

July 21, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Madam Secretary:

Markle Connecting for Health is pleased to provide feedback on the U.S. Department of Health and Human Services' implementation of the Meaningful Use program under the HITECH (Health Information Technology for Economic and Clinical Health Act) portion of the American Recovery and Reinvestment Act (ARRA). In the enclosed comments, we discuss four areas that present significant opportunities for Stage 2 Meaningful Use requirements:

1. Patient engagement as a key public benefit of the program, including the ability of individuals to view and download key personal health information online as a core requirement in Stage 2.
2. A strategy that includes options and flexibility for participating doctors and hospitals to deliver information that satisfies MU requirements for coordination of care.
3. The need to align quality-reporting requirements with various initiatives to improve health and health care, to emphasize automation of data collection and reporting, and to require summary statistics only for MU quality measures.
4. The importance of defining a comprehensive set of privacy and security safeguards as part of MU requirements.

Thank you for your continued leadership to improve health and health care through the power of information.

With appreciation,

Markle Connecting for Health collaborators

cc:

Donald M. Berwick, MD, MPP
Administrator, Centers for Medicare and
Medicaid Services (CMS)

John Halamka, MD, MS
Vice Chair, Health IT Standards Committee

George Hripcsak, MD, MS
Co-Chair, Health IT Policy Committee
Meaningful Use Workgroup

Farzad Mostashari, MD, ScM
National Coordinator for Health Information
Technology, Office of the National Coordinator
for Health Information Technology (ONC);
Chair, Health IT Policy Committee

Jonathan Perlin, MD, PhD
Chair, Health IT Standards Committee

Joshua Seidman, PhD
Acting Director, Meaningful Use, ONC

Paul Tang, MD
Vice Chair, Health IT Policy Committee;
Chair, Health IT Policy Committee Meaningful
Use Workgroup

Tony Trenkle
Acting Chief Information Officer and Acting
Director of the Office of Information Services,
CMS

The following comments were formulated by a collective view informed by the many and diverse collaborators within the Markle Connecting for Health community, and are supported by:

Christine Bechtel
National Partnership for Women and Families

Hunt Blair*
Department of Vermont Health Access

Adam Bosworth
Keas, Inc.

William Braithwaite, MD, PhD, FACMI
Anakam Inc.

Jeff Brown
Wal-Mart Stores, Inc.

Silas Buchanan
The Cave Institute

Mark R. Chassin, MD, MPP, MPH
The Joint Commission

Seth Cohen
Castlight Health

Jennifer Covich Bordenick
eHealth Initiative

Brian L. DeVore
Intel Corporation

Steven Findlay, MPH
Consumers Union

Daniel T. Garrett
PricewaterhouseCoopers

Douglas A. Gentile, MD, MBA
Allscripts Healthcare Solutions

Mark Gorman
National Coalition for Cancer Survivorship

Adrian Gropper, MD
MedCommons

Jim Hansen
Dossia Consortium

Douglas M. Henley, MD, FAAFP
American Academy of Family Physicians

Joseph M. Heyman, MD
Wellport Electronic Health Network

Gerry Hinkley, JD
Pillsbury Winthrop Shaw Pittman LLP

Michael B. Jackson
Adobe Systems, Inc.

William F. Jessee, MD
Medical Group Management Association

Scott Kennedy
Target Corporation

David Kibbe, MD, MBA
The Kibbe Group LLC;
Chair, ASTM International E31 Technical
Committee on Healthcare Informatics

Allan M. Korn, MD, FACP
Blue Cross and Blue Shield Association

Joseph C. Kvedar, MD
Partners HealthCare System Inc.

David Lansky, PhD
Pacific Business Group on Health

Janet Marchibroda
Bipartisan Policy Center

Philip Marshall, MD, MPH
Press Ganey

Deven McGraw, JD, MPH, LL.M.
Center for Democracy & Technology

** Federal, state, and city employees collaborate but make no endorsement.*

Howard Messing
Meditech

Thomas G. Morrison
NaviNet

Peter Neupert
Microsoft Corporation

J. Marc Overhage, MD, PhD
Siemens Healthcare

Amanda Heron Parsons, MD*
Primary Care Information Project, NYC
Department of Health & Mental Hygiene

