HHS Priorities
*for America's Health Care*

# Establishing the Pathway to Personalized Health Care

**http://www.hhs.gov/myhealthcare**

**United Kingdom Parliament**
**House of Lords**
**June 6, 2008**

# Agenda

- HHS Initiative Goals and Activities
- Progress Report
- Challenges and Opportunities

# Secretary's Vision

- **Personalized Health Care:** "Health care is tailored to the individual. Prevention is emphasized. Propensities for disease are identified and addressed through preemptive intervention. Discovery and innovation move drugs to the market and to medical practice faster and at lower cost."
- **The Long Term Objective:** Advances in basic research have positioned us to harness new and increasingly affordable potential in medical and scientific technology. With clinical tools that are increasingly targeted to the individual, our health care system can give consumers and providers the means to make more informed, individualized, and effective choices.
- **The Secretary's 2-year Objective:** Establishes concepts and priorities that support health care system transformation to achieve long term objectives.

# Secretary's Vision

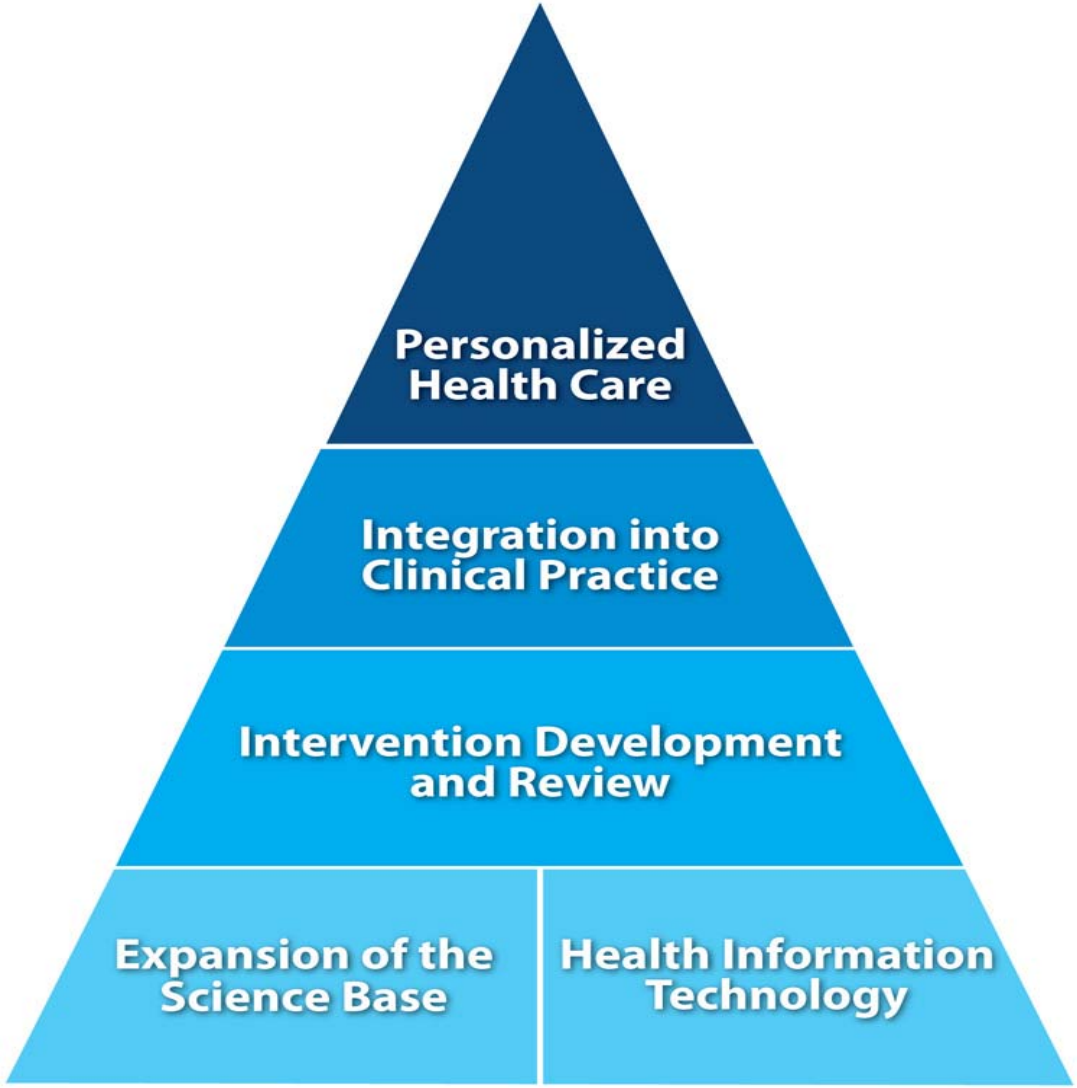
HHS Secretary Mike Leavitt launched the Personalized Health Care Initiative to align work in three areas toward the goal of more effective and individualized care for patients. Major areas include:

- research and development in genomic and molecular medicine,
- adoption and networking of health information technology, and
- accelerated development and use of evidence-base care.

