May 7, 2012

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 pertaining to the two notices of proposed rulemaking recently issued on the incentive program for the Meaningful Use of electronic health record technology.

In the enclosed letter, advanced by a diverse array of health leaders, we offer our comments and recommendations regarding strategic opportunities to support health goals and quality measures, patient engagement, care coordination, and privacy and security.

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:

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Markle Connecting for Health Collaborative Comments on the Proposed Rulemaking for Stage 2 Meaningful Use

These comments were jointly developed with a broad array of collaborators of the Markle Connecting for Health Steering Group.

The release of two notices of proposed rulemaking (NPRMs) on the incentive program for the Meaningful Use of electronic health record (EHR) technology marks a major, positive step forward in the nation's efforts to improve health and health care by putting modern information technology (IT) tools at the fingertips of medical professionals and consumers alike. [1]

Markle Connecting for Health, a public-private collaborative, applauds the U.S. Department of Health and Human Services (HHS) for proposing an important set of regulations to improve health outcomes, increase the cost-effectiveness of care, encourage innovation, and protect privacy. In particular, the proposed rules:

- State that the goal of health IT is to improve health quality and efficiency.

- Establish metrics for health improvement rather than focusing merely on acquiring technology.

- Promote patient engagement as a key aspect of Meaningful Use.

- Make the ability for patients to securely view online, download and transmit their health information core to Meaningful Use and a requirement of the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program (Certified Health IT).

- Support the National Quality Strategy, make progress aligning quality improvement efforts, and mitigate the need for duplicative reporting.

- Encourage the extension of communication and feedback cycles among individuals and care teams beyond episodic, office-based encounters.

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[1] Medicare and Medicaid Programs: Electronic Health Record Incentive Program-Stage 2 Notice of Proposed Rulemaking, 77 Federal Register 45 (March 7, 2012), pp. 13698-13829. http://www.regulations.gov/#!documentDetail;D=CMS-2012-0022-0001.

Health Information Technology: Standards, Implementation Specifications, and Certification Criteria: Electronic Health Record Technology, 2014 Edition Notice of Proposed Rulemaking, 77 Federal Register 45 (March 7, 2012), pp. 13832-13885. http://www.regulations.gov/#!documentDetail;D=HHS-OS-2012-0004-0001.

- Encourage progress on interoperability and care coordination.

While the proposed rules take substantial steps in the right direction, our comments offer specific suggestions for clarifying the regulations and ironing out workable implementation details to achieve the urgent priorities of this effort: improving health and efficient use of health care resources, protecting privacy, and encouraging innovation and broad participation across many health care settings.

In this set of collaborative comments, advanced by a diverse array of health leaders, we offer our comments and recommendations on the NPRMs in four distinct categories:

  I.   Health goals and quality measures
  II. Patient engagement
  III. Care coordination
  IV. Privacy and security

I.   Health Goals and Quality Measures

Consistent with our past collaborative comments,[2] the NPRMs make great strides in reaching new heights in quality improvement by working to align Meaningful Use with the National Strategy for Quality Improvement in Health Care (National Quality Strategy) and a host of other federal quality improvement efforts. The Meaningful Use priorities clearly embrace a culture where patients and health care professionals actively engage in quality improvement and understand the circumstances under which information is shared, as well as trust that risks will be minimized through transparent policies and practices. We encourage HHS to build on this progress as we move closer to improving outcomes through Meaningful Use.

Specifically, we recommend that HHS make health goals clear and explicit, leveraging the health goals of the National Quality Strategy. In addition, we call on HHS to take additional steps towards aligning Meaningful Use and other quality reporting initiatives, by aligning goals and priorities, sharing similar quality reporting requirements, and prioritizing meaningful quality measures.

Seamlessly integrating quality reporting into the provision of care rests on our ability to automate the capture and reporting of quality measures, and we recommend that HHS make this a priority. Going forward, we encourage HHS to outline a clear vision for quality improvement to provide a signal to the community in preparation for improved outcomes in Stage 3.

