U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI): Improving Health and Accelerating Personalized Health Care Through Health Information Technology and Genomic Information in Population- and Community-based Health Care Delivery Systems

AGENCY: U.S. Department of Health and Human Services

ACTION: Request for Information

SUMMARY

Advances in medicine, biomedical science, and technology present opportunities for enabling health care practices to be increasingly patient-specific by taking into account individual differences in health states, disease processes, and outcomes from interventions. Often referred to as *personalized health care*, the desired impact of these types of health practices is improved effectiveness and safety of medical practices. These health benefits may be manifested through new approaches for predicting disease risk at an early time point, enabling preemption of disease processes prior to full manifestation of symptoms, analyzing the effectiveness of different interventions in specific populations based on their genetic makeup, and preventing the progression of disease and the related complications.

For the purpose of achieving a broader understanding of rapid changes occurring in the health care setting that may have an impact on the future of personalized health care, HHS requests input from the public and private sectors on plans for developing and using resources involving health information technology (IT) and genetic and molecular medicine, with specific reference to incorporating these capacities in evidence-based clinical practice, health outcomes evaluations, and research.

Dates: Responses should be submitted to the U.S. Department of Health and Human Services at or before 5:00 p.m., EDT, January 2, 2007.

Addresses: Electronic responses are preferred and may be addressed to PHCRFI@hhs.gov. Written responses should be addressed to U.S. Department of Health and Human Services, Room 434E, 200 Independence Avenue S.W., Washington, D.C. 20201, Attention: Personalized Health Care RFI

A copy of this RFI is also available on the HHS website at http://www.aspe.hhs.gov/PHC/rfi. Please follow the instructions for submitting responses.

The submission of written materials in response to the RFI should not exceed 75 pages, not including appendices and supplemental documents. Responders may submit other

forms of electronic materials to demonstrate or exhibit key concepts of their written responses.

Public Access: Responses to this RFI will be available to the public in the HHS Public Reading Room, 200 Independence Avenue, S.W., Washington, D.C. 20201. Please call (202) 690-7453 between 9:00 a.m. and 5:00 p.m. to arrange access. The RFI and all responses will also be made available on the HHS website at http://www.aspe.hhs.gov/PHC/rfi. Any information you submit will be made public.

Do not send proprietary, commercial, financial, business confidential, trade secret, or personal information that should not be made public.

For Further Information Contact: Dr. Gregory Downing, Personalized Health Care Initiative, (202) 260-1911

Supplementary Information: Advances in medicine, biomedical science, and technology present opportunities for enabling health care practices to be increasingly patient-specific by taking into account individual differences in health states, disease processes, and outcomes from interventions. Often referred to as *personalized health care*, the desired impact of these types of health practices is improved effectiveness and safety of medical practices. These health benefits may be manifested through new approaches for predicting disease risk at an early time point, enabling preemption of disease processes prior to full manifestation of symptoms, analyzing the effectiveness of different interventions in specific populations, and preventing the progression of disease and the related complications.

The application of interoperable electronic information technologies (IT) in the health care setting provides new opportunities to collect and analyze information about diagnostic and therapeutic interventions, as well as health care outcomes. With many potential applications, integrated data analysis of multiple parameters of health care practices has the potential to support new approaches to evaluating health outcomes, developing the evidence base for best practices, identifying individual differences in response to therapies, supporting research on new interventions, automating the process of detecting and reporting notifiable disease conditions and health care-associated infections to public health surveillance systems, and enhancing safety.

In the past year, the American Health Information Community (AHIC), a chartered Federal advisory committee, has made recommendations to the Secretary to advance the development of electronic health records (EHR). AHIC's activities and recommendations support a nationwide approach to developing digital and interoperable health IT systems that ensure the privacy and security of patient information. Already underway are efforts to support consumer empowerment, health safety and improvement, and public health protection through broadly deployed, harmonized information systems. As a result of the deployment of these capabilities throughout the health care system, new avenues are emerging to apply information about individual health experiences toward

improved transparency about the quality and cost of health care and transformation of health care delivery, as well as decision support for health practitioners.

