FDA based the burden estimates in Table 1 of this document on past experience with direct contact with the medical device manufacturers and anticipated changes in the medical device manufacturing patterns for the specific devices being monitored. FDA estimates that approximately 125 manufacturers would be contacted by telephone and/or electronic mail 3 times per year either to obtain primary data or to verify/validate data. Because the requested data represent data elements that are monitored or tracked by manufacturers as part of routine inventory management activities, it is anticipated that for most manufacturers, the estimated time required of manufacturers to complete the data request will not exceed 30 minutes per request cycle.

Dated: June 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15641 Filed 6–25–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children Request for Nominations

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of request for nominations.

SUMMARY: The Health Resources and Services Administration (HRSA) is seeking nominations of qualified candidates to be considered for appointment as members of the Advisory Committee on Heritable Disorders in Newborns and Children (Committee). The Committee provides advice, recommendations, and technical information about aspects of heritable disorders and newborn and childhood screening to the Secretary of Health and Human Services. HRSA is seeking nominations of qualified candidates to fill three positions on the Committee.

Authority: Section 1111 of the Public Health Service (PHS) Act, Title XI, § 1111(g)(1) (42 U.S.C. 300b–10(g)(1)), as amended by the Newborn Screening Saves Lives Reauthorization Act of 2014. The Committee is governed by the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.), and 41 CFR part 102–3 and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees.

DATES: Written nominations for membership on the Committee must be received on or before July 27, 2015.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to Ms. Lisa M. Vasquez, Genetic Services Branch, Maternal and Child Health Bureau, Health Resources and Services Administration, *lvasquez@hrsa.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Lisa Vasquez, Genetic Services Branch, Maternal and Child Health Bureau, HRSA, at *lvasquez@hrsa.gov* or (301) 443–4948. A copy of the Committee Charter and list of the current membership can be obtained by accessing the Advisory Committee Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

SUPPLEMENTARY INFORMATION: The Committee is chartered under section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b–10, as amended by the Newborn Screening Saves Lives Reauthorization Act of 2015 (Act). The Committee was established in 2003 to advise the Secretary of the U.S. Department of Health and Human Services regarding newborn screening tests, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. In addition, the Committee provides advice and recommendations to the Secretary concerning the grants and projects authorized under section 1109 of the PHS Act and technical information to develop policies and priorities for grants, including those that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns, and children having or at risk for heritable disorders.

The Committee is governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App. 2), and 41 CFR part 102–3, which set forth standards for the formation and use of advisory committees. The Committee reviews and reports regularly on newborn and childhood screening practices for heritable disorders, recommends improvements in the national newborn and childhood heritable screening programs, and recommends conditions for inclusion in the Recommended Uniform Screening Panel (RUSP). The Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the RUSP and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg–13, non-grandfathered health plans and group and individual health insurance issuers are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (*i.e.,* in the individual market, policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

Nominations: HRSA is requesting nominations to fill three (3) positions for voting members to serve on the Committee. Nominations of potential candidates for consideration are being sought for individuals who are medical, technical, public health, or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing, or specialty services for newborns and children at risk for heritable disorders; who have expertise in ethics (*i.e.,* bioethics) and infectious diseases and who have worked and published material in the area of newborn screening; members of the public having special expertise about or concern with heritable disorders; or members from such federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary. Interested applicants may self-nominate or be nominated by another individual and/or organization.

Individuals selected for appointment to the Committee will be invited to serve for up to 4 years. Members who are not federal officers or permanent federal employees are appointed as special government employees and receive a stipend and reimbursement for per diem and any travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee, as authorized by section 5 U.S.C. 5703 for persons employed intermittently in government service. Members who are officers or employees of the United States Government shall not receive additional compensation for service on the Committee, but receive per diem and travel expenses incurred for attending Committee meetings and/or conducting other business on behalf of the Committee. Nominees will be invited to serve during calendar year 2016.