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[2] "Markle Connecting for Health Collaborative Comments on Stage 2 Meaningful Use," Markle Connecting for Health. Last modified July 20, 2011. http://www.markle.org/publications/1656-markle-connecting-health-collaborative-comments-stage-2-meaningful-use (accessed on April 16, 2012).

Make Health Goals Clear and Explicit

Recommendation: Increase alignment with the goals of the National Quality Strategy

As a starting point, HHS may articulate goals from the National Quality Strategy[3] when communicating the final rule on Meaningful Use, such as:

- Reduce preventable hospital admissions and readmissions.

- Improve patient, family, and caregiver experience of care related to quality, safety, and access across settings.

- Improve the quality of care transitions and communications across care settings.

- Promote cardiovascular health through community interventions that result in improvement of social, economic, and environmental factors.

- Promote healthy living and well-being through community interventions that result in improvement of social, economic, and environmental factors.

Future updates to the National Quality Strategy and corresponding stages of Meaningful Use should build on this foundation and include health goals that are clear and explicit, such as those reflected in the Achievable Vision for 2015, proposed to the Health IT Policy Committee.[4] For example:

- 50% fewer preventable medication errors

- The racial/ethnic gap in diabetes control halved

- Preventable hospitalizations and re-admissions cut by 50%

Discussion:

As we addressed in previous collaborative comments, clear and explicit health goals are key to the success of Meaningful Use. In the absence of clear and explicit 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 Quality Strategy was an important step toward fully addressing this critical issue.

Aligning the Meaningful Use program requirements with the goals of the National Quality Strategy is critical for the program's success, but it is also imperative that the health goals are clearly articulated in program requirements. Articulating the health goals will provide a north star for providers, patients,

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[3] "2012 Annual Progress Report to Congress: National Strategy for Quality Improvement in Health Care," U.S. Department of Health and Human Services. http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf (accessed May 4, 2012).

[4] See "Meaningful Use Workgroup Presentation" to the HIT Policy Committee meeting (June 16, 2009): http://healthit.hhs.gov/portal/server.pt/document/873878/application_vnd_ms-powerpoint (accessed on April 16, 2012).

policymakers, technologists, and the broader community, as well as benefit the coordination and planning of quality improvement efforts and encourage innovation. The application of explicit health goals promises to be a helpful tool in developing future requirements and measuring the program's success. As HHS works to update the National Quality Strategy, it is imperative that the opportunity is taken to refine the health goals to be more clear and explicit and to articulate these goals in the Meaningful Use program.

Align quality improvement efforts

Recommendation: Take necessary steps to align quality reporting requirements and health objectives across Meaningful Use and other quality improvement efforts, such as the Physician Quality Reporting System's (PQRS) EHR Reporting Option, the 2012 Medicare EHR Incentive Program Pilot for EHs and CAHs, and the Medicare Shared Savings Program.

To help ensure effective alignment:

- Consistently support the goals and priorities of the National Quality Strategy and Meaningful Use.

    o Use the goals of the National Quality Strategy to guide the priorities of quality improvement efforts and articulate these goals clearly to the public.

    o Apply the Meaningful Use priorities of improving quality, safety, efficiency, and reducing health disparities; engaging patients and their families in their care; improving care coordination; improving population and public health; and ensuring adequate privacy and security protections for personal health information across quality improvement efforts.

- Adopt consistent and comparable quality reporting requirements where possible.

    o Quality measures should be comparable across programs, reinforcing overall goals and priorities.

    o Quality reporting mechanisms should be consistent and streamlined to support the seamless integration of information gathering and reporting activities into the provision of care and not place onerous time and administrative burdens on providers and their staffs.

    o Summary statistics should be submitted to the Center for Medicare and Medicaid Services (CMS) for each Meaningful Use quality measure, defined as simple numerators/denominators reflecting the experience of the provider's entire patient population.

As a starting point, we encourage that the above recommendations be addressed in the proposed Meaningful Use quality reporting options (the PQRS EHR Reporting Option and the 2012 Medicare EHR Incentive Program Pilot for EPs, EHs, and CAHs). Reporting options that lack the objectives and

requirements of Meaningful Use would risk shortchanging the overall program and the potential for improving health and health care.

