CONSUMER/PATIENT PRINCIPLES OF EIGHTAHIC BREAKTHOUGH INITIATIVES

Breakthrough Initiative	*Openness & Individual Participation and Control*	*Purpose Specification and Minimization/ Collection Limitation/ Use Limitation*	*Data Integrity and Quality & Security Safeguards and Controls*	*Accountability and Oversight & Remedies*
PHRs	• Universal and recognized definition of PHR must be established. • Consumer recommended definition of PHR: "With available standardized and certified software, consumer has the ability to access all health records from providers to incorporate into a personal health record that will be maintained and controlled/owned by the consumer." • Note: Currently PHRs are not covered by HIPPA.	• Software to create PHR must be: ✓ Affordable ✓ User friendly ✓ Convenient ✓ Must have ability to send specific information to providers without having to send the whole PHR. ✓ Must be coded to allow providers to send information direct to the PHR without accessing information from the PHR. • Caregivers/power of attorney or designated family member must be able to develop a PHR for patient, including minors, and have access to it. • For patients who are unable to access and/or	• Software to create PHR has to be secure according to proven security standards. • PHR must be available in at least two formats: ✓ Computerized ✓ Card • Security must be consistent with those of the banking and securities industry with security and redundancy upgraded routinely to prevent hacking, corruption, and loss of data. • Emergency alternative power sources must be standard to assure long-term security of data in the primary storage location.	• PHR must be patient controlled/owned. • Punishments for unauthorized use or access of PHR must be severe enough to discourage any attempts and should be the same as if this were a financial transaction. • HHS through an office of health information technology security and compliance. • Regulation and enforcement through the U.S. Department of HHS and the U.S. Department of Justice.

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		manage PHRs due to stage of illness, mental incapacities and/or any combination of social/economic factors, the patient may confer caregiver authority to hospice organization representatives, physicians or their representatives. • During this time of transition, consumers/patients need the flexibility of various models for storage of PHRs to include but not be limited to freestanding PHRs, independent PHRs and record locator programs that are fully electronic and interoperable. • Providers should be willing to provide patients with information about their health electronically. • Patients must be provided with a copy of their		

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		medical records, electronically, within a specified timeframe of payment for services rendered.		
Medication Record	• Medication Record should be part of the PHR	• Software should be encoded to allow: ✓ Record of medications to be kept on the PHR. (including over-the-counter medications, vitamins, and supplements. ✓ Provider to e-prescribe and send copy to patient's PHR simultaneously. ✓ Pharmacists to send drug interaction warnings to patient and cost of medication at the same time. ✓ Reporting of	• Pharmacists cannot share medication records without permission of patient. • Providers should have the ability to access patient's list of medications with patient's agreement. • Patients' medication record will not be available to employers, insurers and credit agencies. • Pharmacies can only provide aggregate deidentified patient information to insurers when seeking to become or maintain approved provider status.	• Patients will have the ability to record and maintain list of medications and cost as well. Record could be used for tax purposes and could sensitize patient to overall spending habits for medications.

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		✓ adverse reactions to physician electronically.		
Health Record Locator	• There should be no need for a separate locater system if software is developed for PHR to locate and access medical records from providers.	• Should be built into PHR software. • User friendly • Affordable	• Security should be built into software to allow patients to locate and access personal records from a provider without the provider having access to the patient's records.	•
Registration Info	• Patients should have the ability to pre-register electronically using information from their PHR.	• Software should allow patients to access their own file in a provider's office (with the proper coding) in order to update their records. This could save costs by cutting down on admin costs for providers.	• Must be secure to allow patient access to own records but limited access in provider's office to employees, i.e. physician or designated healthcare professional, including but not limited to office RN, business manager, billing clerk, and/or office practice manager. • Coded so that if unauthorized user accesses patient's file, the patient will be notified electronically immediately.	• Requires close working relationship between provider and patient to assure that the provider/ patient relationship is confidential and records are secure with no leaks to insurers*, employers, and /or credit agencies. *Insurers may have access to required billing information only, such as dates of service, diagnosis, and specific billing codes for services and/or medications provided.

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E-Rx	See Medication Records.			
Quality monitoring and reporting	• There should be nationally known standardized quality performance measures electronically tied to PHRs. • Patients should have the right to know what the measures are. A list should be provided to the patient on each office visit.			• Reporting of medical errors should include patient report as well.
Chronic disease monitoring	• For those patients with chronic diseases, reminders must be built in their PHR to help patients monitor their disease, i.e. taking medications, testing, and dates of visits. • Lab and scan results that are sent to the physician must be sent electronically with narrative attached to the patient through the PHR	• PHRs should allow for entry of general practitioners, specialists, emergency care provider fields with a chronic care area to note historic and current chronic care protocols.		

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	at the same time.			
Biosurveillance	• A more transparent process should be established so that patients are better notified and informed about the existence of public health surveillance systems.	• Because the collection and use of data has not been limited to biosurveillance, but epidemiological studies as well, there should be open debate to address concerns about privacy and public trust.	• There should be clear, national standards for how information is being collected, used, and stored, with regulatory guidance and enforcement.	• There should be some binding legal agreement between legal entities and public health authorities that clearly outlines respective roles. • Voluntary privacy and security standards should be developed where strong laws are not at play. The standards should direct that there is no collection, use, or sharing of individually-identifiable information. • There must be sanctions for any violated standards, and there needs to be adequate training and coordination to ensure adoption and implementation.