April 22, 2013

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: Interoperability RFI
Hubert H. Humphrey Building
Suite 729D
200 Independence Avenue, SW
Washington, DC 20201

Submitted via Federal eRulemaking Portal

RE: BILLING CODE 4150-45-P Notice for Comment, Request for Information, Advancing Interoperability and Health Information Exchange

Dear Acting Administrator Tavenner and Dr. Mostashari:

Thank you for the opportunity to comment on the Notice for Comment, Request for Information on advancing interoperability and health information exchange published in the Federal Register on March 6, 2013 (BILLING CODE 4150-45-P).

Health IT Now (HITN, www.healthitnow.org) is a diverse coalition of health care providers, patient advocates, consumers, employers and payers who support the adoption and use of health IT to lower costs while improving quality, safety, and clinical outcomes. The comments in this letter reflect those of Health IT Now, and not necessarily those of our individual members.

Many think the silver bullet to high health costs and poor healthcare quality lies in creating more incentive programs for health IT or in tweaking interoperability standards to get vocabulary or data content just right. In other industries, the key to improving quality, outcomes and costs rests in an organic (self-organizing) business case for use of technology to improve value (cost and quality) and to become more productive (output and cost). We believe that the U.S. health care system lacks a compelling business case to improve value or productivity. Many aspects of our current health care system encourage inefficiency, promote waste and facilitate concentrated and consolidated markets aided and abetted by data silos. In some instances, federal policy and taxpayer dollars subsidize this waste.

This is why we are encouraged HHS is taking a broader view of the multiple levers at the Department's disposal to change the business case for information exchange. We are encouraged that CMS and ONC have requested additional information and recommendations on potential policy and programmatic changes designed to broaden electronic health information exchange across providers and new ideas to promote interoperability. These broader approaches

are more likely than discrete incentives to promote HIT adoption and use, because they base payment for services on quality and efficiency metrics. We believe this approach will make the business case for providers to employ technology productively, which in turn will begin to address the seemingly intractable problems of cost, quality, outcomes and safety endemic in American health care.

HITN strongly supports the Department's vision of an information-rich, person-centered, high performance health system where, "…every health care provider has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes." What follows are our thoughts on initiatives that we believe will be most impactful to promoting interoperability and information exchange.

I. Care Coordination and Interoperability

Care Coordination Models

HITN believes that Meaningful Use (MU) program standards are insufficient to successfully support care coordination models, especially those being implemented as part of the Affordable Care Act. These include medical homes, Accountable Care Organizations, hospital readmission prevention programs and others that hold vast potential to lower costs and improve health outcomes. There is also a timing disconnect between Meaningful Use standards, whose more robust information exchange and query policies are only now being contemplated for 2016, and the technology needs of care coordination models that are operational today.

HITN is in the process of documenting the gap in current MU standards with the technology needs of current care coordination needs. For example, an information sharing platform that allows providers to view clinical and cost history in near real time is a core need of any program that involves multiple providers who coordinate care for a patient. Such an information tool is not contemplated by current MU policy.

To address this problem and to promote success in ACA's various payment and delivery models, CMS could require, via its contracting process, the following in 2014:

- Include a capability to exchange key clinical information (for example, problem and medication list, allergies, test results, etc.) as outlined in Stage 1 of Meaningful Use, but eliminated by the Stage 2 final rule.
- Adopt the HHS Health IT Policy Committee's Stage 3 recommendations for transitions of care (*SGRP 303)* that require a summary of care document must be sent for at least 65% of transitions or referrals.
- Adopt the Query, receipt of external information request, and view, download and transmit requirements also suggested by the Policy Committee for Stage 3.
- Require summary of care records be available electronically upon request, not just on a transition of care or referral.
- Replace the meaningful use of EHRs as a measure of quality in the ACO program with the much more robust measure of participation in and use of services through an HIE as a quality metric.

