



NCVHS Hearings on Personal Health Record

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CONNECTING FOR HEALTHSM
MARKLE FOUNDATION *A Public-Private Collaborative*

The Roles of Federal Agencies in Supporting Personal Health Records

- Scope of this project
 - Review current federal activities
 - Identify policy considerations
 - Suggest framework for planning appropriate federal roles
- Agencies interviewed
 - CMS
 - ONCHIT
 - FDA
 - VA
 - DoD
 - CDC
 - NCI
 - AHRQ
 - ASPA
 - ODPHP
 - NLM

Rationale for Federal Role in PHR

- The President has set a national goal of universal “personal electronic health records” within a decade.
- PHRs are an important tool in achieving the widely espoused health care and public health goals of:
 - patient-centered care
 - greater consumer control and empowerment
 - improved chronic care management
 - fuller translation of the knowledge base.
- PHRs represent a natural extension of many current federal roles.
- PHRs provide a new means for achieving federal policy goals.
- Federal government has unique leadership role, including NHII.
- Federal government has unique public interest role cutting across market-based health care activity.
- Policy and health care environments recognize the need for connectivity (including that between EHRs and PHRs).

Purpose defines role:

1. Health care provider: military and veterans; American Indians; provider of last resort (DoD, VA, IHS, HRSA clinics)
2. Payer (CMS)
3. Regulator (FDA, OCR)
4. Researcher (AHRQ, NCI, CDC)
5. Disseminator of the knowledge base (NLM, AHRQ)
6. Public educator (CDC, NLM, ODPHP, AHRQ)
7. Leader, facilitator, policy-setter (ASPE, ONCHIT)
8. Employer (OPM)

What is a PHR?

- No uniform understanding or definition
- Connecting for Health “attributes”:
 - Controlled and understood by consumer/patient
 - Accessible from any place, any time
 - Private and secure
 - Transparent
- Three other attributes are elusive or achievable now only for a few patients:
 - Information across a lifetime
 - Information from all health care providers
 - Easy exchange of information
- Variations in implementation
 - The medium
 - The data
 - The functions

The Roles of Federal Agencies in PHR

- Three forms of federal engagement with PHRs:
 - The PHR extends and enhances current agency activities; a new platform for business-as-usual.
 - The PHR enables new agency roles and activities; the agency moves into new areas with an eye to the wider environment.
 - The PHR is part of implementing a transformational vision for health care and population health.

Perceived roles for federal agencies

- **Visioning and strategic leadership for population health and health care**
 - Improving health care quality, safety and efficiency—the deep foundation.
 - Envisioning the desired health care/public health system for achieving the above goals, and facilitating movement in that direction (also realizing the goals of health equity, patient-centered care and empowered consumers).
 - Providing direction for modernization and redesign of health care delivery system.
 - Improving systems for public health, epidemiology, biosurveillance, drug event monitoring, error reporting, etc.
- **Leading and facilitating standards-based approaches (and thereby enabling innovation to continue)**
 - Providing integrating tools and functions not provided by private sector entities.
 - Encouraging attention to neglected areas (e.g., patient-supplied data standards).
 - Participating in multiple standards development endeavors.
 - Getting the federal “house in order” — e.g., by implementing CHI.
 - Creating tipping points (notably, through CHI).
- **Regulation related to privacy and standards**
 - Enforcing and modifying the HIPAA Privacy Rule.
 - Ensuring compliance with HIPAA administrative simplification standards.
 - Managing agency regulations (FDA, CMS, etc).

Perceived roles for federal agencies

- **Facilitating the evolution of PHRs**
 - “Showing the way,” especially to scalability; sharing what it learns with industry.
 - Conducting and sharing research on what works and doesn’t — impact, value.
 - Bringing providers into necessary roles through incentives, education.
 - Educating consumers, preparing the user base; social marketing.
- **Providing direct services**
 - PHRs (VA, DoD)
 - as PHR creator
 - as PHR purchaser (3rd party tools)
 - Data to populate PHRs (many sources)
 - Ancillary personal health management content and tools (many sources)

Issues requiring attention:

1. Affecting *all* PHR efforts

- Privacy and information control issues (including public perceptions in this area — both fears and demonstrated willingness to participate)
- Security issues
- Legal issues
- Cost issues
- Interoperability with other PHRs and with EHRs

Issues requiring attention:

2. Affecting *Federal* PHR efforts

1. How do anticipated roles in and uses of PHRs relate to overarching federal, HHS and agency objectives?
2. What financial costs are associated with government assuming different types of responsibilities? How will they be borne?
3. How will the federal government promote interoperability?
4. Assuming the existence of standards and interoperability, how much consistency and standardization of the PHR model is necessary for 1) the country and 2) government programs? Should government define requirements for PHRs? If so, using what criteria?
5. What particular privacy concerns and issues are associated with a direct federal role in offering a repository of personal health data?
6. Can/should there be a government-wide stance toward encouraging innovation in this field? What would this stance mean for government activity? What is the potential impact of VA, DoD & CMS vendor requirements? How can such requirements serve the public interest?
7. What decisions are needed regarding regulation and certification? How will they be made? Should a consensus process be used?
8. Additional considerations for federal roles: internal capacity, track record, consistency with agency and wider federal objectives, intra- and inter-agency coordination, and public and industry trust.

Federal agency staff consensus

- There is high-level enthusiasm for the PHR among many change agents and big thinkers inside government, as elsewhere. This enthusiasm exists side by side with recognition of challenging issues on the ground that must be worked through.
- High level of agreement about two complementary federal roles:
 - the importance of federal leadership in facilitating standards-based approaches, and
 - the importance of encouraging, not stifling, innovation because this is a learning process and period.
- Federal agencies must strike a balance between *clarifying what they want to accomplish* and how PHRs serve these desired ends, on the one hand, and *supporting experimentation*, on the other.
- “Federal” can mean either integrated, coordinated government action or a disparate array of uncoordinated initiatives by federal entities. Some form of coordination or high-level agreement and visioning are needed as the framework for federal involvement with PHRs, together with ongoing partnerships with those outside government.

Preliminary recommendations for further discussion

- An appropriate and effective federal role with respect to PHRs requires both a guiding, transformational vision and collaboration toward consensus on addressing these key issues:
 - Federal access to and responsibility for personal clinical data.
 - Federal role vis-à-vis private sector. (Do feds facilitate private market or displace it?)
 - Federal willingness to let patient be owner of data, vs. depend on provider as intermediary/custodian.
 - To what degree do all federal agencies plan to make use of, support, refer to a single PHR model, vs. generating their own; who's responsible for keeping everyone on board?
 - Federal “policies” regarding PHR, including patient’s right to access, control, audit, authorize users – should these be uniform across Federal programs, or across entire country? Are these “rights” afforded to all? (digital divide)



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