align HIT standards for quality measurement and improvement across Medicare and Medicaid programs when appropriate.</p> <p>Accelerate alignment and implementation of electronic clinical quality measures, electronic decision support interventions, and electronic reporting mechanisms.</p> <p>Develop standards and policies to enable electronic management of consent and health information exchange among providers treating patients with sensitive health data such as those with behavioral health conditions or HIV.</p> <p>Strengthen data provenance to enhance providers’ confidence in the original source of the data they receive.</p>
Patient engagement	<p>Support appropriate patient access to their health information.</p> <p>Support appropriate access to a patient’s health information by family care givers.</p> <p>Make HHS standardized data available to patients wherever possible.</p>

Source: GAO analysis of HHS data.

^aHealth Level 7 International is an organization that develops standards for exchanging electronic health information. These standards define how information is packaged and communicated from one entity to another, setting the language, structure, and data types required for integration between systems.

Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

FEB 28 2014

Linda T. Kohn
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Kohn:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "*ELECTRONIC HEALTH RECORDS: HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones*" (GAO-14-242).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

The Department of Health and Human Services' (HHS) General Comments to the Government Accountability Office's (GAO) Draft Report: "ELECTRONIC HEALTH RECORDS: HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones" (GAO-14-242)

HHS appreciates the opportunity to review and comment on GAO's draft report. The Health Information Technology for Economic and Clinical Health (HITECH) Act, as part of the American Recovery and Reinvestment Act of 2009, promoted the adoption of health information technology and promoted health information exchange (HIE). The Act also mandated GAO to report on the effects of the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program activities, the adoption of electronic health records by providers, the reduction in medical errors, and other quality improvements.

The electronic exchange of health information is a key element of Meaningful Use and ultimately will be critical for the success of the Affordable Care Act's delivery system reforms. In March 2013, HHS issued a request for information (RFI) to seek input on a series of potential policy and programmatic changes to accelerate electronic HIE across providers, as well as new ideas that would be both effective and feasible to implement. Based on the comments and feedback received in response to the RFI, HHS has begun to take definitive steps to accelerate HIE through policy guidance, grant funding to states, and development of standards and certification.

These actions, among others, will lead to expanded patient access to their own electronic health information no matter where and when they receive care. They will also help to facilitate the routine sharing of health information between multiple providers in a variety of settings, such as hospitals and physicians, hospitals and nursing homes/other post-acute care providers, and behavioral health providers and community-based providers.

Within HHS, the Office of the National Coordinator for Health Information Technology (ONC), Assistant Secretary for Planning and Evaluation, Centers for Medicare and Medicaid Services (CMS), Substance Abuse and Mental Health Services Administration (SAMHSA), Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) are collaborating to identify specific actions that could be undertaken across HHS programs to accelerate interoperable health information exchange (HIE). As described in the GAO report, electronic HIE is expected to enable timely access to information to improve care coordination and reduce unnecessary health care spending. To that end, the Department has been identifying specific opportunities to encourage interoperable HIE across the care continuum, including between providers eligible for the EHR Incentive Programs and providers who are not eligible for these EHR incentive payments. The following describes some of the specific actions that are being implemented to support widespread electronic HIE:

- Issuing **State Innovation Model** awards that fund HIE and EHR adoption among long-term care and behavioral health providers to enable multi-payer service delivery and payment models.
- Funding **Health Care Innovation Awards** which will fund up to one billion dollars of new awards that will test new models of value-based payment enabled by HIE.
- Calling on **Medicare Advantage** plans to advance beneficiary access to their health information through Blue Button.

The Department of Health and Human Services' (HHS) General Comments to the Government Accountability Office's (GAO) Draft Report: "ELECTRONIC HEALTH RECORDS: HHS Strategy to Address Information Exchange Challenges Lacks Specific Prioritized Actions and Milestones" (GAO-14-242)

- Releasing the **Blue Button Plus Implementation Guide** to provide data holders with a toolkit to meet and go beyond the provider requirement in Meaningful Use Stage 2 for enabling patients the ability to view, download, and transmit their health information.
- Approving **Medicaid waivers** that require HIE plans and related federally funded expenditures to enable Medicaid transformation.
- Identifying and working in collaboration with private sector Standards Development Organizations to fill key gaps in health IT standards to better support information exchange at times of transitions in care and when care is shared across clinical disciplines and providers.

Below are the two recommendations included in the GAO report and HHS's response to those recommendations.

GAO Recommendation 1

GAO recommends that the Centers for Medicare & Medicaid Services (CMS) and ONC develop and prioritize specific actions that HHS will take consistent with the principles in HHS's strategy to advance health information exchange.

HHS Response

HHS concurs with this recommendation. The Department (including CMS and ONC) recognizes the challenges described in the report. HHS has already begun the process of developing and prioritizing specific action items that HHS will take, consistent with the principles in the Principles and Strategy for Accelerating Health Information Exchange. HHS has also already begun to take action on some of the prioritized items.

GAO Recommendation 2

GAO recommends that the CMS and ONC develop milestones with time frames for the actions to better gauge progress toward advancing exchange, with appropriate adjustments over time.

HHS Response

HHS concurs with this recommendation. The Department (including CMS and ONC) has already begun the process of developing milestones with time frames for the actions to better gauge progress toward advancing exchange. HHS also agrees that appropriate adjustments to these milestones and time frames will be necessary over time.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Linda T. Kohn, (202) 512-7114 or kohnl@gao.gov

Staff Acknowledgments

In addition to the contact named above, Will Simerl, Assistant Director; La Sherri Bush; Thomas Murphy; Monica Perez-Nelson; Roseanne Price; Andrea Richardson; Teresa Tucker; and Rebecca Rust Williamson made key contributions to this report.

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