

**DISCUSSION DRAFT, 3:30 p.m., April 24, 2006**

May XX, 2006

The Honorable Michael O. Leavitt  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Leavitt:

The American Health Information Community (AHIC) identified and prioritized several “breakthroughs”, health information technology applications and uses that could produce a specific tangible value to healthcare consumers.

The charges for the AHIC Consumer Empowerment Workgroup were therefore both broad and specific to something which could be achieved in the near term.

**Broad Charge for the Workgroup:**

To make recommendations to the Community to gain wide spread adoption of a personal health record that is easy-to-use, portable, longitudinal, affordable, and consumer-centered.

**Specific Charge for the Workgroup:**

To make recommendations to the Community so that within one year, a pre-populated, consumer-directed and secure electronic registration summary is available to targeted populations. Make additional recommendations to the Community so that within one year, a widely available pre-populated medication history linked to the registration summary is deployed.

The Work group agreed on the following objectives to guide the development of recommendations to meet these charges.

Primary Objectives:

- a. Create measurable value for consumers, patients and families for improved health outcomes, cost, and convenience.
- b. Ensure privacy and security protections and consumer control of their personal health information contained in the PHR.

Secondary Objectives:

- c. Create measurable value for health system participants.
- d. Establish an initial “building block” for supporting expanded PHR availability and portability.

- e. Enhance interoperability among PHRs and other digital health information systems such as EHRs and other PHRs.

**The Workgroup’s deliberations highlighted a number of key issues with respect to the specific charge:**

1. Privacy and security safeguards and consumer control of personal health information related to PHRs need to be established and enforced.
2. There is currently no widely accepted standard definition or functional specifications for the PHR or for information exchange with PHRs.
3. Appropriate incentives for PHR adoption among consumers and providers must be identified and supported.
4. There is a general lack of awareness among consumers regarding the availability and value of PHRs.

This letter provides both context and recommendations for how these issues can be addressed to enable access to an electronic registration summary and medication history in targeted populations.

## **SUMMARY AND BACKGROUND**

**Summary:** The President’s ten (10) year goal, announced in 2004, of improving healthcare using information technology, including an electronic health record and a personal health record for every American who wishes to have one, can move forward through the recommendations made by the Consumer Empowerment Work Group (CEWG) of the American Health Information Community (AHIC). This work group has been working to understand and address the issues related to policies, interoperability and consumer awareness of a registration summary or “electronic clipboard” and a medication history so that recommendations can be made to the Secretary.

**Background:** There are many advocates of the premise that the successful deployment of some form of easily accessible, personal health information could be one of several keys to engaging individuals to be more actively involved in their own care and care management. Consumer engagement with PHRs could, in turn, increase efficiency in the health care system, lower overall costs, and improve health care information access.

The universe of Personal Health Records – including medication histories and registration summaries – is one where few standards exist for data content, format, functionality, interoperability, use guidelines, privacy or security policies, development, deployment, education, outreach, etc. There is little common understanding of the usefulness and purpose of these tools today and there is little demand in actuality; current interest is largely found among the employer, health plan and vendor communities. Nonetheless, many health care experts believe that widespread utilization of consumer-centric health information that is presented in a more user-friendly, intelligible format may indeed have short- and long-term benefits with respect to consumer health and healthcare utilization. Understandably, however, potential users of these tools have

legitimate concerns about managing data access, ensuring privacy and security, the lack of interoperability, and the lack of user support, and general availability of the tools.

While some PHRs are being sold to providers who then make them available to their patients, few, if any, automatically populate these tools with patient-specific information. They are often “shells” that are to be populated by the individual or a caregiver who must dedicate many hours to entering all of the relevant data. There is little consistency in the manner in which tools can be accessed by providers once they are filled in; the availability of the information even to a sponsoring provider in his or her office is limited, since providers may not have computers on their desks or in their exam rooms where they meet with patients. Employers as well are increasingly offering PHRs to their employees. One vendor, for example, imports claims data from the various health plans under contract to the employer and populates the PHR tool. The availability of these data to the healthcare provider or the exportability of these data by the patient for other uses is not assured.

In many discussion groups and forums, interest in personal health records (including medication histories) is based upon their being able to:

- 1) Provide information to all providers consistently (common source for the same data);
- 2) Track medications (prescriptions, over-the-counter medicines, and supplements);
- 3) Track diagnoses, conditions, test results, hospitalizations, and treatments;
- 4) Provide emergency access to health information to providers and family members or other caregivers.

