

August 29, 2011

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

Dear Madam Secretary:

Re: NCVHS Recommendations to Achieve the Goals of the PCAST Report on Health Information Technology

The National Committee on Vital and Health Statistics (NCVHS) is the statutory public advisory body on health data, statistics, and national health information policy to the Department of Health and Human Services (HHS).

The December 2010 “Report to the President, Realizing the Full Potential of Health Information Technology to Improve Healthcare For Americans: The Path Forward” by the President’s Council of Advisors on Science and Technology“(PCAST Report) presents a bold vision for an interoperable health information system for our nation. The NCVHS Executive Subcommittee and each of its four Subcommittees – Quality; Standards; Privacy, Confidentiality, & Security; and Population Health – reviewed the report and found alignment between the overall vision of the PCAST Report and concepts put forward by NCVHS in prior letters and recommendations. However, NCVHS believes that additional steps will be necessary to realize the overall PCAST vision.

NCVHS supports the vision of a nationwide interoperable health information system presented in the PCAST Report and applauds PCAST support for concepts that have been priorities for NCVHS as outlined below:

- Improving clinical care efficiency and decision making through an effective health IT infrastructure;
- Enabling universal data exchange, thereby fostering “network effects” that increase the utility of information both for individual patients and in aggregate;
- Structuring the information in Electronic Health Records (EHRs) for real-time re-use, e.g., public health, comparative effectiveness research, treatment quality assessment, adverse event detection, while protecting against unintended linkages to individuals;

- Strengthening privacy and security protections as information is transferred, aggregated, and used; and
- Providing information in a manner that enables patients to become more involved in their care.

NCVHS notes, however, that there are significant gaps between the PCAST Report vision and the current state of the digital infrastructure for health information and health care. The PCAST Report intentionally and importantly calls for transformative—not incremental—changes in our nation’s approach to building an interoperable and usable, health information infrastructure. NCVHS advocates for achieving interoperability on an accelerated timeline while using an incremental approach, building on the progress to date, and at the same time evaluating innovative models and related considerations regarding technology, clinical value, privacy protection and attendant governance and policies.

NCVHS observes that sweeping change carries a notable level of execution risk. Sweeping change, especially in the area of data exchange standards, may have unintended consequences, such as impeding current provider adoption of electronic health records (EHRs), slowing progress toward care models reliant on this infrastructure, and sacrificing progress to date on standards harmonization. In the words of one NCVHS member, “before we commit to exchanging *everything*, we should focus on exchanging *something* on a national basis.”

NCVHS urges that for the near term we continue to build upon current data standards work while recognizing the need to conduct research on a new information architecture. NCVHS cautions that the proposed metadata tagging and data access services proposed in the PCAST Report could lead to unintended consequences for privacy and also require the establishment of national standards and oversight. NCVHS also notes the importance of ensuring the model builds in an infrastructure for patient perspectives and choice and supports revisiting the issue of patient identification and matching.

While NCVHS supports the goals of PCAST Report’s transformative vision, the recommendations in this letter address critical steps needed to bring this vision into reality, while maintaining current progress. NCVHS offers observations and recommendations in the following five areas that can be used to establish an aggressive 3-5 year *incremental* plan for transitioning from the current state of health IT to one that will support the goals envisioned in the PCAST Report.

- Infrastructure Components and Standards (universal data exchange language, metadata tags, data element access services)
- Privacy issues, including metadata tagging at the data element level and de-identification of data
- Implications for Quality Measurement and Patient-Centered Measurement
- Implications for Population Health and Research
- Patient identification methods

Observation 1 – Infrastructure Components and Standards: The PCAST Report calls for development of a new “universal data exchange language” to support interoperable exchange of “tagged data elements” and establishing a Data Element Access Services (DEAS) infrastructure -- a mechanism to index, search, and access health information across the universe of systems where such information resides. The PCAST Report recommends that metadata ‘tags’ would include information about the provenance and consumer privacy preferences of each tagged data element. In the PCAST vision, offerers of DEAS will then be able to allow seekers of data (providers, researchers, and others) to make queries across multiple systems in a federated approach to identify where data about a patient resides and, with appropriate access controls, allow the retrieval of such data. The metadata tagging and DEAS mechanisms exist today in the commercial internet environment and are used by applications such as search engines.

The basic concepts of metadata and tagging of health information (at granular levels and at higher levels of aggregation, such as the entire electronic health record or specific sections or documents of a record) create an imperative to first define, test, and establish national standards that define the content structure and the terminology/vocabulary to be used in the metadata tags, if the system is expected to be interoperable across organizations.

Further, the PCAST Report-recommended approach would require new and complex technical capabilities and information infrastructure components such as DEAS not currently in place in health care. Focusing data exchange and standards harmonization work in crucial areas (instead of, or concurrent with, developing a new universal exchange language, granular metadata tags, and a DEAS infrastructure) would continue to accelerate progress in the use of health information technology to keep pace with the needs of our healthcare delivery system.

