

PERSONALIZED MEDICINE GUIDING PRINCIPLES

- I. Genomic-based personalized medicine (PM) including the use of genetic diagnostics and gene-based treatment modalities constitutes the practice of medicine.
- II. PM laws, regulations, and policies must preserve and enable physician discretion to provide, utilize and/or direct the use of the most appropriate diagnostic and treatment options and recognize that physicians are essential to the PM team.
- III. Physicians continue to play a central role in PM discovery, research (including clinical trials), and product and service development and delivery. Physicians drive scientific inquiry and innovation that promotes PM and patient access.
- IV. Given the training of physicians and their direct relationship to patients, physicians have a central role to play in the development of laws, regulations, and policies that impact the clinical implementation of PM, which includes diagnostic testing, the interpretation of testing within the clinical context, and targeted therapies. Testing alone will not dictate patient treatment. A physician's diagnostic interpretation and interpretation of test results in the context of the patient's clinical situation and the treating physician's clinical expertise along with the patient's preference will guide treatment options.
- V. It is essential to build a stable clinical genetics infrastructure including workforce investments that are commensurate with development and the application of new genetic knowledge to the prevention and treatment of human disease.
- VI. As personalized medicine matures, health information technology will play a key role in these advances. Investments in standards, bioinformatics, and health information technology infrastructure will be required to actualize the promise of PM in health information technology.
- VII. PM coverage and reimbursement policies should not dictate which diagnostic or treatment options are available to physicians and should take into account the role of physicians in driving PM innovations, development, and application of improved products and services in this arena.