Occurring in parallel with the advances in health IT are advances in molecular and genetic medicine. This science-based approach to medicine is now in the early stages of entry in health care through the introduction of diagnostics and treatments that target specific genetic and molecular features of disease processes. Applications of this science and technology provide useful information to aid in patient care through more accurate diagnosis and treatment at an individual level. The availability of genetic information (especially the availability of this information as part of the EHR), and the ability to aggregate these data and correlate them with outcomes or other relevant findings from multiple sources, could greatly expand our capacity for personalized health care, providing more specific individual information for prevention, diagnosis, and treatment; pointing toward clinically useful markers; enabling safer and more effective use of existing therapies; and identifying potential fruitful areas for development of new or refined therapies.

New pathways are emerging for affordable and more effective health care practices through personalized health care. The ability to integrate new scientific knowledge, especially our growing understanding of the human genome, into the health care setting in an efficient and timely fashion will rely on robust, reliable and secure information sources in electronically interoperable systems. Many public and private organizations are engaged in the planning for future collections and integration of health data for this purpose. This request seeks information that will facilitate a broader understanding of directions being taken and the productive role that Federal health agencies might play in facilitating progress, avoiding unnecessary barriers, and achieving optimal benefit from the opportunities now before us.

Information Requested

For the purpose of achieving a broader understanding of rapid and emerging changes occurring in the health care setting that may have an impact on the future of personalized health care, HHS requests input from interested parties on plans for developing and using resources involving health IT and genetic and molecular medicine, with specific reference to incorporating these capacities in evidence-based clinical practice, health outcomes evaluations, research, and transformation of health care delivery.

Input is sought on the interest and current planning activities of health care systems and related organizations on the needs and applications of these transformative aspects of personalized health care. Specific areas for comment include:

- Concepts on anticipated approaches for the use of EHR and population- and community-based health care system databases for longitudinal data collection in addressing:
  - Disease susceptibility
  - Clinical course and outcomes

  - Treatment response
  - Evidenced-based clinical decision support
  - Optimal healthcare delivery systems
- Anticipated applications of genomic-based clinical testing in medical decision-making, safety assessment, and risk management
- Establishment of biospecimen resources obtained from clinical medical services for application in research, clinical trials, health services planning, clinical effectiveness, and health outcomes evaluations
- Organizational or institutional practices to address ethical, legal, and social implications regarding the use of patient information, including genetic data, to support personalized health care
- Examples of utilizing large clinical data repositories for practical clinical research to discover effective technologies, therapeutics, diagnostics, and prevention strategies for different populations
- Issues and challenges associated with incorporating genomic information as a part of a broad longitudinal data collection
- Needs for community-wide standards or best practices that will facilitate large-scale data integration and exchange to benefit personalized health care
- Feasibility and potential benefits for establishing linkages of institutional or organizational data resources with private and publicly available health databases
- Development of ontologies across different clinical data repositories that will facilitate the utility of the data for answering clinical research questions
- Models for linking clinical data repositories across disparate care providers
- Examples of the use of disease registries to track specific diseases and response to drug therapies across different subpopulations
- Models for prioritizing analyses to fill gaps in evidence of effectiveness of therapeutic interventions for different populations
- Strategies for accumulating patient data necessary for research that may not be available through EHRs
- Concepts or models on the potential use of clinical data and related resources for research applications
- Models of cost-benefit analysis for integrated data systems, EHR, and clinical resources to inform medical decision-making
- Opportunities and challenges for the development of electronic tools to aid in the integration and analysis of large datasets of clinical parameters to assist in outcomes evaluations

Potential Responders

HHS anticipates responses from a broad range of individual organizations that have interests in health systems change and personalized health care. Some examples of these organizations include:

- Community health delivery systems
- Health maintenance organizations

- University-based health systems
- State and local public health departments
- Other Federal agencies
- Advocacy groups and public interest organizations
- Consumer and patient interests groups
- Health care professional societies
- Trade industry organizations
- Purchasers of health care
- Health information technology industry vendors

Date: October 30, 2006

John Agwunobi, M.D., M.P.H., M.B.A.
Assistant Secretary for Health
U.S. Department of Health and Human Services

BILLING CODE: xxxx