During the Workgroup deliberations, it became apparent that in order to develop the recommendations for the specific charge – to enable the availability of electronic registration summary linked to a medication history to targeted populations – these data would not necessarily be stored and managed by a single type of PHR provider. Thus, many of the recommendations inevitably begin to address the broad charge even to realize the short-term goal. We expect that we will continue to refine many of the recommendations related to PHRs after the Workgroup has had more of an opportunity to hear additional testimony and deliberate on the more complex issues pertaining to the broader charge.

### **Interoperability and Policy**

Our recommendations address both the need for a sustainable process to address issues related to policies and interoperability over time and the practical short-term needs in support of an early implementation of the breakthrough.

The Community acknowledges that the minimum data set required for the registration summary and medication history as defined by this breakthrough is just a small subset of a much more comprehensive PHR. The Workgroup also recognizes the importance of establishing of a technical, policy and business infrastructure that will enable widespread

adoption of the basic functions of registration summary and medication history exchange while supporting innovation within the PHR space. We therefore want to encourage the use of this foundational PHR infrastructure for the maintenance and exchange of PHR-related information that goes beyond the minimum data set. We envision that vendors and sponsors of PHRs will want to provide these extended services – using both standardized data and images and, in some cases, unstructured data or “free text”. These forays into extending the functionality of the PHR will, in the future, lead to further expansion of the fully adopted minimum PHR data set and exchange standards that would undergo the same specification and certification process as is being developed in this first iteration of our efforts. We want to support the exchange of these data that fall outside the domain of our minimum data set amongst trading partners so long as they abide by the principles and precepts established for the initial scope of the consumer empowerment breakthrough.

The issue of data integrity is always an issue, but becomes even more important to ensure data integrity when PHRs permit data to be exchanged among consumers, providers and payers. PHRs must be able to clearly distinguish data entered by or modified by patients and caregivers from unmodified data imported from providers or payers.

**Recommendation 1.0:** The Health Information Technology Standards Panel (HITSP) should be charged with addressing the initial set of technical standards challenges in support of the consumer empowerment breakthrough through the delivery of initial standards. In doing this work, HITSP should review and consult with ongoing industry efforts to develop PHR standards.

*Specifically, the Community recommends that HITSP’s work on the technical standards aspects of the Consumer Empowerment breakthrough continue in accordance with the scope and principles developed through the work of the Community and the AHIC Consumer Empowerment Workgroup. HITSP’s detailed specifications and related work products should include the following:*

- *specifications for a core registration data set,*
- *specifications for medication history,*
- *specifications for identifying vocabularies and code sets that will ensure semantic interoperability of exchanged information,*
- *messaging, authentication and security standards,*
- *development of a process for the continuing expansion of the PHR exchange standards and functional specifications beyond this initial breakthrough, and*
- *appropriate documentation in support of the above work products. (Please refer to attachment at Appendix A: work group members background research and AHIMA)*

Sectors of the health care industry have made notable progress toward the development PHRs and related technologies for consumers. However, there is insufficient common knowledge about the functions, features and business processes of these tools. In

particular, little is known about privacy and security policies and practices governing the use of PHRs because the existing infrastructure is a loosely defined “network” consisting of thousands of sponsors and other participants such as providers, technology vendors, health plans, and pharmacy benefit managers. The Workgroup deliberations highlighted the need for a more comprehensive understanding of current market practices in order to inform evolving recommendations related to vendor privacy and security policies, standards adoption, PHR functional specifications, and other business practices.

**Recommendation 1.1:** HHS should perform a market analysis with the goal of comprehensively describing to the AHIC the various functions and features of personal health records (PHRs) as well as the policies and business practices of existing vendors, sponsors and other stakeholders regarding PHRs and related technologies. This market analysis should include an environmental scan to understand the potential value of and unmet demand for PHRs across populations and an analysis of the privacy and security policies of PHR providers that takes into account the intermediary networks’, application sponsors’ and data suppliers’ policies and practices.