Carol Raphael, MPA
Visiting Nurse Service of New York

Dan Rode
American Health Information
Management Association

John Rother
AARP

Peter A. Schad, PhD
RTI International

Scott Schumacher, PhD
IBM Information Management

Raymond W. Scott
Axolotl Corporation

Mark Segal, PhD
GE Healthcare IT

Thomas E. Sullivan, MD
DrFirst.com

Kenneth Tarkoff
RelayHealth

Charlene Underwood, MBA
Siemens Medical Solutions

Robert Wah, MD
Computer Sciences Corporation

Jeb Weisman, PhD
Children's Health Fund

Markle Foundation

Zoë Baird Budinger
President

Carol C. Diamond, MD, MPH
Managing Director, Health
Chair, Markle Connecting for Health

** Federal, state, and city employees collaborate but make no endorsement.*

Markle Connecting for Health Collaborative Comments on Stage 2 Meaningful Use

These comments represent a collective view informed by the many and diverse collaborators of Markle Connecting for Health.

Markle Connecting for Health is pleased to provide feedback on the general direction of the U.S. Department of Health and Human Services' (HHS) implementation of the Meaningful Use (MU) program under the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009. This letter summarizes comments from the Markle Connecting for Health community on some of the proposed requirements for Stage 2 of this important program.

Markle Connecting for Health is a public-private collaborative with representatives from organizations across the spectrum of health care and information technology.

In general, we support a reasonable approach of phasing “menu” requirements into “core” requirements over the course of the program without creating new burdens for manual counting by participating physicians and hospitals. We discuss four areas that present significant opportunities for Stage 2 Meaningful Use requirements:

1. **Patient engagement** as a key public benefit of the program, including the ability of individuals to view and download key personal health information online as a core requirement in Stage 2.
2. A strategy that includes options and flexibility for participating doctors and hospitals to deliver information that satisfies MU requirements for **coordination of care**.
3. The need to align **quality-reporting requirements** with various initiatives to improve health and health care, to emphasize automation of data collection and reporting, and to require summary statistics only for MU quality measures.
4. The importance of defining a comprehensive set of **privacy and security safeguards** as part of MU requirements.

Each of these areas is discussed in detail below.

1. Patient Engagement

The participation and support of the public will be central to the nation's ability to attain the health goals of HITECH, such as improving care coordination, controlling chronic diseases, addressing disparities, enhancing medication safety, or using health care resources efficiently. The electronic information sets required to be delivered to patients in MU Stage 1—most importantly, problem and medications lists, allergies, lab results, and visit summaries—provide an excellent foundation for Stages 2 and 3.

We support the recommendation of the Health Information Technology Policy Committee (HITPC) to include the capability for individuals to view and download copies of their own health information in Stage 2 MU requirements. Markle Connecting for Health has emphasized the download capability as a critical building block for patient engagement and market innovation.¹ According to a 2010 Markle Foundation survey, roughly two-thirds of both the general population and doctors agreed that patients should have the option to view and download their personal health information online.²

The Markle Connecting for Health community has recommended that the download capability be a core requirement of certified health IT and an allowable means for physicians and hospitals to satisfy patient engagement requirements in MU Stage 2.

Broad Vision for Patient Engagement

As articulated in previous collaborative comments,³ the rationale for supporting the download capability begins with a broad vision for individual participation in transforming health care. This vision:

- Considers individuals as information participants—not as mere recipients, but as members of the care team, information contributors, knowledge creators, and shared decision makers.
- Shifts paradigms so that information is not provided to individuals only upon request, but is delivered routinely after every visit in a format that matches the individual's needs and wishes.
- Encourages the extension of communication and feedback cycles among individuals and care teams beyond episodic, office-based encounters.

¹ *Policies in Practice: The Download Capability*, Markle Common Framework for Networked Personal Health Information, August 31, 2010: <http://www.markle.org/publications/1198-policies-practice-download-capability>.

² *Public and Doctors Alike Support Allowing Individuals to Download Their Own Health Information*, Markle Health in a Networked Life, January 31, 2011: <http://www.markle.org/publications/1441-public-and-doctors-alike-support-allowing-individuals-download-their-own-health-in>.

³ *Collaborative Comments on the Proposed EHR Incentives Program, Public Comments on the Centers for Medicare and Medicaid Services' Notice of Proposed Rulemaking for the Electronic Health Record Incentive Program (CMS-0033-P)*, Markle Connecting for Health, Engelberg Center for Health Care Reform at Brookings, Center for American Progress, March 15, 2010: <http://www.markle.org/publications/113-collaborative-comments-proposed-ehr-incentives-program>.

