DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Committee on Heritable Disorders
in Newborns and Children
5600 Fishers Lane, Room 18A19
Rockville, Maryland 20857
www.hrsa.gov/heritabledisorderscommittee

June 23, 2015

The Honorable Sylvia Mathews Burwell
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

During the May 11-12, 2015 meeting of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee), the Committee had a discussion on Amendment 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 (Act). The amendment states:

> SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH.
>
> (a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.
>
> (b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act.
>
> (c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations.

A panel of speakers provided information about the Secretary's Advisory Committee on Human Research Protections' (SACHRP) recommendations on the research uses of newborn dried blood spots and described various state models for obtaining consent for sample storage and future research and the initial impact of their implementation. The Committee discussed the impact of this amendment on newborn screening programs and the potential impact of the forthcoming Notice of Proposed Rulemaking to make changes to the

Federal Policy for the Protection of Human Subjects (i.e., the Common Rule).

Based on the discussion, the Committee determined that more clarification and guidance is needed for State newborn screening programs on how to implement this amendment. As such, I am providing you with the Committee's six recommendations for Secretarial consideration:

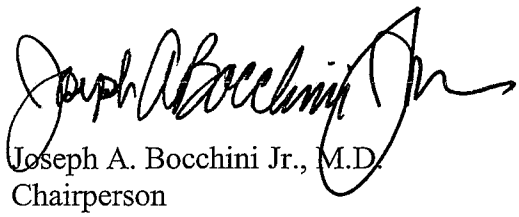
The ACHDNC recommends that the Secretary of Health and Human Services (HHS) should:

1. Adopt the SACHRP Recommendations Regarding Research Uses of Newborn Dried Bloodspots and the Newborn Screening Saves Lives Reauthorization Act of 2014.
2. Partner with States to inform the development of guidance for Institutional Review Boards that distinguishes between the use of dried blood spots for research and non-research in the context of required, routine newborn screening program activities such as quality assurance, quality improvement and method development for new tests for conditions currently recommended for screening and for conditions being evaluated for possible inclusion on the Routine Uniform Screening Panel..
3. Partner with States to inform the development of guidance for Institutional Review Boards on models for broad informed consent for using residual dried blood spots to perform newborn screening research.
4. Partner with States to inform the development of guidance for Institutional Review Boards that identifies appropriate models for broad informed consent for states that choose to store residual dried blood spots for future research purposes.
5. Create and distribute communication materials targeted to professional organizations associated with obstetricians, nurses, midwives, and other health care workers who care for pregnant women and to the public on the importance of newborn screening and options for parents to participate in newborn screening research.
6. Consider mechanisms to fund States for translational research to:
    a. Develop practice/evidence-based guidelines on informed consent for use of residual dried blood spots which include a cost effectiveness analysis.
    b. Monitor research activities that require informed consent.

The Committee believes it is important to understand how requiring informed consent for storage of NBS samples for future research affects clinical newborn screening rates and encourages States to monitor these rates and compare them before and after policy implementation, taking into consideration any alternative explanations for changes. States are also encouraged to monitor who consents and who does not. This information could be valuable in determining what communication and educational materials are needed so that the overall newborn screening rate remains high and that the availability of stored NBS samples for research reflects the US newborn screening population.

On behalf of the Committee, we look forward to receiving your decision on these recommendations. Please know that the Committee stands ready to be of service to you to help strengthen the newborn screening programs that play such an important role in improving the health of the Nation's children.

Sincerely yours,



Joseph A. Bocchini Jr., M.D.
Chairperson

cc: Debi Sarkar, M.P.H.
Designated Federal Official
Health Resources and Services Administration