Based on this analysis, the Consumer Empowerment Workgroup will, no later than 9/30/2006, continue to develop recommendations on a set of business practices and enablers intended to encourage the adoption of interoperable personal health information. The Workgroup will consult with experienced service providers and user groups to identify and recommend a set of best practices with a goal of encouraging adoption of the uniform registration summary and medication history data. Such recommendations may address:

- *Education and incentives for providers to accept the uniform registration summary and medication history data set from all patients*
- *Education and incentives for patients to create, maintain, and allow providers to access their uniform registration summary and medication history data set. This would include alternate mechanisms for accepting PHR derived printouts of the registration summary and medication history as an acceptable substitute for the traditional “clipboard”*
- *Development of a standardized minimum data set by PHR sponsors*
- *Development of uniform user templates (e.g., for school clinics, camps) for presenting registration data in electronic or printed form for patient-directed secondary uses of the data contained within the PHR*
- *Development of mechanisms for allowing consumers continued access to established PHR services – even if the initial relationship with a PHR sponsor has changed*

HHS should continue to support the private-market development of software applications and related services that support the breakthrough. We believe that patients and caregivers will adopt various services based on perceived value and their level of trust in the sponsor and approach; likewise, healthcare providers will select software products that interoperate with PHRs based on the value they gain and their level of confidence in

the data provided through the PHR. The building of “value” and “trust” can be aided by the creation of a robust technical and policy infrastructure; ultimately, widespread adoption of PHRs will require a supportive cultural, social, and business environment. Mechanisms are needed in the short term to ensure privacy and security safeguards adequately protect consumer interests. Certification of PHRs and enforcement of PHR provider privacy policies are two potential mechanisms for ensuring the adequacy of privacy and security safeguards in the marketplace.

**Recommendation 1.2:** HHS should determine the right balance between enforcement of the privacy policies of PHR providers and the certification of privacy and security requirements for PHRs and how together they can help protect consumers’ interests. In order to inform this determination, HHS should develop a white paper in consultation with the Federal Trade Commission and the American Health Lawyers Association to summarize the state and federal statutes that authorize enforcement of PHR providers’ privacy policies and identify potential gaps in coverage and opportunities for use of the current statutes.

The Community wants to ensure that patients are empowered with information about their own health and with tools for managing that information. Patients are empowered when they have options and are able to make informed choices. We see data portability as a key element to realizing this goal. Patients should be able to move their data easily – not only from their PHR to their provider’s EHR, but also from one PHR to another PHR.

**Recommendation 1.3** The Certification Commission for HIT should ensure that requirements for EHR-PHR data exchange are incorporated in the certification criteria and process for ambulatory and inpatient EHRs. Standards development organizations, such as Health Level 7, should coordinate with the HITSP to develop a roadmap for the development of a basic PHR functional model and conformance criteria to enable the accelerated development of minimum set of criteria and a process for PHR certification. *(needs to be further considered/refined by work group to get consensus on this recommendation.)*

When a patient wants to deliver registration and medication history information from his PHR to his physician’s office, there will clearly be instances where the physician office will not be prepared to handle electronic information. The PHR can still be very useful and empowering tool for the patient if he knows that his doctor will accept a standardized printout of his information as a substitute for the “clipboard”. By creating this expectation through incentives or requirements, we are acknowledging the value of the patient’s time. There will be data sets that are beyond the scope of the standard registration summary and medication history and that will still be part of a clinician’s clipboard (a reproductive history in the case of a fertility specialist, for example). In these instances, it is appropriate to require the patient to fill out a form or complete an intake history. But there should be no reason to repeat the questions for which answers are available from the standard outputs of the PHR.

As the industry evolves with the ability to populate PHRs with data from the range of health care provider electronic records (EMRs, EHRs), software vendors who create the EHR tools should strive to include PHR interoperability features so that provider-generated data, when appropriate, can be imported into the PHR when requested and authorized by the PHR account holder (consumer) in a timely manner. Using medication history as an example, the industry could agree that, if a prescription is sent electronically, the data could be downloaded to the PHR within several hours of being picked up by the patient (assuming the patient's request and authorization)

**Recommendation 1.4** Industry should establish benchmarks for ensuring timely responses to consumer requests for various types of data. These benchmarks should focus on optimizing consumer access to their personal health information.

Finally, to meet the primary objective to create measurable value for consumers, patients and families for improved health outcomes, cost, or convenience, the Workgroup considered various target populations to meet the specific charge. Patients with chronic conditions that are frequent users of the health care system were determined to be the most likely to derive value from the availability of an electronic registration summary and medication history. This includes pediatric and Medicare populations with chronic conditions who are likely on multiple concomitant medications. Particular consideration was given to the sick pediatric population since there are opportunities to start a longitudinal PHR to follow a patient over his or her lifetime while demonstrating the short term value of this information to families and providers of chronically ill children.

