March 10, 2014

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
601 New Jersey Avenue, NW
Washington, DC 20580

Re: Health Care Workshop, Project No. P131207

To Whom It May Concern:

The Health IT Now Coalition is pleased to comment on several of the issues raised in the Commission's Notice of February 24, 2014 with respect to the Health Care Workshop. 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 health outcomes. The comments in this letter reflect those of Health IT Now, and not necessarily those of our individual members.

Background

The Meaningful Use Program represents an almost $30 billion federal effort, funded with taxpayer dollars, to define and implement an interoperable nation-wide health information network that will increase the quality of healthcare in America while reducing its cost. Many times that sum are being spent by health care providers and others to implement the systems and rework clinical and administrative work to meet the changing demands of new reimbursement models.

Interoperability--the ability to electronically share information across healthcare systems, individual providers and patients – is critical to achieve this shared goal. In 2005, the RAND Corp. published an analysis estimating that EHR adoption has the potential to save $81 billion a year provided the technology is interoperable. When RAND recently released a follow-up study, analysts found their original cost-savings estimates have not come to fruition. Dr. Art Kellermann, the RAND study's senior author, stated, "The failure of health information technology to quickly deliver on its promise is not caused by its lack of potential, but rather because of the shortcomings in the design of the IT systems that are currently in place." Health IT Now would take Dr. Kellermann's statement a step further and argue that the design of the IT systems are not the problem; it is the standards in the federal incentive program that have failed

to meet RAND's caveat: We are not close to a truly interoperable IT infrastructure, and we believe three main factors contribute to the lack of interoperability:

1. Lack of standardized vocabulary and data
2. Suboptimal transport standards, and
3. "Walled gardens" or business practices that block the exchange of clinical and administrative data and that are employed primarily to capture market share and consolidate provider markets.

Information Blocking

A walled garden refers to a limited set of technology or media information provided to users with the intention of creating a monopoly or secure information system. This business practice barrier to interoperability does not just thwart the federal and private efforts to more fully share clinical information to better patient outcomes, information blocking also consolidates provider markets and may create inappropriate referral patterns that financially benefit provider and vendor colluders. In this practice, health care providers or electronic health record vendors have contracts that block information exchange between electronic health record systems.

Information blocking occurs not because different technologies or standards prevent data transfer between electronic health records, but because some electronic health record vendors or health care providers engage in this activity as a business practice. This is not a technology problem, but a competition issue.

For the past three years we have been exposing the problems associated with the business practices associated with information blocking, particularly in the federal Meaningful Use program. Patient care and outcomes are suboptimal because health care providers only see partial views of a patient's medical history. As a result, tests are duplicated, sometimes resulting in unnecessary risk to patients, including exposure to harmful imaging. Most certainly, costs to taxpayers, federal program beneficiaries, commercial premium payers and uninsured individuals are greater than otherwise, resulting in additional waste. For example, about 20 percent of diagnostic tests in Medicare are duplicative.

Unfortunately, this problem is well known to federal regulators. In 2012, then National Coordinator for Health Information Technology Dr. Farzad Mostashari stated, ""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."

Industry and provider sources indicate that the establishment and propagation of walled gardens is done to sell additional EHRs or to facilitate vertical and horizontal integration by controlling the flow of clinically relevant health information. For example, one vendor of EHRs has boasted to providers that so long as all providers implement their technology solution, systems will be interoperable and that "it doesn't work when you mix and match vendors".

More recently, some vendors have begun charging additional fees to allow providers to extract patient data from their systems, even though the marginal cost of providing that data is small.

Meanwhile, taxpayers are subsidizing business practices in an information sharing program that blocks information. Information blocking also erodes provider trust in the systems they use and leads to unsafe clinical environments because partial information on a patient leads to medical errors and adverse events.

We suggest information blocking is not acceptable. Business models built around such data silos have no place in a healthcare system experiencing the challenges currently faced in this country. These business models certainly have no place in a taxpayer funded program designed to facilitate information exchange.

How Widespread is the Problem?