- Enables individuals to compile copies of their information on a timely basis and share it through a wide variety of applications and services of their choosing.
- Creates new patient engagement performance measures that are directly tied to health improvement goals.

The journey toward this vision starts by improving access to information.

Adopting Efficient Information Delivery Mechanisms

In order to begin to turn this vision into reality at scale, we need more widespread adoption of efficient mechanisms to deliver personal health information directly to patients. The MU financial incentives provide a short window of opportunity to stimulate participating doctors and hospitals to implement essential building blocks for greater patient participation. Today, vital steps include:

- **Making the secure online view and download capability a requirement of certified and qualified health IT under HITECH.** The technical requirements should include automation of counts of basic utilization (e.g., number of doctor or hospital visit summaries delivered, number of patients who log in, number of electronic downloads requested and delivered). It should be relatively easy to certify that a system can deliver human-readable health information via a secure connection. This will prevent the provider from having to negotiate this basic capability with each vendor and make the capability a standard feature of qualified health IT.
- **Making the secure online view and download capability a core requirement to serve as a means by which providers and hospitals may deliver the patient engagement information** (e.g., doctor or hospital visit summaries, problem and medication lists, lab results, etc.). As we discuss below, participating doctors and hospitals should be able to deliver this information via paper copies if preferred by the patient. The online view and download mechanism should be required as another means to deliver this information.
- **Making secure online view and download capability an allowable means by which providers and hospitals may deliver electronic copies to patients upon request under Section 13405(e) of HITECH,**⁴ which establishes an individual's ability to request information in electronic format from electronic health records (EHRs) and have it sent to a service of the individual's choosing. (See Appendix A for a summary of policy recommendations on how the individual could make such authorizations.)

There are roughly 1 billion doctor's office visits by patients in a single year in the United States.⁵ The Markle survey revealed that substantial portions of patients and doctors perceive that important

⁴ Health Information Technology for Economic and Clinical Health (HITECH) Act of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, §13405(e).

⁵ *National Ambulatory Medical Care Survey: 2007 Summary*, November 3, 2010: <http://www.cdc.gov/nchs/data/nhsr/nhsr027.pdf>.

information is sometimes lost in their conversations.⁶ Both patients and doctors also indicated that doctor and hospital visit summaries are delivered infrequently today. Such summaries delivered directly to patients can help in their retention of information, self-management, and coordination of care; therefore, the provision of after-visit summaries must be a core expectation of Meaningful Use.

Some have expressed concern that it will be difficult for providers to implement a download capability, or for vendors to get systems ready for Stage 2 of Meaningful Use. Yet much of the heavy lifting already has happened through Stage 1 requirements; this effort is mostly about putting existing capabilities together to support patient engagement. Basically, a download capability combines the existing capabilities Meaningful Users have in place to enable them to create clinical summaries (both as human-readable text and structured as a CCD or CCR) and to enable patients to access their health information online. The experience at the U.S. Department of Veterans Affairs (VA), Medicare, and TRICARE demonstrate that this basic capability has value to patients and can spur private sector innovation. When the VA enabled patients to download their information, the private sector responded by demonstrating a wide range of applications that made that information useful to patients (e.g., making it easier to know when to take medications, storing medical images, connecting with peers who have similar health conditions). The download capability is an important initial step for patients to engage with their care and, very literally, take their information with them where they need it to go.

Specific Requirements of the Download Capability

Through months of public-private collaboration, more than 50 organizations have endorsed a set of Markle Connecting for Health recommended practices for implementation of the download capability that build on the Markle Common Framework for Networked Personal Health Information. The recommendations are detailed in [Policies in Practice: The Download Capability](#).⁷ We contextualize them below for MU Stage 2.

Secure online access as a requirement: The ability to view and download personal health information must be accessible to the patients of an eligible professional or an eligible hospital from an online site with appropriate security precautions in place. That means the identity of each individual given credentials to access his or her own data must be proofed to an acceptable level of accuracy, and the individual must present an acceptable token (e.g., unique user name and password combination) upon login in order to get access to the data for view and/or download. (See Appendix A for a discussion of individual authorizations of personal health information sharing between two parties.)

⁶ *Many Doctors and Patients Perceive Gaps in Their Communications*, Markle Survey on Health in a Networked Life, January 31, 2011: <http://www.markle.org/publications/1438-many-doctors-and-patients-perceive-gaps-their-communications>.

⁷ *Policies in Practice: The Download Capability*, Markle Common Framework for Networked Personal Health Information, August 31, 2010: <http://www.markle.org/publications/1198-policies-practice-download-capability>.

