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

Dear Mr. Posnack:

On behalf of the Society for Participatory Medicine, I am writing to provide our reactions to the *Report to the President Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward*, submitted by the President's Council of Advisors on Science and Technology (PCAST) in December 2010, in response to the December 10, 2010 Federal Register Request for Information calling for comments on the PCAST Report.

The Society for Participatory Medicine has individual and institutional members nationwide comprising patients, non-professional caregivers, and clinicians. It was founded to study and promote participatory medicine, which is centered around networked patients shifting from being mere passengers to responsible drivers of their health, and providers who encourage and value them as full partners. For further background on the Society and its tenets, we invite you to peruse the Society's website (<http://participatorymedicine.org>), its online journal, *The Journal of Participatory Medicine* (<http://jopm.org>) and its blog, *e-patients.net* (<http://e-patients.net>).

We applaud PCAST's goal of developing a harmonized structure for the national exchange of health information, and we are pleased to offer a series of specific recommendations which we believe are critical to ensure that the information may flow as freely as needed, and to ensure that all patients have the opportunity for meaningful input to the design of this new system, for access to their health data, and for input into the ways in which data that pertains to them is used.

As empowered, engaged patients we want clinical aggregation of our health care data to be done with us, not to us. The best way to do that is to give us the opportunity to aggregate our own health data first. Specifically, the Society's position is that each and every patient must have full rights to his or her health information, as peers on

any health information network. We recognize that this goal may not be immediately achievable in its entirety, but elements of this goal may be achieved over time. (These elements are set forth below in order of difficulty, beginning with the easiest to achieve.) In the long run, each patient should have the right, and the easily exercised ability, to

1. Access all of their own health data. (The right to receive data)
2. Share information in the record with other individuals or organizations, privately or publicly, as the patient sees fit. (The right to send freely)
3. Aggregate data in a meaningful way from multiple sources (e.g., multiple physicians, clinical labs, imaging centers), before anyone else does, or at least as soon as anyone else does. (The right to aggregate)
4. Flag errors and add comments, and have comments acknowledged even if not “accepted”, in an automated and trackable fashion. (The right to correct data)

The Society is technology agnostic. For purposes of this discussion, our key comment, and our goal for the national HIT infrastructure, is that **every patient must be a full peer on the health information network**. Based on the technology that is currently available and in development, this goal is achievable **now**. We do not see PCAST as embracing this goal in its report, and we believe that failure to do so represents at best a lost opportunity, and at worst a trampling of patients’ rights. The vision of the future as articulated by PCAST retains a view of the patient as the subject of care, not as a participant in his or her own care. While there is certainly a place for medical experts and expert systems, the central role of the patient in directing his or her care, in shared medical decision making, must be formalized in our national health information exchange strategy.

We offer some technology-specific comments only because we believe that some technologies are more likely to lead to the realization of our goals sooner, more effectively and efficiently than others. These goals, however, are independent of, and primary to, any particular technology.

We are very concerned by PCAST’s exclusive emphasis on a new XML standard, just as we are by the legacy systems that focus on data access and interchange through the IHE. XML is a powerful standard, which is capable of representing any given set of information in countless different ways. A national technology strategy that centrally relies on a command-and-control approach to having all users everywhere implementing XML-based standards identically is a non-starter. IHE has taken years of consensus building, yet adoption is limited at best. IHE is still years away from consistent broad-based adoption. It is almost entirely moot to discuss the tagged XML PCAST model as an improvement over IHE. Like IHE, a PCAST XML interchange strategy will take years or decades to build strong adoption. We need the power and intelligence of full semantic interoperability using XML as a basis, but we should not simply wait for it to happen.

Tools such as those under development through the Direct Project may allow patients to assume their role as full peers on the network sooner rather than later. The Direct Project represents one alternative approach to solving this problem. It is currently in beta testing at multiple sites, and will reportedly be ready for broader deployment within the next six to twelve months. “The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send encrypted health information directly to known, trusted recipients over the Internet.” (See <http://directproject.org>; accessed January 13, 2011.) The Direct Project currently aims to be compatible with IHE XML standards, and can reportedly support PCAST-inspired XML standards as well. The

Society appreciates the design of approaches like the Direct Project, which can enable patients to participate as full peers on the network, unlike IHE and the PCAST models.

A rich XML-based 'smart' HIE architecture, like IHE or something based on the PCAST recommendations, can and perhaps should be developed and rolled out over time, but there is a crying need to address the lack of patient access and patient parity with respect to health information as soon as possible.

Rolling out an alternative or interim system now, instead of waiting for implementation of IHE or the PCAST XML standard, will effectively put patient data in the hands of every patient now, rather than years or decades from now. In a similar vein, we applaud the VA's Blue Button Project, which has taken the first step of giving every VA patient access to his or her patient data, now, rather than something more polished later.

How will patients use this data? While we at the Society have many ideas about what we would like to try, no one really knows how engaged patients will innovate to improve their own care, once they have access to improved data. But that information -- what patients want to do with their own data -- is critical to the long-term success of any health information exchange effort.

To the degree that a national strategy chooses to invest in complex XML-based health information exchanges like PCAST-XML or IHE, funding should be provided to create freely accessible provider portal software. This provider portal software should be specifically designed to give patients direct access to their data encoded in their choice of simple formats as well as advanced XML formats. The portal should enable patients to send their data to individuals, organizations and HIE services that they trust as well as allow patients to download the data directly, so that they can do whatever they want with it. It is not enough to prevent the data silos that have dominated Health IT for so many years. These silos should be opened to the patient first and health care providers should be asked to use the same portals as patients with careful, evidence-based scrutiny of special privileges for role-based access.

An aspirational goal for health information exchange should be to make it more broadly bi-directional. To the extent that provider portals become able to accept incoming messages in human-readable, XML-based and innovative formats, patient understanding and access to what is being said about them will be critical to building the trust we all depend on.

Again, **empowered, engaged patients want the aggregation of their health data to be done with them, not to them.** It is not possible for anyone to truly understand what might be possible with fully integrated health records. By giving patients access to the privilege of aggregation first, they will be able to inform the information exchange process as a whole. They will know just what kind of privacy privileges they want. By allowing patients into the big tent early on, the feedback to be garnered from patients will improve the next steps of the process – data standardization and data authentication – by demonstrating the ways in which patients want to access, modify, react to and share the data in their health records.

Ultimately, patients need to have a better window into the privacy and security of their health information – beyond the protections afforded under HIPAA – so as to be able to understand how their data is being shared and used for “health care operations” and ensure that it is being shared, used and aggregated only in a manner that respects the limits imposed by law and by patient agreement.

We suggest that health information exchange should learn to navigate health information with and through patients, rather than presume to navigate around them.

We are available to discuss these recommendations with you and your staff.

Sincerely,



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