The combined effect of these advances should yield a ***health care system*** that provides more precise and higher-quality care for each patient, with greater cost-effectiveness than is possible at present.

The Secretary's Initiative addresses crucial early steps in a process that is likely to engage a generation's worth of work.

# Building a Base for Personalized Health Care



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# Is your Healthcare Personalized?

To personalize your health care in the future, will your plan/provider:

…assess your family health history (inherited disease risks)?

…utilize genetic testing capabilities to assist diagnosis?

…utilize pharmacogenomic information in prescribing?

…have genetic tests performed in federally certified labs?

…offer preventative advice based on your genetic information, lifestyle, and environment?

…support your use of a personal health record (PHR) and your clinician's use an electronic health record (EHR) to capture relevant health information?

…use clinical decision support tools?

…follow proper privacy laws concerning your genetic information?

…help you understand the relative costs/benefits/risks?

…make quality information readily available and engage you in decisionmaking?

# Goals : PHC Initiative

***Goal 1:***

**Link Clinical and Genomic Information to Support Personalized Health Care**

*A.* Establish an interoperable public/private data partnership of networks to deliver information on individual medical outcomes and linking findings to genetic laboratory test.

- Provides a standardized, open electronic system to link genetic test results used in medical practice and individual response to treatments
- Delivers to researchers findings on medical outcomes years faster
- Provides evidence base for developing more individualized and effective treatment
- Supports pioneering HIT work for linking clinical data, and helps broaden the evidence base underlying quality of care standards.

# Goals : PHC Initiative

***Goal 1 (cont.):***

**Link Clinical and Genomic Information to Support Personalized Health Care**

*B.* Establish Common Pathway for Data Integration through Electronic Personal Health Records

- Utilize American Health Information Community (AHIC) Personalized Health Care Working group to consider policies for facilitating the inclusion of genetic test and family health history information in electronic health records

# Goals : PHC Initiative

*Goal 2*

**Support the Appropriate Use of Genetic Information**

- Protect individuals from genetic discrimination
- Encourage policies and practices that provide sufficient protections to consumers that genetic test information is used only for medical benefit
- Provide oversight of genetic testing to assure analytical and clinical validity
  - Regulation of testing platforms and systems
  - Proficiency in practices for performing tests and data interpretation
- Standardize access policies to federally funded clinical genetic databases of genetic information

# Policy Actions

- **Executive Order 13410, April 2004**

  President Bush established a priority to advance electronic health records:

  – To advance the vision of developing a nationwide interoperable health information technology infrastructure

  – To achieve the goal of widespread adoption of interoperable health IT by 2014

- **Genetic Information Non-discrimination Act of 2008**

  President Bush signed into law on May 21, 2008

  – To prevent discrimination of employment on basis of genetic test results and genetic predisposition to disease

  – To prevent denial of health insurance coverage on basis of genetic test results and genetic predisposition to disease

# American Health Information Community Working Group on PHC

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**Broad Charge for the Workgroup:**

Make recommendations to the American Health Information Community for a process to foster a broad, community-based approach to establish a common pathway based on common data standards to facilitate the incorporation of interoperable, clinically useful genetic/genomic information and analytical tools into electronic health records to support clinical decision-making for the clinician and consumer.

**Specific Charge for the Workgroup:**

Make recommendations to the American Health Information Community to consider means to establish standards for reporting and incorporation of common medical genetic/genomic tests and family health history data into electronic health records, and provide incentives for adoption across the country including federal government agencies.

http://www.hhs.gov/healthit/ahic/healthcare/

# PHC Workgroup – Vision and Priorities

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**Personalized Health Care is a consumer-centric system in which clinicians customize diagnostic, treatment, and management plans**

**Four perspectives were identified as important to the vision**

- Consumer
- Clinician
- Researcher
- Health

**Four priority areas across each perspective**

- Genetic/Genomic Tests
- Family Health History
- Confidentiality, Privacy, and Security
- Clinical Decision Support

# Health Information Technology Accomplishments

## Recommendations accepted by the AHIC on July 31, 2007: Genetic/Genomic Tests and Family Health History

- Use case development to describe the technical requirements for electronic communication between the laboratory, clinician, consumer, and electronic health record in the areas of:
  - Genetic/Genomic Tests
  - Family Health History
- Study the validity and utility of family health history information
- Examine pilot projects to evaluate a core set of family health history information gathered in the electronic health record
- Increase the knowledge base regarding genetic/genomic tests

**Final Use Case available at: http://www.hhs.gov/healthit/usecases/phc.html**
**Recommendations letter available at:**
**http://www.hhs.gov/healthit/documents/m20070731/6b_phc_letter.html**

# Health Information Technology Accomplishments

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## Recommendations accepted by the AHIC on February 22, 2008: Newborn Screening

- A use case should be developed to describe the information exchange for newborn screening to ensure timely and accurate delivery of information for clinical decision-making, and to facilitate quality assurance within the screening system.
  - Reference matrix of NBS tests for appropriate standards development
  - Quantitative reporting of NBS results should be encouraged
  - HHS should determine the most appropriate ways to facilitate the adoption and development of electronic systems for NBS
- HHS should work with state stakeholders to accurately identify, analyze, and develop solutions to address any misperceptions or misapplications of state privacy laws that may affect the timely transmission of newborn screening results.
- A taskforce should be formed to develop a plan for and descriptions of a patient-based information registry of newborn screening data within twelve months.

