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

September 21, 2011

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

Dear Dr. Howell:

As indicated in my letter to you on April 20, 2011, I determined that the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children's (SACHDNC) recommendations pertaining to the addition of Critical Congenital Heart Disease (CCHD) screening to the Recommended Uniform Screening Panel (RUSP) were not yet ready for adoption. Consequently, I referred the SACHDNC's recommendations to the Interagency Coordinating Committee on Screening in Newborns and Children (ICC) for additional review and input regarding implementation. I asked the ICC to review the evidence gaps described by the SACHDNC and propose a plan of action to address: identification of effective screening technologies, development of diagnostic processes and protocols, education of providers and the public, and strengthening service infrastructure needs for follow-up and surveillance. I have received and reviewed the requested ICC Plan of Action.

As you know, congenital heart disease causes up to 3% of all infant deaths in the first year of life. Heart defects affect about 7 to 9 of every 1000 live births, one quarter of which could be detected and potentially treated by measuring blood oxygen saturation. Given this reality and the available information on the effectiveness of screening, I have decided to adopt the SACHDNC's first recommendation to add CCHD to the RUSP. In addition, I am requesting that the SACHDNC collaborate with the Health Resources and Services Administration (HRSA) to complete a thorough evaluation of the potential public health impact of universal screening for CCHD, as required by the authorizing statute, section 1111 of the Public Health Service Act (42 U.S.C. § 300b-10(b)(4)).

In arriving at my decision, I considered the recommendations from the ICC Plan of Action, the External Evidence Review, and the CCHD Workgroup Report. In addition to providing keen insight into the importance of early detection of CCHD, these reports have identified remaining evidence gaps about the public health impact of universal screening for CCHD. I have concluded that these evidence gaps should receive closer attention as implementation occurs. Specifically, it would be beneficial to states, health care facilities, and individual clinicians to have the SACHDNC and other public health experts, partner with HRSA to provide information about a number of issues, including but not limited to the following:

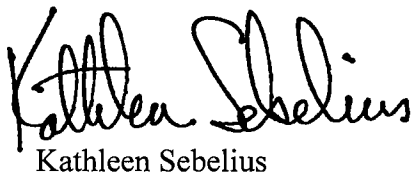
- What will be the impact on state health departments, including staffing needs, to implement this program? What are the roles of the state health departments?
- What capability is present to ensure that all babies are screened and their results are communicated to providers, including assuring that those not screened at birth receive a screen?

Regarding the four SACHDNC recommendations for action by the National Institutes of Health, Centers for Disease Control and Prevention, and HRSA to address recognized evidence gaps (Recommendations #2-#5), I have decided to adopt these recommendations. I will direct the named agencies, as well as other relevant HHS agencies, to proceed expeditiously with implementation, as described in the attachment, as feasible. I am taking this action because I believe that as we move forward, these activities will add important foundational information regarding the potential impact of implementing universal screening for CCHD, strengthen the platform on which to build the critical infrastructure for universal screening, and provide states with the data necessary to consider requiring that this condition be added to their existing newborn screening programs.

I would like to commend the SACHDNC on your success in creating and implementing an external scientific evidence review process for rare conditions that incorporates systematic evidence-based and peer-reviewed recommendations. I am encouraged by the emerging evidence base for the utility of early diagnosis and detection of CCHD via measurement of blood oxygen saturation, as well as the momentum and commitment that is evidenced at the state and federal levels to support implementation and investigation of successful screening programs. While we collectively engage in the remaining work that needs to be completed, HHS will continue to encourage states, health care facilities, and individual clinicians to provide this screening and contribute to the knowledge base in this important area.

I am committed to advancing screening for CCHD, and I appreciate the contributions of the SACHDNC in assisting HHS and states to explore ways to enhance newborn and child screening to improve the health of infants born in the United States.

Sincerely,



Kathleen Sebelius

Enclosure:
Interagency Coordinating Committee on Newborn and Child Screening (ICC): Screening for Critical Congenital Heart Disease: A Federal Agency Plan of Action - Summary of Federal Activities

Interagency Coordinating Committee on Newborn and Child Screening (ICC): Screening for Critical Congenital Heart Disease: A Federal Agency Plan of Action
SUMMARY OF FEDERAL ACTIVITIES*

Research

***SACHDNC Recommendation**: NIH shall fund research activities to determine the relationships among the screening technology, diagnostic processes, care provided, and the health outcomes of affected newborns with CCHD as a result of prospective newborn screening.*

2011 - NIH will build upon the robust research portfolio of improving outcomes in children with congenital heart disease, including the National Heart, Lung, and Blood Institute's (NHLBI) Bench to Bassinet program.
2011-2015 - NIH will encourage and fund research to evaluate the impact of newborn screening on morbidity and mortality from congenital heart disease.
AHRQ's report, *Registries for Evaluating Patient Outcomes: A User's Guide, Second Edition*, (http://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&mp=1&productID=531) will be reviewed by **NIH** and the **CDC** to inform the development of registries to address research questions regarding screening for CCHD.

Surveillance

***SACHDNC Recommendation**: CDC shall fund surveillance activities to monitor the CCHD link to infant mortality and other health outcomes.*

2011 - CDC will evaluate the current capacity of existing population-based state surveillance and tracking to monitor the effectiveness of CCHD newborn screening programs to prevent infant mortality and morbidity.
2012 - CDC will conduct a cost-effectiveness analysis of newborn screening, in collaboration with NIH, for the early identification of children with CCHD.
2012-2015 - CDC will collaborate to leverage an electronic health record framework for congenital heart disease, including CCHD.
NIH's National Library of Medicine (NLM) will assist with the development of expanded laboratory coding terminology for blood oxygen saturation measurements and echocardiogram results integrated into electronic medical records and as part of health information exchange systems.

Screening Standards and Infrastructure

***SACHDNC Recommendation**: HRSA shall guide the development of screening standards and infrastructure needed for the implementation of a public health approach to point of service screening for Critical Congenital Cyanotic Heart Disease.*

2011 - HRSA will support the development, dissemination and validation of screening protocols and newborn screening infrastructure.
2011 - HRSA will support state Title V programs in assessing, promoting and coordinating infrastructure to support a population-based approach to CCHD screening.

2012-2015 - HRSA will provide support for a demonstration program for newborn screening for CCHD.
FDA's Center for Devices and Radiological Health (CDRH) will provide guidance to industry and FDA staff on pulse oximeters.

Education and Training

SACHDNC Recommendation: *HRSA shall fund the development of, in collaboration with public health and health care professional organizations and families, appropriate education and training materials for families and public health and health care professionals relevant to the screening and treatment of CCHD.*

2011 - HRSA will expand its newborn screening educational efforts to include CCHD.
2012-2015 - HRSA will provide ongoing development of new tools and support as needed.
2012-2015 - CMS will support educational efforts through guidance issued to state Medicaid Directors for screening, follow-up and treatment that is medically necessary for children enrolled in Medicaid, as required under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.

** Agencies will carry out activities proposed in this plan, commensurate with available resources.*