Comments on the Secretary’s Advisory Committee on Genetics, Health and Society
Report U.S. System of Oversight of Genetic Testing:
A Response to the Charge of the Secretary of HHS

The American Academy of Nursing comprises more than 1500 top nursing leaders from education, management, research and practice sectors. Academy Fellows hold such leadership positions as university professors; research scientists; hospital chief executives and vice presidents; university deans; clinicians in practice, hospital, community and home healthcare settings; and political appointees or government staff at the state and federal levels. The Academy is constituted to anticipate national and international trends in health care, and address resulting issues of health care knowledge and policy. By far, one of the most significant healthcare trends impacting the entire nursing profession, healthcare and the public in the 21st century is genetics and genomics. The Academy and the Academy’s Genetic Healthcare Expert Panel appreciate this opportunity to comment on the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS) draft report U.S. System of Oversight of Genetic Testing: A Response to the Charge of the Secretary of HHS and recognize that this represents a work in progress.

The American Academy of Nursing commends the Committee on its efforts to assess the systems of oversight and regulation of genetic tests. Healthcare is benefiting from the unprecedented and ongoing work elucidating the genetic/genomic basis of health, illness, disease risk, and treatment response. The integration of genetic and genomic technologies in the clinical arena has unprecedented healthcare implications. The Academy commends the Committee on recognizing that the benefit of this burgeoning technology is dependent on establishing the analytic and clinical validity for every test. The Academy provides the Committee with the following considerations in regards to the existing statement:

Analytic Validity, Proficiency Testing, and Clinical Validity

1. The Academy is very concerned about the decision of the Centers for Medicare & Medicaid Services (CMS) not to create a genetic testing specialty and associated proficiency testing, a reversal in their previous position. The Academy strongly supports establishing a genetic testing specialty and associated proficiency testing for all laboratories performing genetic tests. Given the clinical and ethical implications of genetic information rendered from genetic tests, we encourage that the Committee strongly recommends that CMS take action without any further delay to establish a minimum degree of quality required of any laboratory performing genetic tests. The Committee’s recommendation of further study on the issue of performance assessment should be executed while instituting genetic specific proficiency testing so as not to delay assessment of the quality and caliber of genetic testing laboratories.

2. The Academy commends the Committee for recognizing the need for interagency coordination in the oversight and regulation of laboratory developed tests and strongly supports the need to convene the relevant agencies to make recommendations on further regulation of genetic tests. This coordination effort should not delay instituting genetic specific proficiency testing.
Communication and Decision Support

1. The Academy strongly concurs with the Committee’s recognition that there are deficiencies in genetic/genomic knowledge of all healthcare practitioners. The Academy is very concerned that the Committee has not recommended that the HHS allocate resources to address these knowledge deficiencies. In today’s fiscal climate, education efforts will be extremely hampered by the lack of financial support to develop and implement innovative genetic/genomic education strategies.

Genetics and genomics have now become a central science for all healthcare providers. The greatest challenge is reaching those providers already in practice. Despite years of calls for more education in genetics and genomics, little progress has been made (Harvey et al., 2007). The benefit of any educational effort will not be realized without participation of the practicing provider and evidence that the knowledge is embedded in practice.

2. The Academy recommends an adjustment in the education strategies for all health care providers to one that starts with system and practice change. There needs to be a shift from the traditional education approaches to one supporting the embedding of genetic/genomic knowledge into practice. Evidence of the genetic/genomic knowledge being embedded into practice should be a component of every patient record for hospital/institution accreditation. For example evidence could include that the family history and patient/family education materials address genetics. A successful model of this recommendation is the interdisciplinary program for integration of genomics into practice at the Mayo Clinic in Rochester, Minnesota (Pestka et al 2008). Another successful exemplar that demonstrates the Academy’s recommendation of focusing on change in practice, is the process used so that pain has become the 5th vital sign to be assessed on every patient and documented in patient records.

It is important to recognize that strategies requiring licensed providers, to provide evidence of completion of genetic/genomic continuing education (CEs) at the time of licensure renewals may not change practice but may inform health care professionals of the significance of the content for practice. When there is evidence of the application of genetics/genomics in practice regulators will be influenced to include the expectation of genetic/genomic knowledge for all healthcare providers in licensing and accreditation.

3. To facilitate the shift of the education focus to practice, SACGHS may want to invite representatives of accrediting bodies such as the Joint Commission (JCAHO) and Health Facilities Accreditation Program (HFAP) to a meeting to demonstrate the significance of the application of genetics/genomics to practice.

4. The Academy strongly encourages the Committee to enhance their recommendations to HHS on genetic/genomic knowledge education and practice. As described, education needs to focus on practice and how to embed the knowledge in practice. The Committee’s recommendations on communication and clinical support will not be realized without the key foundation of an adequate healthcare practitioner knowledge base in genetics and genomics. The Academy believes it is faulty to presume that healthcare providers with genetic expertise are sufficient in number and adequately prepared to support best genetic test practices in the absence of adequately competent practitioners. This perspective represents a narrow view of the scope and breadth of genetic tests already clinically available. First, many clinically available tests are supported by practitioners other than genetic experts, for example, OncotypeDX®, a multi-gene assay performed on early stage breast cancer tumors. Standards of practice for OncotypeDX® utilization and support clearly lie in the domain of the oncology specialist and not with the genetic expert. This genetic test is one of a number of tests that illustrate the implications and applications of genetic tests outside the scope of
practice of the genetic expert as well as outside the umbrella of genetic services. This further supports the need for education in genetics and genomics for all healthcare providers.

**Summary**

In summary, the American Academy of Nursing recognizes that genetic and genomic discoveries have the potential to decrease the public’s disease burden and morbidity of the public’s health as well as improve upon safety and quality of healthcare. The potential benefit to the public’s health will not be realized if genetic tests are not adequately regulated to assure minimum quality and healthcare providers remain inadequately prepared to incorporate these tests into their practice.

Fellows of the American Academy of Nursing represent the national leaders in the entire nursing profession and the Academy’s Genetic Healthcare Expert Panel represents national and international leaders in genetic nursing. The Academy is uniquely poised to engage our Fellows, the Expert Panel and other key stakeholders to develop an interdisciplinary initiative to increase the competency of healthcare professionals in genetics and genomics as well as develop standards and practices that assure the highest possible levels of health care with an emphasis on nursing contributions.

**References**