By adopting these changes, we believe CMS and ONC could "fill the gap" between MU standards and care coordination needs. Considering about 4 million Medicare beneficiaries will receive care from about 250 Medicare ACOs this year and millions more will receive care in a medical home or other coordinated model, doing so will help to dramatically improve interoperability and information exchange across sites of care and between different providers.

eMeasures and Coding for Care Coordination

The RFI suggests developing new e-specified measures of care coordination that encourage electronic sharing of information following transitions in care, and incorporating this information multiple federal quality programs. We believe CMS and ONC should collaborate with interested stakeholders and develop new eMeasures. These should be incorporated and aligned across federal programs such as MU, PQRS and the ACO programs. Specifically, HITN recommends:

1. Prioritizing new eMeasures based on overuse and misuse of care, with a focus on efficiency and outcomes. Most measures used in the various quality reporting programs concentrate on process and underuse. CMS should strike a balance in these programs by adopting an equal focus on efficiency measures.

2. CMS should explore additional codes to reimburse for care coordination, including via telehealth, within fee-for-service and as a part of new care models. CMS should explore tying the codes to actual use of electronic information. As part of last year's Medicare Physician Payment rule, CMS adopted two new codes for post-discharge transitional care management that includes communication and coordination with the patient and other health care providers. The codes include services that require information and technology to be maximally successful, including reviewing discharge instructions, follow up on pending diagnostic and lab results, education of patients and caregivers, referrals and scheduling issues. We support expanding CMS' coding approach to reimburse other providers for care coordination activities and by targeting payments to care in coordinated models.

3. Health IT Now supports alignment of quality reporting measures wherever possible across programs. Reporting should be required electronically to reduce administrative burden and to capture data, and information on performance should be available publicly.

Problems associated with quality measures are well understood, notably that gaps in measures, especially related to efficiency, go unfilled and good measures are left unused in Federal programs. We ask the ONC and CMS to adopt quality metrics that will help record and incent high value health care.

Meaningful Use Standards

As part of any interoperability and information exchange strategy, we suggest ONC and CMS become much more aggressive in development and/or adoption of standards for interoperability and exchange that support care coordination across CMS programs, including:

- Transport standards that account for diversity in delivering data;
- Vocabulary and data standards that uniformly promote standardization;
- Better alignment of standards and health information exchange policy to capitalize on the infrastructure supported by public and private HIEs; and
- An end to subsidies for business practices that block information.

As Health IT Now has argued elsewhere[1], interoperability and information exchange are the cornerstones to achieving care coordination, quality improvement and better patient engagement. Without the ability for patients and providers to easily locate and securely exchange health information, we believe the effectiveness of the Meaningful Use program will be limited.

II. *Low Rates of Adoption and HIE Across Settings of Care and Providers*

While there has been significant progress in adoption and use of health IT for those providers who are eligible for EHR incentive payments, we remain concerned about the low rate of adoption for providers ineligible for MU incentives, including post-acute and long term care providers, pharmacists, and mental and behavioral health providers.

As a result, we suggest using the multiple payment levers that CMS has at its disposal to expand the circle of providers who use technology to improve care and care coordination. The Department also has resources and options available to address barriers to interoperability through non-payment tools, including contracting, conditions of participation, quality standards and the Stark exception and anti-kickback safe harbors.

In the RFI, CMS and ONC outline a number of program changes that may help providers exchange health information, including:

- Require or encourage Medicare ACOs to exchange health information as part of patient engagement or coordination;

- Require CMMI applicants to demonstrate HIE in future solicitations; and

- Employing CMS Conditions of participation or coverage (CoPs) to require timely electronic exchange of health information to improve patient safety.

Address Information Blocking

[1] See Comments on Stage 1, 2 and 3; ONC's Patient Safety Action Plan and comments on PCAST report, available at www.healthitnow.org.