Specific data sets should be viewable and downloadable by patients: *For MU Stage 2, we recommend a core requirement of giving patients secure access for viewing and an option for downloading information already included in the Stage 1 MU patient engagement data sets, such as problem and medication lists, allergies, laboratory results, and doctor/hospital visit summaries.* It is very important to note that this MU requirement would not imply a need to offer a fully functional patient portal or personal health record (PHR), nor would it extend to all components of a patient’s historical record. Patients will still be able request their paper records under the Health Insurance Portability and Accountability Act (HIPAA).

Of course, practices that exceed this core requirement, by either making more information sets available online to patients or by offering a fully functional patient portal or PHR, should qualify for the MU incentives.

Helping people make informed choices: Any organization offering the download capability should inform individuals about the choice to download information and confirm that the individual really wants to do it. The interface must enable individuals to make informed choices.

Our collaborative has endorsed a set of policies and practices recommending that, when an individual is downloading from a secure online service to a computer or a device, the provider of the download capability should do the following:

- Provide a clear, concise explanation of the download function and its most fundamental implications for the individual.
- Provide prominent links that enable individuals to view more details about the download process, including what basic security precautions they can take on their own, how the service answers questions (e.g., through direct communication, FAQ page, or other means), and who they should contact if they believe some of the downloaded information is in error.
- Obtain independent confirmation from the individual (i.e., such as a “yes” response to a question) that the individual wants to download a copy of personal health information.
- Such independent confirmation should be obtained after presenting the individual with, at minimum, the following clearly stated information:
 - Health records can contain sensitive information.
 - If you download sensitive information to a shared or unsecured computer or device, others might see it.
 - You are responsible for protecting the information that you download, and for deciding with whom to share it.
 - Are you sure you want to download a copy of your personal health information to the computer or device you are using?⁸

⁸ *Policies in Practice: The Download Capability*, Markle Common Framework for Networked Personal Health Information, August 31, 2010: <http://www.markle.org/publications/1198-policies-practice-download-capability>.

Electronic copies and paper: It is essential to think about this opportunity from the perspective of both patients and providers. According to the 2010 Markle Foundation survey, roughly two-thirds of both the general population and doctors agreed that patients should have the option to view and download their personal health information online.⁹

Of course, not all people are online. Patients must be able to choose whether they wish to receive copies of their information on paper or in electronic format (including secure online access/download), or both.

The “both” option is critical. Even if patients get a paper summary after a doctor visit or hospital discharge, it may still be useful for them to be able to view or download a copy of that information later online. A piece of paper may be lost or a lab result may lag a clinical encounter by a few days. For these and other reasons, MU technology should make it easy for providers to give patients secure online access to view and download the priority types of information in the patient engagement requirements of MU (e.g., summaries of visits, lists of problems, medications, allergies, immunizations, procedures, and laboratory and diagnostic test results). This approach is not only convenient for patients, it is ultimately lower burden for providers compared with handling all patient requests for medical records manually.

Data formats: Options are also critical when it comes to the formats of information for patients to download. HHS should require that the information be accessible to patients in human-readable format. Additionally, if the data are available in the standardized clinical summary formats endorsed as MU standards (i.e., CCD or CCR), the patient should have an option to download that data in those formats. The bottom-line requirement for human readability ensures that people will not need to use a specific application or service in order to see their own health information. They should have the option of viewing and downloading their information through ubiquitous Internet browsers and common software formats (e.g., text, spreadsheet, PDF).

In addition to supplying the information to individuals in human-readable text as well as CCD or CCR formats, providers also may provide an option for individuals to download the information available in whatever clinically codified languages or structured formats that the providers’ systems use. Directionally, this will enable consumers to benefit from future applications of their own choosing, which may be able to consume specific clinical code sets and controlled vocabularies in order to create richer functionality or decision support.

These options are essential to engage people with varying needs, wishes, and technology sophistication. They also enable innovation in services that can add value to the downloadable data with the individual’s permission, including emerging mobile applications.

⁹ *Public and Doctors Alike Support Allowing Individuals to Download Their Own Health Information*, Markle Health in a Networked Life, January 31, 2011: <http://www.markle.org/publications/1441-public-and-doctors-alike-support-allowing-individuals-download-their-own-health-in>.

