

designation annually and assume that an average of 70 hours is needed to prepare such a request.

We estimate 205 respondents will submit 261 requests for fast track designation requests annually and assume that an average of 60 hours is needed to prepare such a request.

Of the requests for fast track designation made per year, we granted approximately 224 requests from 392 respondents, and for each of these granted requests, a premeeting package was submitted. We therefore assume an average burden of 100 hours per respondent for preparing a premeeting package.

Finally, we estimate 33 respondents will submit 38 requests for RMA designation and assume that an average of 60 hours is needed to prepare such a request.

Dated: November 12, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Public Health Service Act and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting to be held on Tuesday, December 1, 2020. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at <https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html>.

DATES: Tuesday, December 1, 2020, from 10:00 a.m. to 2:45 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required. Please register online at <https://www.cvent.com/d/17qsn> by the deadline of 12:00 p.m. ET on Monday, November 30, 2020. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT:

Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18W66, Rockville, Maryland 20857; 301-443-0721; or ACHDNC@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. The ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13). Under this provision, non-grandfathered group health plans and health insurance issuers offering group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following:

- (1) Presentations on the decision making criteria and matrix used to evaluate conditions nominated to the RUSP;
- (2) review of newborn screening implementation for the following RUSP conditions: Severe combined immunodeficiency (SCID), critical congenital heart disease (CCHD), Pompe disease, mucopolysaccharidosis type I (MPS I), X-linked adrenoleukodystrophy (XALD); and
- (3) overview of the Review of Newborn Screening for Spinal Muscular Atrophy (SMA) report and vote on whether to submit this review to the Secretary.

In July 2018, SMA was added to the RUSP, and the Secretary requested a follow-up report that assesses the

impact of implementing screening for SMA. Following the overview of the Review of Newborn Screening for Spinal Muscular Atrophy report, the Committee is expected to vote on whether to submit this review to the Secretary or whether further action is warranted prior to its submission.

The agenda for this meeting does not include any plans for recommending a condition for inclusion in the RUSP. Agenda items are subject to changes as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, are also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to provide a written statement or make oral comments to the ACHDNC must be submitted via the registration website by Friday, November 27, 2020, by 10:00 a.m. ET.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

This meeting is being announced less than 15 days prior to the scheduled meeting due to an administrative issue that has now been resolved.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Treatment and Prevention of Neuropathic Pain With P2Y14 Antagonists

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Saint Louis University, ("SLU"), a non-profit university located in Missouri, in its rights to the inventions and patents listed in the