THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 23, 2010

R. Rodney Howell, MD
Chairperson
Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
5600 Fishers Lane, Room 18A19
Rockville, MD 20857

Dear Dr. Howell:

Thank you for your letter and corresponding White Paper from the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) regarding Heritable Disorders, Newborn Screening, and Health Reform. I appreciate the Committee's efforts to continue to improve care and services to newborns and children with heritable disorders.

The White Paper specifically identifies several barriers, such as public financing and administrative inefficiencies, to newborn screening system improvements and the SACHDNC suggests four recommendations for the Department of Health and Human Services (HHS). HHS recognizes the need to align efforts to improve the care and outcomes for this vulnerable population and will address recommendations to the extent of its authority.

SACHDNC's Recommendation 1: Encourage Centers for Medicare & Medicaid Services (CMS) to convene an expert panel to address coding changes to streamline the billing process for newborn screening services and recommend improvements to standardization of health transactions.

Recommendation accepted. The lack of a uniform system of codes for billing and payment for newborn screening services results in an administrative burden on payers, providers, and suppliers. CMS will explore options for using an existing expert panel or convening a new panel to recommend a more uniform system of coding and billing of newborn screening services.

SACHDNC's Recommendation 2: Encourage CMS to develop and pilot a payment method for an integrated system of care coordination through the medical home framework for children diagnosed with heritable and congenital disorders as a result of screening.

Recommendation accepted. The CMS is convening a new Maternal, Infant, Child Workgroup this year to provide input into State and Federal efforts to address clinical, policy, and payment issues related to neonatal care and outcomes improvement. This recommendation will be forwarded to that workgroup for consideration. I am also asking the new Center for Medicare and Medicaid Innovation, which is charged with testing new payment methods and health care delivery systems for CMS beneficiaries, to consider medical home models for children with heritable and congenital disorders.

SACHDNC's Recommendation 3: Encourage the adoption and further definition of the Newborn Screening Use Case within the Department's health information exchange endeavors, specifically encouraging CMS to use the Newborn Screening Use Case when defining "meaningful use" of electronic health records and the Office of the National Coordinator (ONC) for Health Information Technology to further facilitate the adoption of the Newborn Screening Use Case.

Recommendation accepted. This recommendation facilitates a standard approach to newborn screening that would permit the electronic exchange of newborn information with the goal of improving the coordination of care. I will direct CMS to address opportunities to adopt and further define the Newborn Screening Use Case through additional rule making as ONC's plans for implementation of meaningful use of health information technology evolves. I also will ask CMS to assess opportunities to use information from the Newborn Screening Use Case in developing the pediatric electronic health record format, as required under the Children's Health Insurance Program Reauthorization Act of 2009.

SACHDNC's Recommendation 4: Support, as allowable, the closure of gaps in insurance coverage for medical foods and foods modified to be low in protein, as recommended by the Committee in April, 2009.

Recommendation respectfully not accepted at this time. HHS recognizes that there is a need for policy to address gaps in coverage for medical foods and foods modified to be low in protein that are essential treatments for certain heritable disorders identified in newborn screening but are not typically considered "medical services." We are currently reviewing SACHDNC's June 14, 2010 letter in which many of these same concerns are raised in the context of enactment of the Affordable Care Act. My forthcoming response to the June 14 letter will address this issue further. I will also ask CMS to review State Medicaid programs to determine if there is opportunity to improve federal guidance to the states regarding existing coverage for medical foods and foods modified to be low in protein.

Thank you again for sharing SACHDNC's recommendations regarding heritable conditions in newborns and children. We will take them into consideration as we move forward particularly with respect to implementation of the Affordable Care Act. I look forward to ongoing collaboration with you as new opportunities evolve across HHS for improving the health outcomes of newborns and children.

Sincerely,

Kathleen Sebelius