Human readability vs. understandability: Under the tight timelines of MU Stage 2, in our view, the minimum requirement of human readability means that information viewable and downloadable online should be in English or another predominant language of the provider's patient population. It is ideal for the terminology to be as patient-friendly and free of medical jargon as possible, as well as translated into languages common to a provider's patient population. However, we do not recommend strict requirements for how understandable the information must be to patients at this stage. It is more important to make the information available conveniently online so that patients can provide vital information to their next provider. There are public and private resources that translate medical jargon and clinical codes into consumer-friendly terms. Demand for such services is likely to increase as more individuals get access to their information online. HHS should monitor feedback from early phases of the MU program and consider whether additional guidance is necessary to make the MU patient engagement requirements more useful for various patient populations in future stages. This also will be important for future guidance regarding Section 13405 (e) of HITECH.

Audit trail: The download capability should include an immutable audit log to keep a record of download events as a fundamental capability of qualified health IT. All imports and exports of information should be tracked in a running log that the individual is able to view securely online.

Patient engagement measures and thresholds: We agree with the general direction of the HITPC to recommend consolidating the different Stage 1 patient engagement requirements for "timely electronic access," "electronic copies," and summaries or instructions to be delivered to patients after doctor or hospital visits. The view and download option is an efficient vehicle to do this. The vital starting point is to create core requirements that encourage participating doctors and hospitals to make its provision a routine service for patients.

Consensus is difficult to find on the specific measures and thresholds that should be required for doctors to meet patient engagement goals in Stage 2 of the program. On one hand, it is clear from current experience with patient portals and PHRs that clinicians play an important role in encouraging consumer adoption and utilization. It might be a lost opportunity if HHS sets only a token threshold for the number or percentage of patients who need to view or download their information online for a provider or hospital to satisfy patient engagement requirements. On the other hand, HHS should not penalize providers whose patient populations are less likely to make full use of this capability.

To address this question, we focus on the big picture. The overall objective is for HHS to encourage that the view and download capability become a common service for all patients, and to use qualified health IT in a way that makes measuring its use an automated function that avoids the need for manual counting. It is important now to establish clear technology certification requirements to make the secure online delivery of personal health information to patients a largely automated task for providers, and to require the technology to have an automated means for counting and calculating the percentage of active patient utilization.

Therefore, qualified health IT or modules certified for MU patient engagement should be required to calculate and report basic numerators for each reporting period, including number of unique patients who

log in securely, number of sessions to view key information like doctor and hospital visit summaries, and number of download requests made and fulfilled. Qualified health IT should also be required to calculate and report basic denominators: number of patients and patient visits during the reporting period.

2. Coordination of Care

Clinical summaries and medication reconciliation: MU rules should encourage progress on interoperability and use of secure electronic provider-to-provider transactions of care summaries when possible. However, asymmetric IT adoption will characterize the U.S. health sector for many years to come; providers with highly sophisticated systems will have to interact with providers with little or no electronic capability for information sharing. For this reason, the requirements for care coordination should include flexibility in allowable options by which information may be shared.

Sharing requires both senders and recipients of information. The rules should not penalize the sender for any lack of technology or capability on the recipient end. There should be flexibility so that eligible professionals and hospitals may get credit for coordinating care when they send summary care records through channels other than direct computer-to-computer exchange among providers. A reasonable rule would require participating providers to possess the capability to send information using secure messaging (e.g., Direct Project or equivalent service) or a health information exchange (HIE), and use reasonable attempts to leverage such capabilities when sending information. However, participating providers should still be considered compliant if another mechanism is required to reach the recipient. If the eligible provider or hospital extracts the information via qualified health IT, it ultimately should be a secondary consideration how the information is received by the next practice. CMS should emphasize that the goal is for information to follow the patient to the next encounter and to be available to inform clinical decision-making. In some cases, the most efficient means by which the information may flow to the next provider will be by providing the electronic information to the patient, for example, via the download capability.

Care plans: Given the tight timelines of MU Stage 2, it is difficult to contemplate a requirement for shared or longitudinal care plans across multiple providers facilitated by health IT. Many comments have noted that there is no industry standard in this area.