Discussion:
Meaningful Use can help accelerate culture and transformations as other quality improvement efforts are aligned with the program's objectives and requirements. We applaud HHS for taking initial steps to align quality improvement efforts with Meaningful Use, as the National Quality Strategy serves as a foundation for overall efforts and the priorities and various quality measures of Meaningful Use are reflected in other efforts. A more coordinated approach to improving health and health care can be achieved through greater alignment of the quality measures, reporting mechanisms, and the application of summary statistics of Meaningful Use.

A natural starting point toward greater alignment is with the proposed quality reporting options for Stage 2. This approach has the potential to support flexibility and coordination within the program. While offering quality reporting options will aid providers' workflow, there are inconsistencies in program requirements. For example, the PQRS EHR Reporting Option for eligible professionals (EPs) applies only three quality measures, rather than the proposed 12 measures for Stage 2 Meaningful Use. In addition, the PQRS program and the 2012 Medicare EHR Incentive Program Pilot for eligible hospitals (EHs) and critical access hospitals (CAHs) require the submission of patient-level data rather than summary data as applied in Meaningful Use.

Prioritize "measures that matter" for health improvement

Recommendation: Prioritize "measures that matter" for health improvement—measures that demonstrate improved health outcomes and greater cost-effectiveness

Discussion:
Prioritize Meaningful Use measures by their potential impact on clear health objectives. The prioritized measures should be outcome-oriented, requiring the progressive use of health information for reporting.

It is critical to focus on outcomes that are meaningful to providers and patients and indicate measurable health improvement and efficiency gains. Selected measures should allow all providers/specialties to participate—whether through measures that are unique to particular specialties or are cross-cutting and could reasonably apply to a wider range of providers (e.g., those for whom more-targeted measures are not feasible in the near term). A focus on patient engagement, patient safety and care coordination, among others, could provide great value for all participants.

Automated Capture and Reporting

Recommendation: Support automated quality measure capture and reporting that can be easily implemented in the short-term. HHS must make it a priority to support the development and identification of measures that can be captured and reported by automated means as a byproduct of use of Certified Health IT. The selection of e-measures should rest on whether the specifications are valid, reliable, and have been tested across a variety of settings in the field.

Discussion:

As we work towards better care through Meaningful Use, it is essential that automated reporting be a priority within the program. Developing, identifying, and testing measures across a variety of settings will help ensure the use of appropriate measures to support program goals. Calculation of measures and transmission capabilities should be enabled by electronic systems, requiring minimal additional work for providers, and allowing them to report summary statistics as a byproduct of using Certified Health IT, whether using a complete EHR or compilation of modules. In addition, it will be critical to ensure that the measures accurately support the clinical intent they were developed to address, especially when being derived from paper-based measures. Quality improvement will depend on providers' ability to assess Meaningful Use measures and results for their patients on a regular basis and use this information to improve care processes and consumer engagement, so they don't need to rely on costly intermediaries.

Communicate a vision for quality improvement

Recommendation: Communicate a vision for quality improvement. As we prepare for achieving advance clinical processes in Stage 2 Meaningful Use and set our sights on improving outcomes in Stage 3, CMS should take the opportunity to provide a signal to the community on next steps for quality improvement. We encourage CMS to outline how the following issues will be addressed within Meaningful Use:

- Applying flexible quality reporting platforms: Ongoing updates to quality measures will require the application of mechanisms to enable providers to calculate new and updated measures without manual entry. Moving forward, these capabilities should be seamlessly integrated into the provision of care and support the automated reporting of summary data.

- Improving data quality and integrity over time: Data quality and integrity should be addressed by providers and CMS and should not require a third party to check every reported result against the underlying data. Strategies to handle data quality and accuracy include:

  o Require that qualified systems have flexible mechanisms to calculate and test Meaningful Use performance on a routine basis, before formal reporting occurs.

  o Offer resources to help vendors and other participants review and test systems data workflows, measure definitions, and mechanisms to recreate source data for reported results as part of the certification process.

- o Evaluate the benefit of periodic audits for data accuracy (via CMS, individual states, etc.) and field testing of data quality and reporting interfaces.

