



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

August 21, 2013

Joseph A. Bocchini Jr., M.D.
Chairman
Secretary's Advisory Committee on Heritable
Disorders in Newborns and Children
Louisiana State University
1501 Kings Highway
Shreveport, LA 71130

Dear Dr. Bocchini:

As indicated in my letter to you on September 7, 2012, I referred the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's (SACHDNC) recommendations pertaining to newborn screening quality assurance using the dried blood spot filter paper serial number to the Interagency Coordinating Committee on Screening in Newborns and Children (ICC) for additional review. Directing states on the manner in which they assure universal newborn screening and timely follow-up is beyond the authority of the Secretary of Health and Human Services, but the issues the SACHDNC raised are important and required thoughtful review. The ICC was charged with reviewing the report and providing input. I have now received the ICC report.

The ICC endorses the SACHDNC objective of quickly verifying whether or not newborn screening has occurred in order to expedite any necessary interventions. The briefing paper raises important issues about the limitations of current procedures and needed improvements. However, while the ICC report affirms the inherent value of developing methods to assure that all newborns have timely, high-quality newborn dried blood spot screening, it does not endorse the specific methods described in the SACHDNC briefing paper.

State newborn screening programs collect newborn dried blood spots (NDBSSs) from virtually all of the four million children born annually in the United States to test for a wide range of congenital disorders. To conduct quality assurance, a common method is to match newborn screening records to birth records, using some combination of deterministic and/or probabilistic techniques. The SACHDNC expressed concern that missed screening or incomplete follow up might not be identified until after the critical time period for optimal intervention because of the time needed to complete matching algorithms. The SACHDNC briefing paper proposed an alternative approach that involved recording the unique serial number on the NDBS collection card in states' electronic birth registrations systems. After carefully reviewing the SACHDNC recommendations, the ICC believes that there are alternatives to these recommendations that could achieve the same goals without some of the limitations associated with the SACHDNC proposals. The ICC identified several concerns with the SACHDNC recommendations: (1) newborn screening quality assurance practices are a matter of state discretion and states have the

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authority to examine alternative approaches; (2) the opportunity to add a field for the NDBS to the U.S. Standard Certificate of Live Birth will not open until at least 2019; (3) the feasibility of utilizing a unique state-specific serial number in state electronic birth registration systems (EBRSs) will vary from state to state; (4) significant questions remain unresolved regarding the use of the NDBS collection card serial number, including questions regarding the security, privacy, and confidentiality of personally identifiable information; and (5) endorsement of the recommended SACHDNC record-matching strategy could discourage states from examining alternative approaches.

Overall, the ICC supports states in determining the most appropriate mechanism to match newborn screening and EBRS records, taking into account state resources and confidentiality, privacy, and data security requirements. The ICC recognizes states' discretion and autonomy in making such a determination, and, further, recognizes the difficulties and uncertainties associated with adding a required field to record the NDBS collection card serial number on the U.S. Standard Certificate of Live Birth in the near future.

Although I will not accept the four SACHDNC recommendations, I am encouraged that HHS agencies expressed a willingness to assist states with newborn screening and data quality assurance as activities fall within agencies' missions and within available resources. I thank you and the committee for continuing to study and bring to light important issues affecting the health of our nation's newborns and children.

Sincerely,



Kathleen Sebelius