Some health care providers and EHR vendors have contracts that block the exchange of information between electronic health records (EHRs) if the EHR product is made by a different vendor or if the sender is not affiliated with the receiving organization. This is a business practice, not a technology or standards issue, and needlessly increases costs while creating patient safety problems. As ONC stated in a recent podcast linked and referenced here (and paraphrasing the final rule): "we will pay close attention to whether the requirements in the rule are sufficient to make vendor-to-vendor exchange attainable for providers. If there is not sufficient progress or we continue to see barriers that create data silos or 'walled gardens,' we will revisit our meaningful use approach and consider other options to achieve our policy intent". We encourage HHS to adopt policies this year to address this problem across federal health programs. We believe the best policy lever to achieve this is through the Stark exception and anti-kickback safe harbors.

Stark Exception

HITN is encouraged that CMS and the HHS Inspector General have proposed to extend and modify the Stark exception and Anti-Kickback safe harbors for donated health IT and services. Currently, the rules include a condition that "[t]he donor (or any person on the donor's behalf) […] not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems."

HHS is seeking comments on whether any modification or new conditions should be added to prevent data and referral lock-in and to encourage the free exchange of data. We share HHS' concern that even when donated software meets the interoperability requirements of the rule, policies and practices sometimes affect the true ability of electronic health record technology items and services to be used to exchange information across organizational and vendor boundaries. HITN believes HHS should seize the opportunity presented by the expiration of these rules to take additional steps beyond those required by the 2006 regulation or the final rule for Stage 2 of the Meaningful Use EHR Incentive Program to ensure that health IT systems are interoperable. As part of the rules, HITN encourages HHS to:

1. Clarify the restrictions apply to both the donor and donee.

2. Clarify that organizations that intentionally or unintentionally block information do not qualify for the exception or safe harbors.

CMS and HHS are contemplating limiting these incentives by excluding certain providers, including, possibly, long term care and post-acute care providers, from the exception and safe harbors. Arguably, the incentives created by the proposed rules are more important to these providers and less important to EPs and EHs who receive direct financial benefit from the MU program. We encourage HHS to retain a broad definition of protected donors to support interoperability and information exchange, particularly for those providers not eligible for Meaningful Use incentive payments.

Conditions of Participation

HITN believes leveraging the conditions of participation to tie clinical standards to treatment protocols, care coordination, planning, and care continuity across provider settings would be an effective, readily available strategy to support health information exchange. We believe payment incentives tied to quality reporting should transition to payment for performance, and that exchange of clinical information tied directly to coordination of care across settings should be a measure of performance.

Identifying Needs

HITN recommends that ONC and CMS work collaboratively with private stakeholders and convene an industry expert panel to identify gaps in information exchange and interoperability specifically focused on post-acute and long term care providers. We suggest this collaborative focus on the following issues:

- Identification of connectivity needs, particularly the availability of broadband.
- Classification and mapping of data needs, especially on transitions of care, between ambulatory, acute and post-acute care providers, including LTC facilities. Specific focus should be made on the data sets necessary to support transitions of care and information exchange in these settings.
- Documentation of best practices in workflow and clinical processes specific to referrals from acute care settings.
- Integration of LTC and post-acute care provider data into HIEs, including copies of information exchange from and to providers of long term care or post-acute care services.
- Identification of successful business models for EHR adopters and HIE users.

CMMI Demonstration to Test Care Coordination Across Settings and Identify Interoperability Problems

We believe that CMMI should build on the Medicare demonstrations of value based payment systems by bundling payments between acute and post-acute care settings. Key metrics for cost and quality improvement should be tied to information exchange and interoperability across these settings, and specifically for care coordination purposes. Discharge planning for post-acute care should also be encouraged via payment prior to discharge. Problems identified through the demonstrations would help to isolate and identify the specific information exchange barriers across providers of care.

HITN also supports expanding care coordination models, such as the Medicaid Medical Home (Section 2703) to the Medicare program through the CMMI process.