- Leveraging data for quality improvement: CMS should feed information in a timely way back to providers, including improvement since the last reporting period, and performance on local and national benchmarks. CMS should track provider-specific performance across various quality improvement efforts.

Discussion:
According to CMS, the conceptual approach to Meaningful Use includes data capture and sharing in Stage 1, advance clinical processes in Stage 2, and improved outcomes in Stage 3.[5] While the NPRMs outline progressive requirements for Stage 2, it should also include a clear signal to the community on next steps for quality improvement.

A starting point for a vision rests on ensuring data quality and integrity. The effectiveness of Meaningful Use in quality improvement efforts will only be as good as the data within it. In addition, a robust quality improvement effort depends on flexible reporting platforms that can be integrated seamlessly into the provision of care. Providing performance and benchmark information back to providers and tracking provider performance will bring quality improvement efforts full circle within the program.

Systems must be able to support providers' needs for information to meet Meaningful Use goals. The underlying objective is to put useful information into the hands of providers and patients to improve care and not to create a compliance exercise.

II.   Patient Engagement

Public support and participation will be central to the nation's ability to attain Meaningful Use health objectives, such as improving care coordination, managing chronic diseases, addressing disparities, enhancing medication safety, engaging patients in their own health, and using health care resources efficiently. The proposed requirements supporting a patient's ability to access and share his or her health information through view, download, and transmit to a 3rd party provide an excellent foundation for reaching these objectives.

Providing individuals access to their own information is well-rooted in Fair Information Practice Principles (FIPPs) and a basic expectation for health IT. Convenient access to one's own personal health information serves as a building block to help people lead healthier lives and receive higher-quality, more cost-effective care.

A recent Markle Survey on Health in a Networked Life found that roughly two-thirds of the American public and doctors support an individual's ability to view and download their personal health information

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[5] "Medicare & Medicaid EHR Incentive Program," Centers for Medicare & Medicaid Services. Slide 4, Last modified 2010: https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads//MU_Stage1_ReqOverview.pdf (accessed on April 16, 2012).

online. [6] Another recent survey by the National Partnership for Women and Families found that respondents who say their doctors have EHR systems and online access to their health information see greater value in EHRs for both their providers and themselves. For example, online users were more likely than the total population of EHR respondents to say their EHR system helps them personally in sharing information with all of their health care providers (72% with online access; 63% without).[7]

The experiences at the U.S. Department of Veterans Affairs (VA), Medicare, and TRICARE with their blue button also demonstrate that even a basic download 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, and connecting with peers who have similar health conditions). Enabling patients to securely access and share their health information online is an important initial step for patients to engage with their care and, literally, to take their information with them wherever they need to go.

As articulated in previous collaborative comments, the rationale for supporting robust patient engagement measures through Meaningful Use, including a patient's ability to access and share his or her health information, 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 manner 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

The journey toward this vision starts by improving access to information and bolstering communication with patients. The recommendations below set forth several areas that HHS can address and support through Meaningful Use to help foster this vision.

Patient Engagement as a Key Public Benefit of Meaningful Use

Recommendation: Continue to support patient engagement as a key public benefit of the Meaningful Use program, including the ability of individuals to view,

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[6] Markle Health in a Networked Life, "Public and Doctors Alike Support Allowing Individuals to Download Their Own Health Information," *Markle Foundation*. Last modified January 31, 2011. http://www.markle.org/publications/1441-public-and-doctors-alike-support-allowing-individuals-download-their-own-health-in (accessed on February 22, 2012).

[7] "Making IT Meaningful: How Consumers Value and Trust Health IT," *National Partnership for Women and Families*. Last modified February 2012. http://www.nationalpartnership.org/site/DocServer/HIT_Making_IT_Meaningful_National_Partnership_February_2.pdf?docID=9783 (accessed on April 16, 2012).

download, and transmit to a 3rd party key personal health information online as a core requirement for Stage 2. Refine this requirement over time based on experience and attestation reports to CMS.

Discussion:

We encourage HHS to continue to support patient engagement as a key public benefit of the Meaningful Use program, including the ability of individuals to view, download, and transmit to a 3rd party key personal health information online as a core requirement in Stage 2. For the last decade, Markle Connecting for Health has emphasized this capability as a critical building block for patient engagement and market innovation.