However, the existing regulation already contains building blocks for experimentation in care planning. Clinical visit summaries already include fields for “instructions.” It would be of high value if these instructions were captured electronically (as simple text) to be included routinely in care summaries shared among doctors upon patient referrals and shared directly with the patients themselves. From the patient’s standpoint, it makes sense to receive timely information in writing after a clinical visit: “What are my next steps?” and “What are the goals of these next steps?” In its requirements for both care coordination and patient engagement, HHS should emphasize the importance of “instructions” and “goals” text fields in clinical visit summaries and hospital visit or discharge summaries. HHS should encourage that Meaningful Users include specific treatment or monitoring goals for their patients, when applicable. There is a growing awareness that plainly stated treatment goals or next steps from doctors can be helpful particularly to patients with chronic conditions or complicated health challenges. Simply by

filling out these existing fields on care summaries, providers can improve communication and coordination of care. It is appropriate that Meaningful Users make simple yet concrete progress on this priority in Stage 2.

More complex care planning experimentation could take place in programs other than Meaningful Use. For example, HHS could investigate potential application of a collaborative longitudinal care plan using distributed approach through SHARP grants or the Beacon program by building applications on top of existing MU functionalities. Or, it could provide incentives for similar experimentation by accountable care organizations (ACOs) and Medical Homes.

3. Quality Reporting

We encourage the Centers for Medicare & Medicaid Services (CMS) to think holistically about the necessary ingredients for providers and patients alike to trust information sharing so that they can make significant and measurable progress. The health care system must embrace and be an active part of creating the kind of change that will be necessary to operate in an environment that supports information-rich health care.

More important than any program specifications or granular reporting requirements, CMS must communicate a broad vision for a “culture of quality improvement” supported by information-rich health care. The culture must engage both patients and health care professionals actively in quality improvement. It must reinforce a commitment to excellence and lifelong learning. In this vision, providers and patients understand the circumstances under which information is shared, and trust that risks will be minimized through transparent policies and practices.

Information sharing and use must be embedded in systems of care designed specifically to improve decisions for patients, their families, and the health care system, always evolving around the needs of patients and reducing administrative burdens. Information gathering and reporting activities should be seamlessly integrated into the provision of care, generate results and benchmarks, meaningfully combine various sources of information, and be available to providers and patients to refine and improve systems of care. Information should support coordinated and appropriate care. This approach must be accomplished without placing onerous time and administrative burdens on providers and their staffs.

The Meaningful Use Program can help accelerate culture and transformations by aligning with and reinforcing other quality improvement efforts such as the Medicare Shared Savings Program and National Quality Strategy.

Clear and explicit health goals are key to the success of the Meaningful Use program. In the absence of clear goals that are well understood by the provider community and the public, efforts to comply with Meaningful Use will risk becoming solely an exercise in compliance with reporting requirements rather than an opportunity to improve health and efficiency using both health IT and changes in care delivery. The National Strategy for Quality Improvement in Health Care (National Quality Strategy) was an important step toward fully addressing this critical issue.

Released on March 21, 2011, the National Quality Strategy includes initial priorities and health goals, which are to be further developed throughout 2011. As stated by HHS, the next version of the National Quality Strategy will reflect specific measures and include short-term and long-term goals. In addition, HHS stated that it will promote effective quality measurement while minimizing the burden of data collection by aligning measures across its programs, coordinating measurement with the private sector, and developing a plan to integrate reporting on quality measures with the reporting requirements for the Meaningful Use of electronic health records.

As HHS works to finalize the requirements for MU Stage 2, it is essential that new requirements reflect the next version of the National Quality Strategy. As indicated by HHS, the first update on the National Quality Strategy will be provided to Congress and the Nation in 2012, including additional detail on how federal agencies are addressing the priorities and health goals in agency-specific strategic plans. To maximize the investments of HITECH and the Affordable Care Act, HHS should align MU Stage 2 and ACO requirements with the priorities and goals of the National Quality Strategy. The Meaningful Use program is regarded as a roadmap for other initiatives. For example, under the Medicare Shared Savings Program, 50 percent of the doctors within an ACO must meet MU requirements. Clear and explicit health goals that are clearly communicated with providers and patients alike are key to the success of the MU program as well as an array of new initiatives that aim to transform the delivery of health care. Without clearly communicated health goals these programs risk being presented to clinicians as a series of reporting requirements rather than as a critical effort to use health IT to improve the quality and safety of care.

At this critical stage of implementation of MU, health care reforms and other initiatives, it is ever more important that HHS align various quality reporting requirements toward overarching health goals and avoid inconsistencies in the various functional requirements. For example, in a recent report, the Government Accountability Office (GAO) echoed concerns about differences in reporting requirements for Meaningful Use and the Electronic Prescribing Program. The GAO calls for the alignment of reporting requirements so that successfully qualifying for incentive payment or for avoiding penalties under Meaningful Use would likewise result in meeting requirements for the Electronic Prescribing Program.¹⁰

Collection of Summary Statistics

As we commented in Stage 1, it will be key to define quality measures that can be captured and reported by automated means, as a byproduct of use of certified EHR systems.

