



# **HHS Priorities** *for America's Health Care*

---

## **Personalized Health Care**

---



# Secretary Leavitt's Priorities

---

- **Personalized Health Care**
- Medicaid Modernization
- Health Information Technology
- Medicare Rx
- Prevention
- Health Care Value Incentives
- Emergency Response
- Pandemic Preparedness
- New Orleans Health Care System
- Global Health



## 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.



# Personalized Health Care: Key Enablers

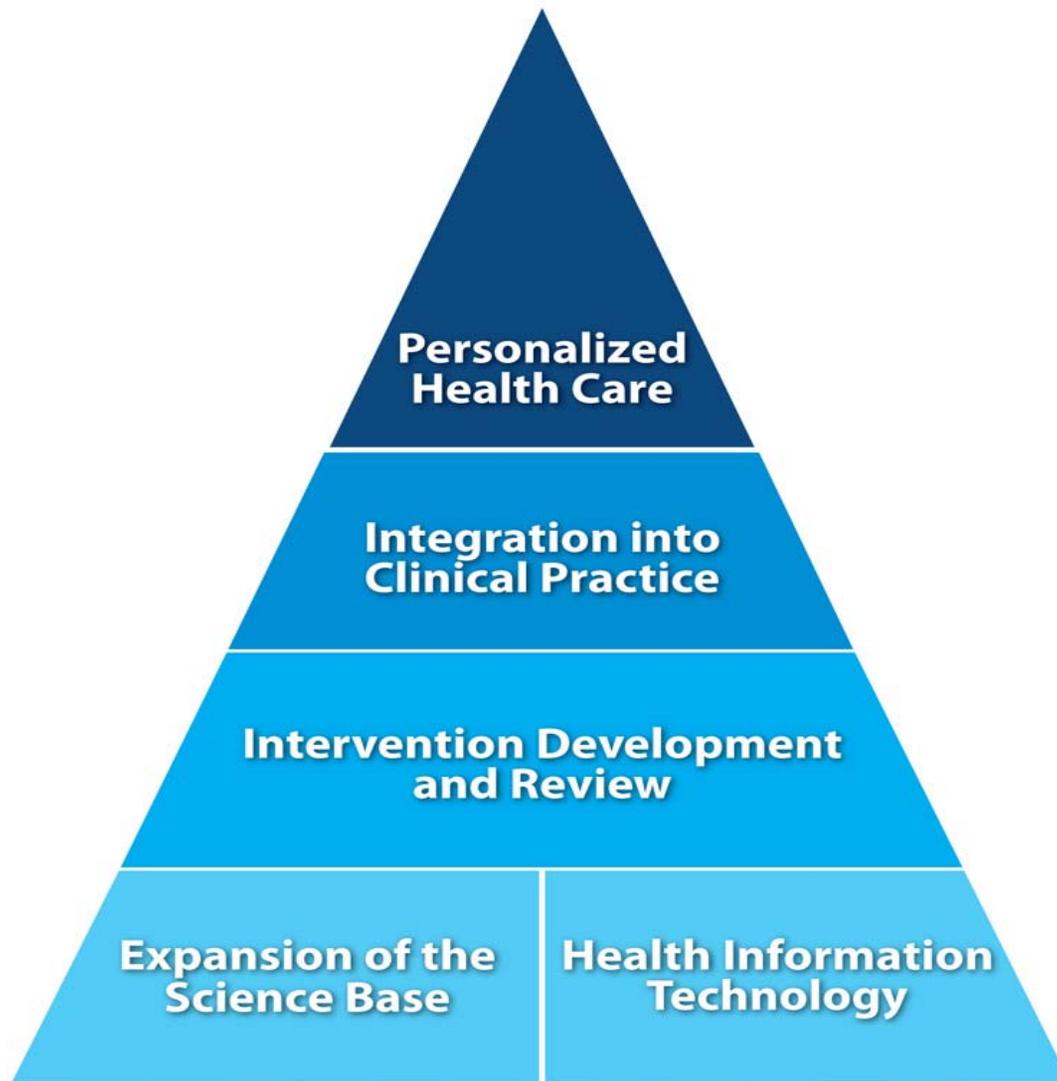
**HHS Priorities**  
*for America's Health Care*

- Rapid advances in science base (e.g., human genome project) in disease processes sets the stage to explain and address individual differences in health states
- Health IT is transforming the health care system by establishing the means for patient-centric care
- The integration of health IT and the genetic information will be transformative in health care practice but difficult to implement
- Critical opportunity to anticipate and plan for the future to achieve maximum beneficial impact



## Building a Base for Personalized Health Care

---





# PHC Planning Process To Date

---

- March/April                      Planning meetings and retreats with OPDIV heads
- May/June                         HHS inventory, visioning, and concept development
- June                                 HHS-wide retreat
- July/August                        Agency-wide discussions and plan development
- September                        Initial Plan adopted by Secretary, OPDIVs, StaffDivs
- October                            AHIC working group formed
- November                        RFI, community engagement and outreach