Many aspects of the proposed rules align with our past collaborative comments on patient engagement. In particular, we encourage HHS to include the following elements in the final rules:

- Supporting a patient's ability to access and share his or her health information through view, download, and transmit requirements and certification criteria

- Enabling 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

- Shifting paradigms so that information is not provided to individuals only upon request, but is delivered routinely after every visit in a manner that matches the individual's needs and wishes

- Enabling patients to access their health information as human-readable text as well as in structured, computer-readable formats

- Requiring Certified Health IT to keep an immutable and patient-accessible audit log for view, download, and transmit events

- Enabling the automated counting of view, download, and transmit to 3rd party events through Certified Health IT to prevent the need for manual counting

- Consolidating the many different requirements in Stage 1 Meaningful Use for enabling patients to access their health information into one requirement

These proposed requirements will provide a robust foundation for engaging patients in the current networked environment.

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 personal health records that clinicians play an important role in encouraging consumer adoption and utilization. It could be a lost opportunity if HHS sets only a token threshold for the number or percentage of patients who need to view, download or transmit their information online for a provider or hospital to satisfy patient engagement requirements. On the other hand, HHS might risk penalizing providers if some patient populations are less likely to make full use of these capabilities.

To address this question, we focus on the big picture. The overall objective is for HHS to encourage that the view, download, and transmit capabilities become a common service for all patients, and to use Certified 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.

Key data can be collected through attestation reports to CMS, and we encourage HHS to maintain the proposed requirement for enabling the automated counting of view, download, and transmit to 3rd party events through Certified Health IT to support this goal. HHS can also play a critical role helping providers to be proactive in encouraging and assisting their patients to view, download, or transmit their health information to a third party.

As a country, we are just starting to understand how to support health in a networked life, and Meaningful Use can be an important catalyst in this effort. However, in order to ensure an environment that adequately encourages innovation, the methods by which providers can engage patients through networked technology should remain flexible. Foundational technology capabilities must be required of certified technology to provide a level of assurance that the technology can be used to achieve Meaningful Use. However, providers should be encouraged to use the tools that allow them to most effectively provide care.

Privacy and Security for View, Download, and Transmit to 3rd Party

Recommendation: Support public confidence by requiring that baseline privacy and security functions can be supported through Certified Health IT for view, download, and transmit to a 3rd party capabilities as well as secure messaging. Also offer support through Regional Extension Centers to help providers employ strong privacy and security practices in this context.

Discussion:
Through months of public-private collaboration, more than 50 organizations have endorsed a set of Markle Connecting for Health recommended practices for implementation of a secure view and 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[8] and provide general direction for the aspects of the proposed rules that enable patients to directly access and share their health information. We contextualize these policies for Stage 2 Meaningful Use in the text below.

Secure online access as a requirement: The ability to view, download, and transmit personal health information to a 3rd party 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

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[8]   Markle Connecting for Health Work Group on Consumer Engagement, "Policies in Practice: The Download Capability," Markle Foundation. Last modified August 31, 2010. http://www.markle.org/publications/1198-policies-practice-download-capability (accessed on April 16, 2012).

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.

We encourage HHS to clarify that the existing certification criterion for authentication, access control, and authorization[9] applies to both patients and healthcare professionals. The proposed criterion would require technology to "Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed."

Helping people make informed choices: Any organization offering a download capability should inform individuals about the choice to download information and confirm that the individual really wants to do it. We support the approach taken by the proposed rules to offer guidance in this area. It will be important to make this guidance easily accessible and understandable for vendors, providers, patients and their families and policymakers.

Our collaborative has endorsed a set of policies and practices on helping people make informed choices on downloading their health information 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:

    o Health records can contain sensitive information.

    o If you download sensitive information to a shared or unsecured computer or device, others might see it.

    o You are responsible for protecting the information that you download, and for deciding with whom to share it.

    o Are you sure you want to download a copy of your personal health information to the computer or device you are using?

