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

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Joseph A. Bocchini, Jr., M.D.
Committee Chairperson
Advisory Committee on Heritable
Disorders in Newborns and Children
5600 Fishers Lane
Room 18W68
Rockville, MD 20857

Dear Dr. Bocchini:

I want to take this opportunity to advise you of my decisions, taking into account the Interagency Coordinating Committee on Newborn and Child Screening's (ICC) review, regarding the Advisory Committee on Heritable Disorders in Newborns and Children's (ACHDNC) recommendations to add Mucopolysaccharidosis type I (MPS I) to the Recommended Uniform Screening Panel (RUSP) and to provide federal funding to state newborn screening programs to implement the screening of MPS I.

The ICC reviewed the ACHDNC's recommendations and external evidence review and solicited new information from agency experts and state newborn screening program directors. In its report to me, the ICC noted challenges associated with the implementation of state newborn screening for MPS I. However, the ICC emphasized that adoption of this recommendation will help increase the number of newborns screened and improve cognitive outcomes for infants with the disorder.

I would like to commend the ACHDNC for its review and analysis of benefits and harms of newborn screening for MPS I. The information from the evidence report, *Newborn Screening for Mucopolysaccharidosis Type 1 (MPS 1),* was taken into account as I reviewed the ICC's report.

Based on the information presented in these reports, I accept the ACHDNC's recommendation to add MPS I to the RUSP. The Affordable Care Act requires that most health plans cover the evidence-based preventive care and screenings provided for in the comprehensive guidelines supported by Health Resources and Service Administration (HRSA). Because the RUSP is a component of these guidelines, a condition added to the RUSP must be covered without cost-sharing. Plans and insurers will have until the first plan year that is one year after the date of adoption of the recommendation to implement coverage. However, it should be understood that addition of MPS I to the RUSP does not constitute a requirement for states to implement screening, only a recommendation.

At this time, I do not accept the ACHDNC's second recommendation to provide additional federal funding to state newborn screening programs to implement screening of MPS I. However, I encourage federal agencies to continue to provide technical expertise and to support states with existing federal resources and activities. For example, MPS I pilot studies and the Newborn Screening Quality Assurance Program are already in place to assist states as they implement screening for MPS I.

I appreciate the Committee's thoughtful consideration of conditions for inclusion on the RUSP and recognize the challenges you face in considering increasingly rare disorders. Thank you for your dedication and continued work to improve the health of our nation's infants and children.

Sincerely,

Sylvia M. Burwell