The draft meeting agenda will be posted on *www.acotmeetings.net* (but the timing of events may be subject to change). Those participating at this meeting should register by visiting *www.acotmeetings.net.* The deadline to register for this meeting is Monday, November 16, 2015. For all logistical questions and concerns, please contact Susie Gingrich, Leonard Resource Group, at 202–289–8322 or send an email to *sgingrich@lriginc.com.*

The public can join the meeting by:

1. (Audio Portion) Calling the Conference Phone Number (1–800–832–0736) and providing the Participant Code (1337210); and

2. (Visual Portion) Connecting to the ACOT Adobe Connect Pro Meeting using the following URL *https://lrg.adobeconnect.com/acot1115* (copy and paste the link into your browser if it does not work directly).

Participants should call and connect 15 minutes prior to the meeting for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: *https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm* and get a quick overview by following URL: *http://www.adobe.com/go/connectpro_overview.*

Call 202–289–8322 or send an email to *sgringrich@lrginc.com* if you are having trouble connecting to the meeting site.

Public Comment: It is preferred that persons interested in providing an oral presentation email a written request, along with a copy of their presentation to Patricia Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, at *pstroup@hrsa.gov.* Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative.

The allocation of time may be adjusted to accommodate the level of expressed interest. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may request it during the public comment period. Public participation and ability to comment will be limited to time as it permits.

FOR FURTHER INFORMATION CONTACT: Patricia Stroup, MBA, MPA, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 17W65, Rockville, MD 20857; telephone 301–443–1127.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–26523 Filed 10–19–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders in Newborns and Children.

Dates and Times: November 3, 2015, 9:00 a.m. to 4:00 p.m.

Place: Webinar.

Status: The meeting will be open to the public. Please register at *https://www.blsmeetings.net/ACHDNCNovember2015/.* The registration deadline is Friday, October 30, 2015, 11:59 p.m. Eastern Time.

Purpose: The Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by the Public Health Service Act (PHS), Title XI, § 1111 (42 U.S.C. 300b–10), was established to advise the Secretary of the Department of Health and Human Services about 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. In addition, the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (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.*, policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

Agenda: The meeting will include: (1) Discussion and vote on the statutory Committee's proposed bylaws, (2) a discussion of nomination process for prospective organizational representatives, (3) a presentation on the Notice of Proposed Rulemaking on Federal Policy for the Protection of Human Subjects and the potential impact on newborn screening research, (4) updates from the Pilot Study Workgroup, Cost Analysis Workgroup, and Timeliness Workgroup, (5) a presentation on transition models from pediatric to adult health care using innovative strategies, and (6) a presentation on current education activities within newborn screening and impact on families and children. There are no votes that involve proposed additions of a condition to the RUSP scheduled for this meeting.

Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's Web site at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders.*

Registration: Registration information will be on the Committee Web site at *https://www.blsmeetings.net/ACHDNCNovember2015/.* The registration deadline is Friday, October 30, 11:59 p.m. Eastern Time.

Public Comments: Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. Advance registration is required to present oral comments and/or submit written comments. Oral public comments are tentatively scheduled for November 3, 2015. Individuals who wish to present oral public comments must indicate this when registering. Written comments may be uploaded on the registration Web site and must be received by the registration deadline (October 30, 11:59 p.m. Eastern Time), as this will allow them to be included in the November meeting briefing book. Individuals who wish to present oral comments and/or provide written comments should identify on the registration Web site the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (*i.e.*, parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated,

the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted. For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: *lvasquez@hrsa.gov*.

Contact Person: Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18W68, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: *dsarkar@hrsa.gov*.

More information on the Advisory Committee is available at *http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders*.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–26524 Filed 10–19–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than December 21, 2015.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program and Collection of Manufacturer Data to Verify 340B Drug Pricing Program Ceiling Price Calculations.

OMB No. 0915–0327—Revision.

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted as Section 340B of the Public Health Service Act (PHS Act; ''Limitation on Prices of Drugs Purchased by Covered Entities''), provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula (''ceiling price''). A manufacturer subject to a PPA must offer all covered outpatient drugs at no more than the ceiling price to a covered entity listed in the 340B Program database. The manufacturer shall rely on the information in the 340B database to determine if the covered entity is participating in the 340B Program or for any notifications of changes to eligibility that may occur within a quarter. By signing the PPA, the manufacturer agrees to comply with all applicable statutory and regulatory requirements.

The purpose of this revision is to include an addendum to the PPA to incorporate the administrative requirement for manufacturer integrity provisions directly addressed in the Affordable Care Act.

Need and Proposed Use of the Information: HRSA is proposing revisions to the current PPA to include an addendum in response to manufacturer integrity provisions implemented in the Affordable Care Act. Section 7102(b) of the Affordable Care Act amends section 340B(a)(1) of the Public Health Service Act (PHSA) to add two new requirements for inclusion in the PPA with manufacturers of covered outpatient drugs:

I. ''Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the ''ceiling price'') and

II. ''. . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.''

These requirements shall be included in the PPA addendum to be signed by manufacturers participating in the 340B Program to ensure that the provisions of the 340B statute requiring inclusion in the PPA are satisfied. The execution of the addendum by manufacturers will fulfill the administrative requirement of the statute that these provisions be included in the PPA. The burden imposed on manufacturers by the proposed requirement of the PPA is minimal because the addendum does not impose requirements beyond review and a signature by the manufacturer.

Likely Respondents: Drug Manufacturers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.