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[9] §170.314(d)(1)

Audit trail: Patient portals should include an immutable audit log to keep a record of view, download, and transmit events as a fundamental capability of Certified Health IT. All imports and exports of information should be tracked in a running log that the individual is able to view securely online. The proposed rules establish the certification criterion necessary to support this important functionality, and we encourage HHS to include this criterion in the final rule.

III. Care Coordination

The proposed rules encourage significant progress on interoperability and the use of secure electronic provider-to-provider transactions of summary of care records. This focus has the potential to foster robust information sharing and improve care coordination.

Past collaborative comments encouraged HHS to endorse a simple specification for a set of open standards necessary for secure transport of data, and we are encouraged by the progress that has been made possible in this area through the Direct Project. The proposed certification criteria to support transport specifications developed under the Direct Project can provide an important foundation for the Meaningful Use program.

Flexibility for Care Coordination Requirements

Recommendation:	Support flexibility for participating doctors and hospitals to deliver information that satisfies Meaningful Use requirements for coordination of care. The Meaningful Use Program should support information sharing, without penalizing the information sender for any lack of technology, system choice, or capability on the recipient end. Complementary efforts are also needed to support robust information sharing across different vendor systems and health care organizations.

Discussion:
While we are supportive of the proposed requirement to share a summary of care record for more than 65% of transitions of care and referrals, we have concerns about aspects of the corresponding requirement for 10% of these summary of care records to be sent electronically to recipients with no organizational affiliation that are also using a different Certified Health IT vendor.

We understand the intent of the requirement to share information with providers using different EHR systems; however, the unintended consequences seem too high to incorporate into requirements for providers. Clinical need should guide referral patterns, not technological capabilities or vendor selection. The rules should not penalize the sender for any lack of technology, system choice or capability on the recipient end. The burden of simply determining the vendor(s) an information recipient uses would be significant; tracking and reporting this information to CMS would be even more difficult. This requirement could also incent providers to refer patients outside of their network solely to achieve a Meaningful Use requirement, potentially comprising patient care and shifting the focus away from the high level goals of improving health and health care.

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 or

platform and use reasonable attempts to leverage such capabilities when sending information electronically. A requirement of this kind would encourage electronic communication without requiring providers to track the vendors used by other organizations.

The intent of the proposed requirement to send summary of care records to recipients using a different Certified Health IT vendor is understandable and there remains a critical need to enable information sharing across these different systems. The health ecosystem is defined by fragmentation and improving care coordination requires information sharing across different care environments. In order to further this goal, ONC should continue to focus on mechanisms for supporting the use of standards that enable information sharing across different environments. Certifying that all EHRs are compliant with Direct protocols, for example, will offer the baseline capability needed to create an on-ramp to interoperability. Certifying bodies may also be in a position to monitor products in the market and evaluate whether a certified product enables its users to share information with clinicians that are using certified technology from different vendors.

IV. Privacy and Security

As HHS refines all areas of the Meaningful Use program, it must be mindful of public and provider expectations for privacy. The starting place is a broad framework of privacy principles based on FIPPs and embraced by ONC and other federal agencies.[10]

The Markle Survey on Health in a Networked Life found that more than 80% 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, informed choices, and ability to request corrections. In past Markle surveys, the public support for these privacy-protective practices consistently has remained very high.[11]

Only when taken as a whole do these principles and related practices constitute a trust framework. Although the proposed rules offer important privacy and security protections, they are only one piece of this 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. Certification by itself is not a proxy for the enforcement of a regulatory framework and it cannot be a substitute for the complete framework of privacy and security protections necessary for trust among users of Certified Health IT. In other words, the existence of privacy and security capabilities in technology does

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[10] "Nationwide Privacy and Security Framework For Electronic Exchange of Individually Identifiable Health Information," Department of Health & Human Services. Last modified December 15, 2008. http://www.healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_10731_848088_0_0_18/NationwidePS_Framework-5.pdf (accessed on April 16, 2012).

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 (accessed on April 16, 2012).

[11] *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 (accessed on April 16, 2012).

not mean that privacy and security protections will be correctly implemented, or that a user's policies and practices will use and further support these capabilities. HHS must be mindful of this interplay moving forward.