To help meet privacy expectations, HHS should continue to clarify that providers will submit to CMS only summary statistics for each quality measure, defined as simple numerators/denominators reflecting the experience of the provider's patient population (e.g., "5/7 of Dr. Smith's patients with hypertension have controlled blood pressure."). As we have emphasized in previous comments, this approach is more achievable and scalable. Although patient-level data will be of great value to individual providers for care

¹⁰ *CMS Should Address Inconsistencies in Its Two Incentive Programs That Encourage the Use of Health Information Technology*, General Accounting Office, February 2011: <http://www.gao.gov/new.items/d11159.pdf>.

and process improvements, it is not needed for CMS to evaluate provider performance in a program of this nature, size, and complexity.^{11,12}

The independent survey commissioned by the Markle Foundation signals overwhelming agreement with this approach among the public and physicians polled. When asked about requirements necessary to make sure that federal incentive money for health IT would be well spent, more than 80 percent of both the public and doctors said privacy safeguards were important.

More specifically, 65 percent of the public and 75 percent of the doctors said it is important that the government *not* collect health information that is *personally identifiable* for health IT or health care quality improvement programs. However, when asked whether they would allow *anonymized* patient data to be used for quality improvement programs, 77 percent of the public and 86 percent of the doctors were somewhat or very willing.¹³ The implications are clear: CMS should require only summary statistics, not personally identifiable data, for MU quality reporting.

4. Protect Privacy

As HHS refines all areas of the program, it must be mindful of public and provider expectations for privacy. The starting place is a broad framework of privacy principles based on fair information practices (FIPs) and embraced by the Office of the National Coordinator for Health Information Technology (ONC) and other federal agencies.¹⁴ Only when taken as a whole do these principles and related practices constitute a trust framework. Because trust is primarily an attribute of entities or participants rather than of software or data, progress will be made primarily through an expanding network of trusted participants. The EHR Incentive Program is a significant opportunity to embed privacy and security protections into business practices. The Markle Survey on Health in a Networked Life found that more than 80 percent of both the public and doctors surveyed considered privacy safeguards to be important requirements necessary to make sure that federal incentive money for health IT would be well spent. Both groups expressed the importance of specific privacy policies including breach notification, audit trail,

¹¹ *Collaborative Comments on the Proposed EHR Incentives Program, Public Comments on the Centers for Medicare and Medicaid Services' Notice of Proposed Rulemaking for the Electronic Health Record Incentive Program (CMS-0033-P)*, Markle Connecting for Health, Engelberg Center for Health Care Reform at Brookings, Center for American Progress, March 15, 2010: <http://www.markle.org/publications/113-collaborative-comments-proposed-ehr-incentives-program>.

¹² *Collaborative Comments on the ONC's Interim Final Rule on EHR Technology*, Markle Connecting for Health, March 15, 2010: <http://www.markle.org/publications/1451-collaborative-comments-oncs-interim-final-rule-ehr-technology>.

¹³ *The Public and Doctors Agree on Importance of Specific Privacy Protections for Health IT*, Markle Health in a Networked Life, January 31, 2011: <http://www.markle.org/publications/1443-public-and-doctors-agree-importance-specific-privacy-protections-health-it>.

¹⁴ *Memorandum for Selected Heads of Executive Departments and Agencies: Health Information Technology Guidance*, Vivek Kundra and David Blumenthal, September 17, 2010: <http://www.cio.gov/Documents/Health-Information-Technology-Guidance.pdf>.

informed choices, and ability to request corrections. In past Markle surveys, the public support for these privacy-protective practices consistently has remained very high.¹⁵

As the most recent Office of the Inspector General report *Audit of Information Technology Security Included in Health IT Standards*¹⁶ noted, there is more to be done in the area of privacy and security beyond technical security standards. In particular, it said, “Security is not just about using the right standards or purchasing products that implement those standards. It’s also about the infrastructure on which those products run and the policies that define how they’ll be used.” Since the promulgation of the Stage 1 MU requirements, the Privacy and Security Tiger Team has done much work to emphasize the importance of a comprehensive, FIPs-based framework and to develop specific policy recommendations based on that framework for privacy and security in the context of information sharing required by MU. The Tiger Team has made substantial progress, although significant work still must be done to incorporate its recommendations in a meaningful way. HHS should incorporate the Tiger Team privacy and security recommendations and guidance into MU stages as feasible. Most importantly, HHS must continue to develop and adopt a comprehensive set of protections in all its health IT work.¹⁷

¹⁵ *The Public and Doctors Agree on Importance of Specific Privacy Protections for Health IT*, Markle Health in a Networked Life, January 31, 2011: <http://www.markle.org/publications/1443-public-and-doctors-agree-importance-specific-privacy-protections-health-it>.