III. Low Rates of Consumer and Patient Engagement

A key path to better health care is engaging patients in their care by facilitating electronic access to their information. CMS an ONC suggest several programs that might improve patient and consumer access to their information, including:

a. Promote the use of Blue Button and Blue Button Plus;

b. Modify CLIA to enable patients to directly access lab results; and

c. CMMI Models.

Blue Button

Blue Button has been lapped by the more robust Blue Button Plus that includes structured data that can be consumed by EHRs. The Administration should retire Blue Button in favor of the update because of the enhanced and consumer friendly functionalities.

Lab Results

Direct access to lab results is an important improvement over the current system. Lab results should also be made available to providers in a standardized, interoperable format that is consumable by EHRs.

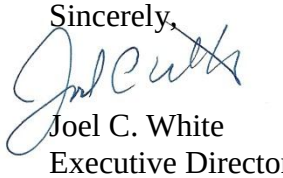
Beneficiary Engagement in ACOs

Currently, the Medicare ACO models include shared savings components that allow taxpayers and providers to share in any efficiency. Beneficiaries do not receive direct financial benefit as a result of these efficiencies. CMMI should test whether providing a rebate on premiums or reduced cost sharing to Medicare beneficiaries for participation in an ACO leads to better consumer engagement in their health, lower costs, and improved quality and outcomes. As part of this pilot, CMMI could also test the use of patient portals or personal health records to determine whether consumers respond to financial incentives to engage in their health with providers through a portal or PHR.

IV. Conclusion

We appreciate the opportunity to respond to the RFI. Attached are responses to the specific questions the Agencies asked in the request. We believe the Administration stands at a crossroads in health information technology policy. HITN's question is whether the Administration will take the lead, leverage the programs under your control, direction and stewardship, and help realize the Department's vision of an information-rich, person-centered, high performance health system where, "…every health care provider has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes." If the answer is yes, HITN and its members stand ready and eager to work with you to improve health care for all Americans.

Sincerely,



Joel C. White
Executive Director

Response to Specific Questions

2. **Which of the following programs are having the greatest impact on encouraging electronic health information exchange: Hospital readmission payment adjustments, value-based purchasing, bundled payments, ACOs, Medicare Advantage, Medicare and Medicaid EHR Incentive Programs (Meaningful Use), or medical/health homes? Are there any aspects of the design or implementation of these programs that are limiting their potential impact on encouraging care coordination and quality improvement across settings of care and among organizations that are market competitors?**

- While the Meaningful Use incentive payments are likely having the most direct impact on EHR adoption, and standards within MU are having a modest impact on information exchange, dollars associated with care coordination are likely driving more information sharing than Meaningful Use. Thus, we would say ACOs, medical homes and Meaningful Use.

- See Sections I, II and III above for a more complete response.

3. **To what extent do current CMS payment policies encourage or impede electronic information exchange across health care provider organizations, particularly those that may be market competitors? Furthermore, what CMS and ONC programs and policies would specifically address the cultural and economic disincentives for HIE that result in "data lock-in" or restricting consumer and provider choice in services and providers? Are there specific ways in which providers and vendors could be encouraged to send, receive, and integrate health information from other treating providers outside of their practice or system?**

- CMS should pay for eVisits by adopting codes within FFS as outlined in Section III above.

- The Meaningful Use download, view and transmit standards preclude data lock, and should be encouraged.

- Current CMS payment policy subsidizes the purchase and use of certified EHRs and EHR modules without requiring the technology to function according to its certification. CMS also allows business practices to block information exchange in the MU program. Changes to the Stark exception and Anti-Kickback safe harbors as outlined in Section II above would help preclude data and referral lock in. Per transaction fees for information exchange should be addressed.