**Recommendations letter available at:**
**http://www.hhs.gov/healthit/documents/m20080226/phc_letter.html**

# Health Information Technology Accomplishments

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## Recommendations accepted by the AHIC on June 3, 2008: Pharmacogenomics/Clinical Research

- **Fostering EHR Data Standards to Enable Clinical Research and Development Activities**
  - Standards and metrics for outcomes analysis and research are needed to allow data exchange, interoperability, and integration of pharmacogenomic tests into clinical practice
  - Demonstrate use of EHRs for clinical research applications
- **Clinical Decision Support in Health Care Delivery**
  - Consider various pharmacogenomics applications when developing clinical decision support policies, research projects, and algorithms
- **Integrating Pharmacogenomics into Medication Prescribing Practices**
  - Develop guidlines associated with dispensing pharmaceutical drugs based on pharmacogenomic test-derived interpretations in inpatient, ambulatory, and mail-order services
  - Develop best practices for integration of label-change information in the prescribing process

**Recommendations letter available at:**
**http://www.hhs.gov/healthit/documents/m20080603/08.2_rec_letter.html**

# Health Information Technology Accomplishments

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## Confidentiality, Privacy, and Security: Publication in *Genetics in Medicine*

- Discussed characteristics of genetic/genomic test information which should be considered when developing policies about information protection
- Described issues related to "genetic exceptionalism
- Intended to guide policy that will facilitate the biological and clinical resource development to support the introduction of this information into health care

## Clinical Decision Support:

- Advance patient-centric care and improve health care outcomes through effective use of CDS.
- Accelerate the successful adoption of CDS in a wide variety of health settings.
- Enhance patient participation in care through thoughtful applications of CDS.

# Major Progress Marks/ Milestones

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- Secretary's Announcement of the HHS Personalized Health Care Initiative Goals
- Completion of the HHS Report **"Personalized Health Care: Opportunities, Pathways, Resources"**
- AHRQ planned implementation of distributed networks approach for evaluating clinical effectiveness of patient-centric care
- Advancement of Health IT initiatives - Standards development for electronic health records to advance personalized health care
- Advances in Genome Wide Association Studies and policies governing data submission and use
- Passage of the Genetic Information Nondiscrimination Act
- HHS work group established to address communication and authorities associated with direct-to-consumer marketing of genetic tests and services
- FDA industry guidance on certain types of genetic testing products

# Major Progress Marks/ Milestones (continued)

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- Report published on the U.S. System of Oversight of Genetic Testing by Secretary's Advisory Committee on Genetics, Health, and Society
- Public Outreach and Communication with Professional Organizations about the Initiative Goals and Activities
- Continued work on adoption and advancement of health IT tools to integrate genetic testing into clinical practice (e.g., family history core data sets, clinical decision support tool development, etc.)
- First reports on evidence for genetic tests in clinical practice from CDC Evaluation of Genomic Applications in Practice and Prevention (EGAPP) (http://www.egappreviews.org/)

# Targeted Areas for Development

- Education and Awareness
  - Consumer-based communications and understanding of patient preferences
  - Engaging psychosocial issues of stigma and health disparities
  - Direct to consumer marketing and advertising practices
  - Stakeholder engagement in defining evidence development and value
  - Implementing practices that encourage the appropriate use of genetic information
- Integration Into Practice
  - Integration of family health history and other clinical decision support tools into practice (partnerships with provider organizations)
  - New approaches to coverage and reimbursement of PHC practices
  - Incentives for adopting genetic testing in clinical practice
  - Advancing co-development and use of Dx/Rx approaches
- Long-Range Visioning, Consensus Development, and Planning

# Challenges on the Horizon

- Disseminating technologies and knowledge into clinical practice
- Identifying the value proposition of personalized health care practices and realizing the return on investment
- Managing clinical data overflow and to overcome information deficits
- Aligning medical product review and evidence development processes to support improved quality of care and efficiencies
- Opening doors for prevention
- Understanding behavioral motivators and impeding barriers to consumers and health care practitioners to engage new science and technologies
- Appreciating the complexity and difficulties ahead
- Rewarding innovation

# Conclusion

**Thank you!**

**Questions and Comments**

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