Comments of the Secretary's Advisory Committee on Genetics, Health, and Society to the Health Information Technology Policy Committee on the Definition of Meaningful Use of an Electronic Health Record June 26, 2009

The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) appreciates this opportunity to comment on the recommendations from the Meaningful Use Workgroup of the HIT Policy Committee regarding the definition of meaningful use.

SACGHS agrees that defining meaningful use of an electronic health record (EHR) is critically important to achieve the ultimate goal of enabling significant and measurable improvements in population health. In general, we also agree with the concept of meaningful use outlined in the "Meaningful Use: A Definition" document and recognize that the proposed EHR-generated quality measures apply to primary care providers and new measures under development will address the work of specialists. We would urge the HIT Policy Committee to represent genetic and genomic information as fundamental information that will need to be integrated into general health care practice rather than as ad hoc specialty information. In our view, intermediate and long-term priorities should assure the ability of the EHR to incorporate and facilitate the use of validated genetic/genomic information across the record.

We concur completely with the inclusion of the Care Goal to "Apply clinical decision support at the point of care," but encourage further development of decision support tools, particularly for dynamic health fields such as genetics. Additional resources will be needed to design and support programmatic and research efforts for clinical decision support in the ordering, interpretation, and application of genetic tests. Clinical decision support for genetic/genomic information in the context of the EHR has the power to prevent potential harms to patients due to misinterpretation of genetic test results and help primary care physicians provide adequate and appropriate counseling. Clinical decision support tools, made available at appropriate times, will enhance patient care. This goal cannot be met unless genetic/genomic information is available in the EHR.

Additionally, any definition of meaningful use of the EHR must be sufficiently flexible to accommodate changes in medical practice that will result from evidence-based practice research and that EHRs must be dynamic and structurally ready to incorporate genetic/genomic information as future technologies reveal advances that are not currently recognized. Two examples in the Health Outcomes Policy Priority of the Meaningful Use Matrix to improve quality, safety, efficiency, and reduce health disparities may help illustrate our points.

- In reference to the 2011 objective of "Implementing drug-drug, drug-allergy, drug-formulary checks," it is critical at this juncture to ensure that pharmacogenomic-informed prescribing can be incorporated in EHRs. Although pharmacogenomic testing is still largely in a developmental phase, an increasing number of validated tests are expected to be available in the near future. Such testing promises to improve patient health and safety through the reduction of adverse drug reactions and enhancement of drug effectiveness. For example, genetic testing is now available to determine the level of expression of the ERBB2 gene (also known as HER2). This test is used to guide decision making in the treatment of breast cancer by identifying which patients should receive the chemotherapeutic agent Herceptin. Such testing is important for disease management and patient safety as well as Medicare and Medicaid cost reduction by appropriately targeting use

of expensive medications. As clinical applications of pharmacogenomic research continue to emerge, EHRs and meaningful use of EHRs must be able to incorporate these advances.

- Regarding the 2011 objective to "Incorporate lab test results into EHR," for the reasons discussed above, this objective should explicitly reference genetic/genomic test results. In addition to enhancing quality and safety of care and ensuring easy access to genetic test results, this objective will help reduce health care costs. Incorporating genetic tests results, coupled with clinical decision support tools that alert clinicians to prior tests, would eliminate unnecessary duplicative testing for heritable mutations, which contributes to health care costs.

As the process moves forward to create an optimal definition of meaningful use, we encourage the HIT Policy Committee to recognize the importance of enabling the incorporation of genetic and genomic information, family history, and newborn screening results into the EHR. Efforts to standardize HIT data standards and the interoperability of the HIT infrastructure must include these elements to prevent proliferation of fragmented and incompatible databases, increased costs to the health care system, and impediments to knowledge generation, data collection, analysis, and research. In this regard, we call your attention to the work carried out by the American Health Information Community's (AHIC) Personalized Healthcare and Clinical Decision Support Workgroups during 2007 and 2008 as well as the ongoing initiatives from the Clinical Data Interchange Standards Consortium (CDISC) and Healthcare Information Technology Standards Panel (HITSP). We know this work and these issues have also been of interest to a related secretarial advisory committee, the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).

To help address recognized gaps in the current EHR landscape relative to representing genetic and genomic information, family history, and newborn screening results, AHIC developed use cases to provide a framework for EHR certification standards in these areas. We would encourage the HIT Policy Committee to embrace the standards previously approved by HITSP and transmit them to the Certification Commission for Healthcare Information Technology for consideration as standards for certified EHRs. In addition, SACGHS urges your advisory committees to take further steps to advance these efforts so that EHRs will have the capability to:

- Acquire clinical data to support comparative effectiveness research in genetics, genomics, and personalized medicine.

- Reduce barriers to the collection of clinical and laboratory data to populate registries proposed to improve care for patients with diseases identified through newborn screening programs, including through initiatives sponsored by the Health Resources and Services Administration (HRSA) in response to the Newborn Screening Saves Lives Act of 2008. This objective could be represented in the "Improve population and public health" priority in the Meaningful Use Matrix.

- Optimize the use of family history in clinical care to include development of clinical decision support tools and the ability to utilize pedigrees within the EHR, which would complement ongoing efforts underway across the Department of Health and Human Services as well as the Department of Defense and the Department of Veterans Affairs to deploy robust family history collection tools in the clinical environment. Documentation of family medical history is represented on the Meaningful Use Matrix in the "Engage patients and families" priority as an objective for 2013. Given the amount of work that has already been done in this area, including deployment of family history collection tools in public and private EHR systems, the objective should be moved up to 2011.

SACGHS wishes to commend the Meaningful Use Workgroup of the HIT Policy Committee for developing a proposed definition of meaningful EHR use. We recognize the complicated nature of this work, particularly given the diverse needs and challenges of reforming our health care system. We hope the Committee will consider our comments in this regard, and we would welcome the opportunity to provide further input as you move forward to advance the development and adoption of meaningful use of EHR.