- Health Information Exchanges have not gained a market toehold even with more than half a billion dollars in taxpayer funded grants. Part of the HIE challenge is a sustainability model, but part of the sustainability problem is a reliance on Direct as the transport standard. HIEs could gain prominence if clinical and claims data populated the HIEs so that the exchanges become a robust repository of valuable information.

5. **How can CMS leverage regulatory requirements for acceptable quality in the operation of health care entities, such as conditions of participation for hospitals or requirements for SNFs, NFs, and home health to support and accelerate electronic, interoperable health information exchange? How could requirements for acceptable quality that involve health information exchange be phased in overtime? How might compliance with any such regulatory requirements be best assessed and enforced, especially since specialized HIT knowledge may be required to make such assessments?**

- Align CMS Health and Safety Standards With the Safety of Health IT.

- HITN supports using the CoPs to discourage unsafe hospital environments when a hospital engages in a business practice of blocking information. Additionally, CMS might use its survey and certification tools to identify unsafe practices related to information blocking and specifically qualify such an environment as contributing to adverse events.

- HITN supports using ONC-ACBs to ensure EHR capabilities work in operational settings to the standards for which they have been certified. As we indicated in our Meaningful Use Stage 2 comment letter, we believe ONC-ACBs should decertify EHR vendor products on a case-by-case basis if the product cannot perform the function as certified due to policies or other efforts to block information exchange made by the vendor. We suggested requiring EHR developers to certify that their products do not block information exchange under EHR certification standards in 2014. We believe that EHR vendors who pursue blocking strategies through one or more products should likewise be decertified. When an exchange failure is reported to an ONC-ACB and it has been determined that it was not due to a technology issue, but rather a provider practice, those healthcare professionals or organizations should be made ineligible for the program.

- HITN believes HHS should help de-risk technology use by establishing process protections that ensure parties responsible for errors are held accountable. These changes would promote patient safety and create a learning process that quickly identifies errors and solves them before adverse events occur. By creating clarity in the legal environment related to EHRs and HIEs, adoption and use would be incentivized, further promoting use of technology that can lower medication and other errors that harm patients. For example, a 2010 Study by MIT and the University of Virginia showed "evidence that hospitals are 33 percent less likely to adopt electronic medical records if there are state laws that facilitate the use of electronic records in court."

- As part of its Patient Safety Action Plan, ONC indicated it will use the MU certification criteria to ensure that EHR technology can facilitate reporting of safety events in AHRQ's Common Formats. We believe this is an important step in ensuring we know better the types and frequency of adverse events. EHR

functionality can automate the reporting process, but it is important that reporting, as the IOM indicates, is confidential and non-punitive. We believe health IT developers need to avail themselves of the same protections under the Patient Safety and Quality Improvement Act that are afforded to healthcare providers.

8. **How can the new authorities under the Affordable Care Act for CMS test, evaluate, and scale innovative payment and service delivery models best accelerate standards- based electronic HIE across treating providers?**

In addition to the comments in Sections II and III above, we urge the Administration to use the authority under CMMI to:

- Test inclusion of pharmacies and pharmacists in providing information and treatment related to medication adherence according to current standards in MU (med reconciliation, eRx, formulary check, etc.) to determine the information exchange necessary to move from transaction based exchange to clinical based exchange and activity.

9. **What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program to maximize beneficiary access to their health information and engagement in their care?**

- Include family history in MU standards.
- Add clinical trial matching as a standard to MU.

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

- Equipment manufacturers of automated lab testing equipment should be required to produce electronic outputs using LOINC codes, rather than proprietary codes. This should include mobile devices used by individuals, including those for non-laboratory observations.

- LOINC codes should be required for results reporting for a specific set of tests defined by ONC. This "common set" was identified previously and consists of about 300 codes that account for >95% of lab results. This list should be maintained and expanded through updates that are readily available to end users.

- LOINC codes should be retained in all secondary uses of data.

- CMS should develop maps between LOINC codes and CPT codes using the data in their claims and laboratory results reporting.