The proposed rules make strides in the right direction. Consistent with our past comments,[12] HHS addressed the Privacy and Security Tiger Team's recommendations to bolster the privacy and security of personal health information by 'shining a spotlight' on encryption of data at rest. We are supportive of the proposed rule's emphasis on the need to address encryption of data at rest as a part of the privacy and security risk assessment.

The recent Program Information Notice requiring recipients of the State Health Information Exchange Cooperative Agreements to submit policies that support a Privacy and Security Framework based on FIPPs also marks progress.[13]

However, HHS must continue to develop and adopt a comprehensive set of protections in all its health IT work and we urge HHS to advance a FIPPs-based framework through the adoption of a policy and security framework that builds on (and fills gaps in) current law. Similarly, HHS can play a key role supporting providers in their efforts to implement privacy and security capabilities by providing guidance and offering resources through existing programs, such as the Regional Extension Centers.

The recommendations below offer additional recommendations for supporting robust privacy and security safeguards through the Meaningful Use program and related activity.

Accounting of Disclosures Requirements

Recommendation: Establish concrete processes to help ensure the next stage of the ONC Health IT Certification Program enables users to support HIPAA and HITECH's Accounting of Disclosures requirements.

- Address the policy and technology questions needed to require accounting of disclosures functionality for the next stage of the ONC Health IT Certification Program.

- Establish a process to develop and/or recognize the technical specifications needed for accounting of disclosures. The process should focus on standards and/or specifications that:

    - Are lightweight and can be implemented across diverse care settings.

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[12] "Markle Connecting for Health Collaborative Comments on Stage 2 Meaningful Use," Markle Connecting for Health. Last modified July 20, 2011. http://www.markle.org/publications/1656-markle-connecting-health-collaborative-comments-stage-2-meaningful-use (accessed on April 16, 2012).

[13] "Program Information Notice: Privacy and Security Framework Requirements and Guidance for the State Health Information Exchange Cooperative Agreement Program," National Coordinator for Health Information Technology, March 22, 2012. http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_0_5545_1488_17157_43/http%3B/wci-pubcontent/publish/onc/public_communities/_content/files/onc_hie_pin_003_final.pdf (Accessed May 4, 2012).

- Can be populated automatically as a byproduct of care processes, without the need for manual entry.

- Can be generated in a way that patients can use and understand.

- Support any final regulations promulgated by the Office of Civil Rights (OCR) to implement the requirements of the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Discussion:

The HITECH Act[14] expanded the Accounting of Disclosure provision under the Health Insurance Portability and Accountability Act (HIPAA) to require covered entities and business associates to account for disclosures of protected health information used to carry out treatment, payment, and health care operations through an EHR. To implement the HITECH Act requirement, OCR published a notice of proposed rulemaking in May of 2011[15] that proposed creating an individual's right to receive an access report indicating who has accessed any electronic protected health information in a designated record set; however, a final rule has not been released.

The HITECH Act provisions are intended to strengthen privacy and security practices by offering patients transparency and accountability about the uses and disclosures of their personal health information held in EHRs. However, the technology needed to support these capabilities is not yet mature and commonplace.

We recognize that it is unrealistic to expect the progress needed to require an accounting of disclosures certification criterion for the 2014 program, but we urge HHS to take proactive steps to address the policy and technology questions needed to require accounting of disclosures functionality in the next certification program. Addressing these questions proactively will help in developing a comprehensive set of policy and technology protections to support transparency and accountability and reduce the likelihood of inadvertent or intentional misuses of information.[16]

Developing the right specifications will require collaboration across both policy and technology domains. In making decisions about how to meet patients' needs for information about the disclosures of their health information, HHS should focus on information that is likely to be most relevant to patients, as well

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[14] Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 115 (February 17, 2009), codified at 42 U.S.C. §§300jj et seq.; §§17901 et seq. http://www.gpo.gov/fdsys/pkg/BILLS-111hr1enr/pdf/BILLS-111hr1enr.pdf.

[15] "HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act." Federal Register 76 (May 31, 2011). https://www.federalregister.gov/articles/2011/05/31/2011-13297/hipaa-privacy-rule-accounting-of-disclosures-under-the-health-information-technology-for-economic#p-3.