NCVHS observes that technical development of metadata tagging and standards is moving forward quickly under the leadership of the Office of the National Coordinator as demonstrated by the ANPRM published in the Federal Register, Vol 76, # 153, August 9, 2011 “Metadata Standards to Support Nationwide Electronic Health Information Exchange.” However, a corresponding policy framework guiding the implementation of this technology has not developed in parallel.

Recommendation 1: Before embarking on the deployment of the new universal data exchange language, metadata tagging, and DEAS infrastructure in health care envisioned by the PCAST Report, HHS should work with all stakeholders to: 1) explore the feasibility of such a system, both technically and operationally through pilot and demonstration projects; 2) develop new policies, including those for governance, privacy, and security, that would be needed in order to implement this new approach; and 3) develop and test national content, format and vocabulary standards for metadata.

Observation 2 – Privacy and Confidentiality Issues and Concerns: The health IT community is in an early state of its thinking with regard to the metadata-tagging approach described in the report. National standards for such approach applied to health care are lacking. The meta-tagging approach to “data liquidity” described in the PCAST Report, as well as the discussion of de-identification, raise a variety of privacy concerns.

An important challenge in pursuing the metadata tagging and DEAS-based approach recommended in the PCAST Report would be the implementation of a standards-based interoperable system to electronically capture, maintain, exchange, and execute consumer privacy choices. NCVHS does not support the use of metadata tagging at the data element level for privacy purposes but rather supports tagging data at a higher level of segmentation. We believe that a data element-level tagging approach would be costly, technically complex, and impractical, could create potential patient safety issues, and ultimately may not provide greater privacy protections. We do believe, and we have noted this in our November 10, 2010, letter (“Recommendations Regarding Sensitive Health Information,” <http://www.ncvhs.hhs.gov/101110lt.pdf>), that there is a need to conduct further research, develop technical standards, and evaluate the feasibility, efficacy, and effect on patient care of implementing segmentation and some level of granular patient consent for use in particular contexts.

Both state and federal laws impose requirements for special handling of certain categories of sensitive health information. Moreover, when parents, guardians, or minors seek access to medical records, state laws may provide that specified categories of information are not subject to such access. In our November 10, 2010 letter, NCVHS recommended that HHS use legally-defined categories of sensitive health information as a basis for segmentation and sequestration research, technical development, pilot testing, and potential future demonstration projects. The aim of these investments, NCVHS said, should be to understand the feasibility, need for technical standards, effects on patient care, efficacy for privacy protection, benefits and costs, and other possible consequences of segmenting these categories. NCVHS selected and defined categories, such as genetic information, substance abuse treatment information, mental health information, and psychiatric notes, because special handling of these categories is required by federal or state law. In light of these recommendations, the approach of the PCAST Report requires study of how metadata-tagging can be developed to meet the legal requirements for special management of defined categories of sensitive health information.

Another important challenge raised by the PCAST Report is the proposed process for de-identification of health information. NCVHS has emphasized the importance of developing appropriate privacy, confidentiality, and security policies and practices with respect to the sharing of information in interoperable health records. In several respects, it is unclear whether the PCAST strategy for de-identifying data will meet these goals. For many forms of data use and re-use, it will be necessary to link data points in a record. One important policy question is how to realize the PCAST Report’s vision of privacy when data linkages across organizations and over time are needed for

other components of its vision. A related challenge here is how the vision of privacy can be implemented for information that is highly likely to describe a single individual, such as genetic information.

The PCAST Report proposes an “automatic”, real-time de-identification process for protected health information in response to a query. This scenario assumes that de-identification is a simple function that can be done automatically in real time or be pre-defined. However, de-identification may require more complex rules respecting current law on selected categories, size of communities and differing data set use in different combinations that may alter risks of re-identification of individuals. For these reasons, in a HIPAA safe harbor de-identification scenario, the protected health information data owner has an affirmative obligation, after removing the list of eighteen protected identifiers, to make an additional determination – that the owner has no “actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.” 45 CFR § 164.513(b)(2)(ii). This determination involves some judgment and does not lend itself to a standard formula or automation across the board. A further consideration is that population health is informed by health and health-care research. States develop their own methods for appropriate de-identification of data when releasing health information, to meet their state mandated requirements. Population health research may be dependent on the use of identifiers to achieve proper linkage of data bases, and state laws may permit different forms of this practice.

Recommendation 2.1: Decisions by HHS to implement the approach in the PCAST Report should be linked from the outset with strategies to align the technology with national policies on privacy and confidentiality. Policy should guide technology, not vice versa.

Recommendation 2.2: The approach of metadata-tagging should be developed with recognition by HHS of legal requirements for the special handling of defined categories of sensitive health information.