## What are the Emerging Opportunities?

---

- Many health systems and public resources are considering the risks and benefits for the incorporation of genetic test information in medical records
- Practical applications of medical genetic tests are already emerging:
  - Identifying risk for disease
  - Confirmatory diagnostic tests
  - Selection of appropriate therapies (pharmacogenomics)
- Technology platform costs for genomic tests are becoming feasible for medical use – and some are already in place
- Multiple standards for the technologies are emerging to facilitate market entry
- Opportunity to contribute to more effective health care delivery system (by enhancing efficacy and safety)



## Genetic-based Tests In Medical Management

---

### Early Detection:

- Newborn screening for metabolic and inherited disorders

### Risk factor determination:

- BRCA1: breast and ovarian cancer

### Treatment selection (pharmacogenomics):

- HER-2/neu: metastatic breast cancer (Herceptin®)
- Oncotype Dx®: multi-gene tests for risk of breast cancer recurrence and treatment selection
- Amplichip®: tests for drug metabolizing enzymes to guide individualized patient dosing regimens of various drugs



## **Building an Interface of HIT, Genomics, and Healthcare**

---

- The genomic framework already exists as DNA is a digital code (A,C,T,G)
- A common, harmonized nomenclature system for genes and disease is already evolving
- Communities already exist that are developing standards for the technology platforms for medical tests but they lack the needed of framework to harmonize their efforts
- The stage is being set for integrating genetic test results into medical system and electronic medical records



# Goals

**HHS Priorities**  
for America's Health Care

## Goal 1:

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

A. "Genomics and Effective Healthcare Data Integration" (GEHDI) - Establish an interoperable public/private data network 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

---

**HHS Priorities**  
*for America's Health Care*

*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) processes to consider policies for facilitating the inclusion of genetic test results in personalized health records
- Establish common policies for access to publicly-funded genomic databases



# American Health Information Community (AHIC)

---

**HHS Priorities**  
*for America's Health Care*

AHIC is the public-private collaborative that sets priorities and oversees and/or endorses HIT standards, certification, the National Health Information Network, and policies on a national level.

- Supported through the Office of the National Coordinator for Health Information Technology
- Chaired by Secretary Leavitt and Dr. David Brailer
- Seven work groups are now established involving over 100 experts and stakeholders – Biosurveillance, Electronic Health Records, Chronic Care, Consumer Empowerment, Confidentiality, Privacy and Security, Quality, and Personalized Health Care
- Work groups develop recommendations to the AHIC and subsequently to the Secretary for action
  - Example: Executive Order requiring adoption of certification standards for electronic health records



## **AHIC Working Group on PHC**

---

Evaluate needs and opportunities to utilize health information technology to advance personalized health care.

- Chaired by:
  - Douglas Henley, American Association of Family Physicians (AHIC member)
  - John Glaser, Harvard Partners
- Representation from Federal agencies, industry, health plans, consumer organizations
- Scope and Broad and Specific Objectives are under development
- Initial work to examine:
  - Opportunities for standards development for inclusion of genetic test information in electronic personal health records
  - Focus on content and information needed for genetic tests to support clinical utility
  - Unique aspects of security and confidentiality needs as applied to genetic test results electronic health records
  - Use case scenarios for clinical applications



# Goals

---

## Goal 2

### **Support the Appropriate Use of Genetic Laboratory Tests in Medical Practice**

- Encourage policies and practices that provide sufficient protections to consumers that genetic test information is used for their medical benefit
  - Patient confidence is paramount to long-term success
  - Regulatory protections
  - Health care providers
  - Technical solutions to provide sufficient security and confidentiality
- 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



# Related Efforts that are Contributing to PHC

**HHS Priorities**  
*for America's Health Care*

## **Secretary's Advisory Committee on Genome, Health, and Society**

- Working group on pharmacogenomics
- Genetic non-discrimination issues
- Genetic test oversight
- Intellectual property of genetic test features
- Other issues...

## **NIH Research Programs**

- Genome-wide Association Studies and related policies
- Genes and Environment Initiative

## **NIH-FDA Interactions**

- Biomarkers Consortium (NIH Foundation)
- Joint workshops and working groups

## **Secretary's Advisory Bodies**

- Evaluation of Genomic Applications in Practice and Prevention
- Committee on Heritable and Genetic Diseases in Newborns and Children



# Communication Strategies

---

## **Engagement with Stakeholders:**

Listening sessions – Identify key value points for consumers, health plans, researchers, other stakeholders

Website development – Supports integration of information underscoring government wide efforts and facilitating dissemination

Request for Information – Identifies what strategies that non-federal government sectors are considering to support personalized health care and opportunities for leveraging

## **Public Messaging Communications Strategy:**

Common Vision – Convey a vision of the potential for “personalizing” and improving health care, and make clear the challenges. Pragmatic views, and of practical clinical importance to support clinical decision support

Common Strategy -- Develop and convey an overview of the steps needed to get “from here to there” that will provide a common gameplan

Priority Goal # 1: Technical Capacity –Support the development of a new capacity for deriving useful information to improve and “personalize” health care through real-time collection of anonymous data on clinical treatments and outcomes nationwide

Priority Goal #2: Information Safety and Usefulness – Address genetic non-discrimination and access to research information.



# Conclusions

---

**HHS Priorities**  
*for America's Health Care*

**Questions and Comments**