**Recommendation 1.5** HHS should work with CMS and AHRQ and other interested federal agencies to pilot PHR programs that measure and demonstrate the value of an electronic registration summary and medication history to patients with chronic disease. These programs should strive to meet all the objectives and relevant recommendations identified by the Workgroup and an evaluation of the results should be reported to the AHIC by 12/30/07.

### **Cross Cutting Policy Development**

Each breakthrough workgroup has identified policy issues which must be addressed in order to establish public trust and lead to the successful adoption and subsequent implementation of the recommendations. The consumer empowerment group, in particular, has recognized that its work brings 300 million new users into the national health information network, raising numerous questions about privacy, data security, consumer control, and trust. Survey data and early user experience confirm that Americans see their personal health information as highly sensitive and will demand that strong protections be in place to assure its proper management, sharing, and use.

Because privacy and security policy issues are integral to realizing the specific charges for each of the four work groups, it may be most productive to create an ad hoc workgroup comprised of existing work group members who are most knowledgeable

about privacy and security policy issues and their practical application. The charge of the ad hoc workgroup would be to frame the issues in the context of each breakthrough, and specify detailed questions that would be deferred to a long-term discussion group who would then make recommendations to the AHIC. It will be the mission of this ad hoc workgroup to build public trust by ensuring structured public input particularly from consumer groups, privacy advocates, technology experts, clinicians, and population health experts to enable a balanced discussion of all the issues.

**Recommendation 2.0** AHIC should create and charge an ad hoc policy workgroup comprised of representatives from each existing workgroup with framing the issues surrounding patient identification, linkage to patient information, authentication, and authorization, in the context of each breakthrough, by specifying detailed questions that will guide policy development. By definition this ad hoc workgroup would be short lived and would focus on identifying detailed questions that would be deferred to an independent, sustainable policy and security advisory body.

The consumer empowerment workgroup feels the new ad hoc workgroup should consider crafting thoughtful questions surrounding:

- Requirements for authenticating individual consumer users
- Patient notification and consent
- Requirements for data management and consolidation (e.g., multiple prescription data records)
- Standards for patient-sourced data
- Requirements to propagate patient-entered data back to data suppliers (e.g., errors, changes in meds use)
- Methods for allowing consumers to permit and control access by others such as providers and caregivers
- Policies for secondary uses of patient-supplied data
- Policies for breaches of private health information

**Recommendation 2.1:** By 9/30/06, HHS should support the establishment of an independent advisory body on privacy and security policies to develop and recommend market and government (state and federal) privacy and security policies to support health information exchange. This proposal should include concrete steps to be implemented no later than 7/1/07.

This advisory body should:

- Be open, public, and transparent
- Include both technical and policy expertise
- Include members from each AHIC workgroup
- Include representatives of all affected stakeholders
- Be limited to a finite set of policy tasks and a predetermined schedule (to avoid “scope creep”)
- Be supported with adequate staffing or consulting resources to give issues proper research and attention



- Seek consensus recommendations that are considered workable by all stakeholders

Please see Appendix B for a detailed discussion of this section.

## **Education**

Neither the goals of the broad charge nor the specific charge of the Consumer Empowerment Workgroup can be realized without adequately educating consumers and the healthcare community about the issues and opportunities related to personal health records. A broad variety of private sector organizations regularly provide health education to their constituents. Examples are organizations such as patient advocates, chronic disease advocates, provider associations and umbrella entities that are trade associations composed of many consumer groups. These private sector organizations are well-positioned to effectively identify ways to segment and reach consumer groups for education purposes. They have well-established grass roots networks with proven track records for communicating information and providing education to their members. Importantly, volunteers have active roles within the organizations with the result that information provided to consumers is considered very credible.

Consumer education needs to be designed so that it is culturally sensitive and available in a variety of forms to meet consumer needs. In the arena of health information technology and specifically for the breakthrough project, consideration should be given to foreign languages, health literacy, basic Internet skills, and general health information technology literacy. In addition, providers are essential to successful consumer usage of personal health records because patients often direct many of their questions to their providers. In particular, specialist physicians (i.e., cardiologists and endocrinologists) who serve chronically ill patients that have multiple prescriptions will play an important role in patient usage of the medication lists associated with the breakthrough project.