Recommendation 2.3: HHS should fund research to identify and develop national standards and best practices for meta-data standardization with consideration of privacy and confidentiality concerns. Key participants in this work could include HL7, NIST, and the Department of Veterans Affairs (VA). HHS should document the standards, privacy, and security issues identified during these studies.

Observation 3 – Quality Measurement Meaningful to Patients: The PCAST report identifies that health IT can help patients become more involved in their own care. NCVHS notes that the role of patients in the digital health infrastructure is not sufficiently described in the report. As described in NCVHS’s letter dated February 17, 2011 (“Aligning Quality Measurement with Needs of Health Reform“: <http://www.ncvhs.hhs.gov/110217lt.pdf>), NCVHS recommends that measure development activities be broadened to include measures that specifically focus on the

needs of patients as they make health care decisions in partnership with their health care team. This calls for a measurement roadmap that identifies a pathway to address information needed to support the patient as a central actor in an interactive relationship with the health care team. Measurement areas would include: patient experience, patient-specific outcomes (outcomes that are stratified, not risk adjusted), functional outcomes, access, patient preference-sensitive measures and measures incorporating consumer-generated data.

The ability of our digital health infrastructure to support consistent data reporting for quality will be important under health reform. There is a pressing need to develop (and support with EHR systems) measures of accountability for both providers and accountable care organizations. The measures need to be useful to consumers, patients, providers, regulators, and payers. Accountability and care coordination must be assessed across the continuum of care with improved and consistent data to provide accurate measures that can be used by all stakeholders to determine how well the health system is performing. NCVHS believes that the connection between patient-oriented and care-team oriented measures is critical to increase accountability, care coordination, and improvement in health care.

Recommendation 3: Given the profound effects that the health system changes being implemented under HITECH and ACA will have on how health care is delivered to and used by consumers in this country, HHS should prioritize creation and funding for development of measures that are meaningful to patients.

Observation 4: Implications for Population Health and Research:

Health care organizations and providers are confronted with rapidly escalating demands to support quality measurement activities and to integrate and coordinate care using health IT systems. It is crucial that, while we envision and work toward a fully interoperable national health information system, we achieve “quick wins” in connecting communities and care teams and in delivering near-term value to clinicians and patients.

In our concept paper “Toward Enhanced Information Capacity for Health” dated May 25, 2010 (<http://www.ncvhs.hhs.gov/100526concept.pdf>), NCVHS argued that national health information capacities must enable not just better clinical care but also population health and the many synergies between the two. NCVHS also noted that health information policy should foster continuous improvement in population health and the elimination of health disparities and support of clinical and health services research, among other topics.

Understanding the population’s health and its determinants relies on multiple data sources, including population surveys, clinical data, administrative data (notably, birth and death records and billing data on use of health services), and public health and environmental reporting systems. As we envision building a comparable capacity for communities and states across America, the quality of information and its timeliness will

be central to success. Work will need to focus on facilitators and barriers to data linkage at state and local levels as a critical part of health information infrastructure, and methods to ensure that linked data sources provide valid health information (including methods to adjust for missing data and methods to protect privacy).

Recommendation 4: HHS should support identification of near-term opportunities to exchange some set of metrics or data across the entire population in a limited time period as a way to demonstrate value and establish linkages among providers, population health departments, and other stakeholders.

Observation 5: PCAST Report recommendations rely on unspecified patient matching methods. The PCAST Reports envisions a health IT ecosystem that does not require the existence of a uniform patient identifier. Rather, it would use associations of intrinsic patient-related information to link data with the appropriate individuals. The Report does not discuss in any detail possible patient identity matching methods, policies and practices. The NCVHS letter of October 30, 2006, on the initial functional requirements for a nationwide health information network (NHIN), (<http://www.ncvhs.hhs.gov/061030lt.pdf>) provides recommendations from the Committee on approaches to patient identity matching. The Committee recommended utilizing a standard person identity/information correlation process to uniquely identify an individual across organizations. This includes the use of reliable, highly sensitive, and specific matching methodologies that use common information such as names, date of birth, gender, and other demographic information. We also recommended utilizing a set of standard policies to resolve identity ambiguities, consistent with applicable levels of accuracy.

Recommendation 5: HHS should evaluate new and existing approaches to patient identity matching in order to develop standards and guidance for accurate linkage of an individual's data.

NCVHS wishes to acknowledge the visionary leadership displayed by PCAST. At the same time, the Committee believes that the nation has made significant progress toward adoption and meaningful use of health IT systems in recent years that should be recognized as foundational. NCVHS urges a focus on areas in which an approach is both aggressive but also cumulative over the next 3-5 years that will result in the "early wins" necessary to accelerate forward progress in critical areas. NCVHS stands ready to support the Department in maintaining this progress.

Sincerely,

/s/

Justine M. Carr, M.D.
Chairperson,
National Committee on Vital and Health Statistics

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Cc: Data Council Co-Chairs
Farzad Mostashari, M.D., Sc.M., National Coordinator for HIT