[16] "HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act; Request for Information," Consumer Partnership for eHealth. Last modified May 2010. http://www.nationalpartnership.org/site/DocServer/OCR__HHS_____Accounting_of_Disclosures___CPeH___ _2010-May.pdf?docID=7664 (accessed on April 16, 2012).

as what is possible to be automatically generated today. This will pave the way for additional useful information to be automatically generated about EHR access and disclosure in the future.

Guidance on Communication with Patients over Non-Secure Channels

Recommendation: Provide formal guidance on whether and how providers can engage in communication over non-secure channels under HIPAA with patients who have either initiated communication on one of these channels or indicated that they would prefer it.

Discussion:

The second stage of Meaningful Use encourages increased communication between patients and their care team over secure channels. Secure communication offers an important tool for engaging patients while protecting privacy and security. However, anecdotal experience suggests that some patients may prefer to communicate over non-secure electronic channels (e.g., e-mail).[17] Despite this experience, the current regulatory environment creates uncertainty about whether and how providers can engage in communication over non-secure channels under HIPAA with patients who have either initiated communication in this manner or indicated that they would prefer it.

The proposed rules' emphasis on information sharing between patients and their care teams brings this issue to the fore and creates a critical opportunity for guidance. Experience from other sectors demonstrates the value of 'meeting consumers where they are' and engaging people with the tools they are already using every day. There may be value in supporting communication with patients through mechanisms such as e-mail if it can be done in a way that makes clear the privacy and security risks and respects patient preferences.

We encourage OCR to work with CMS and ONC to develop and disseminate guidance and to understand the implications for Meaningful Use. When developing this guidance, it will be critical to support patient preferences while also creating a foundation for secure messaging. Guidance should require that providers offer at least one secure option for messaging, but could also enable providers to respond to communication initiated by patients on a non-secure channel.

Privacy and Security Certification of Modules

Recommendation: Support minimal requirements to certify select modules against appropriate privacy and security criteria.

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[17] Joseph C. Kvedar and Sam Bierstock, "Should Physicians Use Email to Communicate With Patients?," The Wall Street Journal. Last modified January 23, 2012. http://online.wsj.com/article/SB10001424052970204124204577152860059245028.html (accessed on April 16, 2012).

Gerstle, Robert S, "E-mail Communication Between Pediatricians and Their Patients," Official Journal of the American Acadamy of Pediatrics, July 1, 2004: http://pediatrics.aappublications.org/content/114/1/317.full (accessed on April 16, 2012).

Discussion:
Under the current certification program, providers are able to use multiple modules to obtain the technological capabilities needed to achieve Meaningful Use. This flexibility allows providers to find a host of products and services that meet the needs of their patients when desirable.

Despite the potential for modules to enable significant flexibility, very few early adopters of Meaningful Use used modules to achieve the Stage 1 requirements.[18] We agree with ONC's assessment that the market for modules may have been unintentionally encumbered by the initial requirement for all modules to be certified against all privacy and security criteria under the 2011 ONC Health IT Certification Program. This requirement created a high level of burden for vendors and potentially limited the market for modules.

Under the proposed rule, these requirements for modules are lifted. Instead, every Meaningful User will be required to use a 'base EHR' that is certified against the privacy and security criteria, and is capable of offering baseline protections. While this approach may enable greater flexibility, it has the potential to create privacy and security vulnerabilities if modules are not capable of supporting the privacy and security functionality of the base EHR. ONC should evaluate the greatest risks posed by this new approach and determine if additional requirements are necessary.

ONC should also address these risks through increased education and outreach to help EPs, EHs and CAHs provide robust protections. The ONC Health IT Certification program cannot anticipate all of the future demands that will be made on technology once implemented, including how products will work together to enable users to protect and secure health information; education and outreach will be critical to address this gap.

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[18] "CMS Medicare and Medicaid EHR Incentive Program, electronic health record products used for attestation" Department of Health and Human Services. Last modified 01/24/2012: http://www.data.gov/communities/node/81/data_tools/6375 (accessed on April 16, 2012).