**Recommendation 3.0:** In the near term, work with appropriate private sector organizations to establish consumer awareness initiatives for selected target populations to promote participation in a breakthrough project with the goal of promoting the benefits of medication lists and registration summary. Private sector organizations such as AARP, the American Heart Association, the National Health Council, the American Medical Association, medical specialty societies, and other voluntary health organizations.

**Recommendation 3.1:** In the longer term, provide incentives (NEED TO IDENTIFY WHO?) to private sector organizations such as patient advocates, chronic disease advocates, and provider associations committed to normalizing the practice of PHRs as a new standard of care through culturally sensitive community based activities and public action models that educate people about the benefits of such records and engage early adopters in coordinated activities

that catalyze the desired social and behavioral outcomes of widespread acceptance and adoption of PHRs. Private sector organizations such as AARP, the American Heart Association, the National Health Council, the American Medical Association, medical specialty societies and other voluntary health organizations.

Federal Government organizations play a key role in consumer awareness and education at the federal, state, and local levels. During the first three months of 2006, HHS demonstrated its long-standing relationships with the states by aggressively participating in more than 30 state pandemic flu summits. The Agency for Health Research and Quality (AHRQ), the Health Resources and Services Administration (HRSA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) have been involved in health information technology activities related to consumers. The Centers for Medicare and Medicaid Services (CMS) have a mature and comprehensive communications program for informing Medicare beneficiaries and providers about health care delivery topics and have plans to conduct a pilot PHR program in 2006 using data available through the Medicare Beneficiary Portal.

**Recommendation 3.2:** HHS should identify and prioritize the activities of its organizations to perform research on ways to educate consumers, fund pilot studies for consumer education and leverage its existing state relationships to promote consumer awareness of the benefits of health information technology (HIT) tools with a particular short term focus on the value of an electronic registration summary and medication history. In particular, the communication and outreach HIT-related initiatives of AHRQ, HRSA, SAMHSA, and CMS should be coordinated through ONC.

Lessons can be learned from other initiatives involving consumers' personal health information. During its fact-finding and research, the consumer education subgroup briefly reviewed a web-based, consumer-owned and maintained personal health record called *FollowMe*<sup>TM</sup>. It was designed to allow people to securely archive important health history information in an easily accessible location (the Internet) which will literally "follow them" wherever their travels take them and throughout their lives. Lessons learned about *FollowMe*<sup>TM</sup> stressed that education and outreach were critical to its success. Notably, it was found that many consumers still do not understand they have the right to their medical information. It seems that although the HIPAA Privacy Rule established a new set of patient rights, consumers feel they received inadequate education and mixed messages about these rights, i.e., patients have new rights regarding their private medical information, but providers are not required to respond quickly to patient requests for access to that information. Patients and family members are confused about their "rights" to access and obtain copies of their own health information. Complicating consumer confusion are federal and state laws pertaining to provider interpretation of patient lab test results before patients can receive these results. Additional consumer confusion is related to the fact that patients might not understand the subtle differences between "personal health records" and "electronic health records."

Consideration should be given to the ideas of the National Health Council and consumer health organizations about ways to reinforce and clarify patient/family caregiver/consumer expectations about their ability to access their medical information in electronic personal health records. It will be important to establish ongoing mechanisms to monitor the effectiveness of consumer education to determine consumer awareness of personal health records, security of sensitive on-line data, privacy protections, “rights” of access to personal health information, electronic health records and related health information technology.

As we think about the overall approach to consumer education for the breakthrough project, it may be helpful to consider other nationwide technology initiatives that have changed the lives of many consumers; one example is Internet-based banking. Today, consumers routinely use on-line banking services even though they might not understand the system and its security protections. Helpful information about consumer education during the initial phases of implementing Internet banking may be obtained from financial services trade associations.

The Consumer Empowerment Workgroup believes further discussions are needed to help assure a long-term commitment to educating consumers about personal health records, electronic health records and eventually a nationwide health information infrastructure. These discussions should include the need to ensure consumers awareness of their ability to control access and disclosure of their personal health information.

Thank you for giving us the opportunity to submit these recommendations. We look forward to discussing the recommendations with you and the members of the American Health Information Community.

Sincerely yours,

/s/

Linda Springer

Co-Chair Consumer Empowerment Workgroup

Sincerely yours,

/s/

Nancy Davenport-Ennis

Co-Chair Consumer Empowerment Workgroup

Attachments