¹⁶ *Audit of Information Technology Security Included in Health IT Standards*. Office of the Inspector General, May 2011: <http://oig.hhs.gov/oas/reports/other/180930160.pdf>.

¹⁷ *The Markle Common Framework: Overview and Principles*. 2006: http://www.markle.org/sites/default/files/Overview_Professionals.pdf.

Appendix A

Section 13405(e) of HITECH establishes the individual's right to request and receive copies of personal health information in electronic format from EHRs and to have those copies sent to a third-party application or service of the individual's choosing.

As part of its *Policies in Practice: The Download Capability* paper, the Markle Connecting for Health Work Group on Consumer Engagement made recommendations for how this can be done securely.

For simplicity:

- Point A is an EHR (where the data were captured, and where the individual has a portal account for online view and downloads).
- Point B is the individual's PHR or other personal health information service (where the individual wants the data to be sent from Point A regularly).

To authorize a connection between Point A and Point B, should the individual be required to give her Point A user name and password to Point B? Or should policies discourage this approach of sharing individual user name and password between the two points?

The Markle Work Group on Consumer Engagement, in its recommendations for the download capability, developed recommendations that clearly discourage sharing user names and passwords between these two entities.

Here is what the Work Group said:

Deploy separate pathways for download requests from the individual, and download requests via automated processes acting on the individual's behalf. Services offering download capabilities should create one URL for the individual to request downloads, and a separate URL to be accessed by machines. This separation of access points for the data is designed to discourage third-party services from asking for or operating with the individual's passwords or other digital tokens to collect the individual's information (even when the individual has authorized such third-party services to receive automated downloads). Further, the separation of access points as a matter of policy should encourage the adoption of standards that let the patient link data sources and PHR services securely without making such password or token disclosures. To set this up, the individual logs in separately at each entity, using different user names and passwords at each, and then authorizes data exchange between the two entities for a given time period or under other constraints. We recommend that organizations providing the download button implement such a standard to handle automated requests from individual-authorized services.

On human-accessible download pages, deploy an effective means to determine whether a human is requesting the download. Although there is no perfect device to determine whether a human is accessing the contents of a URL, CAPTCHAs (challenge-response tests designed to be solvable by a human but not by a computer) are commonly deployed and considered effective. Whether or not a machine-accessible URL is available, we recommend that human-accessible URLs offering downloads use a CAPTCHA or another effective means of ascertaining that a human is indeed requesting the download ...

This capability is currently exhibited by services such as OAuth.

Here is how the Work Group spelled out its rationale:

The practices described here are intended to anticipate the environment if a personal health information download capability becomes ubiquitous, or even if it is offered by a few organizations that maintain tens of millions of records. Assuming that health data is made available for secure-access download, and that it is structured in ways that make it more amenable to automated harvesters, it will be important to do the following:

- Accurately establish the identity of individuals and issue appropriate tokens, with guidance from appropriate federal agencies for the context of online access by individuals to copies of their personal health information.
- Create a separate pathway for the automated harvesting of personal health information downloads. The best way to do this is through the implementation of a standard to separate download requests by humans from download requests from a known partner that is authorized by the individual. Note that the point of the CAPTCHA is not security but differentiation. The CAPTCHA is not to prevent unauthorized parties from accessing the data (the goal of security), but to encourage individual-authorized parties to avoid undesirable practices such as recording or reusing the passwords or tokens that the individual uses at various sites offering the download capability.
- Track and immutably log source information from requesting parties (such as IP addresses) as a means of monitoring and/or investigating potential fraud.
- Provide key time, date, and source information to aid the usefulness of the downloaded information for all authorized downstream users.

Although it is true that nothing can stop individuals from sharing their user names and passwords with various organizations, the Markle Work Group on Consumer Engagement expressed a policy that discourages this practice and recommended a practical standard by which it can be avoided. From a policy perspective, it is important that individuals not be forced to share their user names and passwords across entities as the only means by which they may authorize the sharing of their information.