It is not clear how prevalent or widespread the walled garden problem is because neither the government nor the private sector uniformly tracks this information. We have previously suggested Meaningful Use include a standard to test whether information can be exchanged post-certification between different EHR systems. The test requirement was eliminated when the final standards for Stage 2 were codified. Maintaining the test of clinical exchange would have provided CMS with a valuable tool to determine where exchange problems exist and how to correct them. Likewise, retaining the test would have allowed providers to know if their systems worked. We suggested reporting data exchange test results, even unsuccessful ones, and tracking the details of test and the reason for failure, including the existence of a walled garden. This reporting could be similar to the error reporting system used by Microsoft Office. ONC and software vendors would then have actual data to identify any effort to create data monopolies.

To the extent provider and vendor contracts facilitate monopoly rents and promote consolidation in already heavily concentrated markets, we suggest the FTC and DOJ request information from vendors participating in the program about business practices related to walled gardens in an effort to better understand the prevalence of the problem.

What Can Be Done?

Stark Exception and Anti-Kickback Safe Harbor

While we believe HHS can address this problem through the Stark and Anti-Kickback safe harbor rules by expanding the current condition to prohibit actions that limit or restrict the use, compatibility, or interoperability of the items or services with *other health information technology*. Expanding this language beyond the current Stark and Anti-Kickback rule's focus on electronic prescribing and electronic health records systems reflects the rapidly shifting nature of today's technology to go beyond the care of an individual and manage quality and cost efficiencies across populations. Second, we suggest making clear that no actor can take any actions to limit the interoperability of donated health information technology without running afoul of the federal fraud laws. To this end, HHS could establish a new condition under the exception and safe harbor that clarifies the prohibition against data "lock-in" and require that any written agreement subject to the exception and safe harbor incorporate this new condition. Unfortunately, HHS failed to address this issue in the reauthorization of the Stark exception and

Safe Harbors, and we believe it Congress should create statutory parameters around the Stark exception and AKB safe harbors.

Meaningful Use

While Meaningful Use has facilitated wide spread adoption of EHRs, it has done little or nothing to prevent information blocking. As noted above, MU may have actually facilitated the explosion of vendor systems that propagate walled gardens. HITN supports using accreditation and certification bodies to ensure EHR capabilities work in operational settings to the standards for which they have been certified. We believe EHR vendor products should be decertified 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 suggest requiring EHR developers to certify that their products do not block information exchange under EHR certification standards. 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 a certification body 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. Finally, Congress is contemplating requiring providers to attest they are not knowingly and willfully blocking information exchange as part of participation in the Meaningful Use program. HITN supports these efforts.

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. We believe doing so will create a business case for providers and vendors to proactively and voluntarily tear down barriers to information exchange.

FTC's Role

The FTC has an important role to play to help ensure information flows freely to the benefit of patients, providers in care coordination programs and competitive markets. FTC should closely monitor mergers and acquisitions that are tied to technology trends and that may result from walled garden activities. Of course, a prerequisite for oversight is collection of data to facilitate knowledge of where problems exist and where corrective action may be appropriate. Wherever uncompetitive practices emerge, we encourage the FTC to act swiftly to expose these practices, particularly where taxpayer dollars are at stake. We also encourage FTC to provide guidance to vendors to providers and vendors regarding which practices are uncompetitive and corrective actions that may be taken to ensure adherence to both the letter and spirit of information exchange programs.

There are other issues that would help break down barriers to information blocking. Expanding the role of telemedicine will create both demand and supply side pressure for more robust information flows. One barrier to telemedicine is the requirement that providers obtain

multiple licenses when serving patients across state lines. This archaic requirement mocks our modern world. The Internet is not bound by state lines, so neither should the proper medical licensing needed to assist patients in other states.

Congress established a framework for Department of Defense doctors and patients in 2011. It should do the same for our seniors and the disabled by establishing a sensible, clearly outlined framework for medical licensing between states. FTC's role in monitoring licensure issues is an important opportunity to make recommendations on how states might more effectively collaborate in both licensure requirements and in how disparate definitions of telemedicine inhibit the delivery of services remotely. Expanding telemedicine by reducing cross-state barriers will require exchange of information to effectively treat patients. It remains that if information is blocked, providers cannot practice telemedicine optimally. Because most provider markets are highly concentrated, telemedicine offers new competitive venues in markets previously untouched by competitive forces. We stand ready to assist the FTC in identifying barriers and pursuing solutions to expand provider markets and competition via telemedicine.

Conclusion

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 within your purview, direction and stewardship, and help realize the 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