The following information must be included in the package of materials submitted for each individual being

nominated for consideration: (1) A statement that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes such as expertise in bioethics, evidence review, public health, laboratory, maternal and child health, or clinical expertise in heritable disorders, which qualify the nominee for service in this capacity), and that the nominee is willing to serve as a member of the Committee; (2) the nominee's name, address, and daytime telephone number and the home/or work address, telephone number, and email address; and (3) a current copy of the nominee's curriculum vitae. Nomination packages may be summited directly by the individual being nominated or by the person/organization recommending the candidate.

The Department of Health and Human Services will make every effort to ensure that the membership of the Committee is fairly balanced in terms of points of view represented. Every effort is made to ensure that individuals from a broad representation of geographic areas, gender, ethnic and minority groups, as well as individuals with disabilities are given consideration for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of the Committee.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–15744 Filed 6–25–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Infant Mortality; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Infant Mortality (ACIM).

Dates and Times: July 13, 2015, 8:30 a.m.–5:30 p.m. (EST), July 14, 2015, 8:30 a.m.–3:30 p.m. (EST).

Place: Virtual via Webinar URL: *https://hrsa.connectsolutions.com/sacim_seminar_200/*. Call-In Number: 1.888.942.8170. Passcode: 3494113.

Status: The meeting is open to the public with attendance limited to availability of call-in lines. For more details and registration, please visit the ACIM Web site: *http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/index.html*).

Purpose: The Committee provides advice and recommendations to the Secretary of Health and Human Services on the following: Department of Health and Human Services' programs that focus on reducing infant mortality and improving the health status of infants and pregnant women; and factors affecting the continuum of care with respect to maternal and child health care. The Committee focuses on outcomes following childbirth; strategies to coordinate myriad federal, state, local, and private programs and efforts that are designed to deal with the health and social problems impacting infant mortality; and the implementation of the Healthy Start program and *Healthy People 2020* infant mortality objectives.

Agenda: Topics that will be discussed include the following: HRSA Update; MCHB Update; Healthy Start Program Update; the PREEMIE Act; and, ACIM's recommendations for the HHS National Strategy to Address Infant Mortality, specifically, *Strategy 5: Invest in adequate data, monitoring, and surveillance systems to measure access, quality, and outcomes.*

Proposed agenda items are subject to change as priorities dictate. The most current agenda will be posted on the ACIM Web site.

Time will be provided for public comments limited to 5 minutes each. Comments are to be submitted in writing no later than 5:00 p.m. EST on Friday July 3, 2015.

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the Committee should contact Michael C. Lu, M.D., M.P.H., Executive Secretary, ACIM, Health Resources and Services Administration, Room 18 W, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone: (301) 443–2170.

Individuals who are submitting public comments or who have questions regarding the meeting and location should contact David S. de la Cruz, Ph.D., M.P.H., ACIM Designated Federal Official, HRSA, Maternal and Child Health Bureau, telephone: (301) 443–0543, or email: *David.delaCruz@hrsa.hhs.gov*.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–15741 Filed 6–25–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of an Anti-TSLPR Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application 61/912,948 entitled ''Thymic Stromal Lymphopoietin Receptor-Specific Chimeric Antigen Receptors and Methods Using Same'' [HHS Ref. E–008–2014/0–US–01], U.S. Provisional Patent Application 61/991,697 entitled ''Thymic Stromal Lymphopoietin Receptor-Specific Chimeric Antigen Receptors and Methods Using Same'' [HHS Ref. E–008–2014/1–US–01], PCT Patent Application PCT/US2014/063096 entitled ''Thymic Stromal Lymphopoietin Receptor-Specific Chimeric Antigen Receptors and Methods Using Same'' [HHS Ref. E–008–2014/2–PCT–01], and all related continuing and foreign patents/patent applications for the technology family, to Lentigen Technology, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to:

''The development of a TSLPR–CAR-based immunotherapy using chimeric antigen receptors (CARs) having:

(1) The complementary determining region (CDR) sequences of either
  (a) the anti-TSLPR antibody known as 2D10 or
  (b) the anti-TSLPR antibody known as 3G11; and

(2) a T cell signaling domain