(ASRs); (4) FDA-verified status of open PMRs/PMCs reported in § 314.81(b)(2)(vii) or § 601.70 ASRs; (5) the status of closed PMRs/PMCs; and (6) the distribution of the status by fiscal year of establishment [2] (FY2011 to FY2017) for PMRs and PMCs open at the end of FY2017, or those closed within FY2017. Additional information about PMRs/PMCs is provided on FDA's website at *https://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Post-marketing PhaseIVCommitments/default.htm.*

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–25128 Filed 11–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

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

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

SUPPLEMENTARY INFORMATION: Section 100.2 of VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of HHS (the Secretary), is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court), and will be published periodically in a notice in the **Federal Register**. This figure is calculated using the most recent Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation (KFF) Employer Health Benefits Survey or other authoritative source that may be more accurate or appropriate.

In 2018, MEPS–IC, available at *www.meps.ahrq.gov,* published the annual 2017 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was $6,368. This figure is divided by 12 months to determine the cost per month of $530.67. The $530.67 figure is increased or decreased by the percentage change reported by the most recent KFF Employer Health Benefits Survey, available at *www.kff.org.* The percentage increase from 2017 to 2018 was 3.0 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is $546.59.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is $546.59 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on November 13, 2018.

Dated: November 13, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–25087 Filed 11–16–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Meeting of the Advisory Committee on Infant Mortality

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

ACTION: Notice.

SUMMARY: The Advisory Committee on Infant Mortality (ACIM) has scheduled a public meeting.

DATES: December 4, 2018, 9:00 a.m.–5:00 p.m. ET and December 5, 2018, 9:00 a.m.–3:30 p.m. ET.

ADDRESSES: This meeting will be held in-person and by webinar. The address for the meeting is 5600 Fishers Lane, Room 5W11, Rockville, Maryland 20857. Instructions on how to access the meeting via webcast will be provided upon registration.

Information about ACIM and the agenda for this meeting can be found on the ACIM website at *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.* While this meeting is open to the public, advance registration is required. Registration information and information about the ACIM can be obtained by accessing: *https://www.hrsa.gov/advisory-committees/infant-mortality/index.html.*

FOR FURTHER INFORMATION CONTACT: David S. de la Cruz, Ph.D., MPH, Designated Federal Official (DFO), at HRSA, Maternal and Child Health Bureau (MCHB), 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0543; or *dcruz@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACIM provides advice and recommendations to the Secretary of HHS (Secretary) on HHS programs and activities 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. ACIM focuses on outcomes before, during, and following pregnancy and childbirth, strategies to coordinate a myriad of federal, state, local, and private programs, efforts that are designed to deal with the health and social problems impacting infant mortality, and the implementation of the federal Healthy Start Program.

The meeting agenda is being finalized and tentatively includes updates on HRSA, MCHB, and the Healthy Start Program, an introduction of members, a briefing on infant mortality and health disparity data in the U.S., and future topic areas for ACIM to discuss. Agenda items are subject to changes as priorities dictate. The final meeting agenda will be available 2 days prior to the meeting on the ACIM website: *https://www.hrsa.gov/advisory-committees/Infant-Mortality/index.html.* Refer to the ACIM website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments on the afternoon of December 5, 2018. Written comments must be submitted via email to the DFO, David S. de la Cruz, by 12:00 p.m. ET on Tuesday, November 20, 2018, at *dcruz@hrsa.gov.* Please indicate if your comments will be written only or if you are requesting to present your comments in person during the meeting. All comments (oral and written) will be part of the official meeting record. To ensure all individuals who have requested time for oral comments are accommodated, the allocated time for each comment will be limited to no more than 3 minutes. More complete/longer comments should be submitted in writing. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual

[2] The establishment date is the date of the formal FDA communication to the applicant that included the final FDA-required (PMR) or -requested (PMC) postmarketing study or clinical trial.

presentations are permitted. Comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*e.g.,* parent, family member, researcher, clinician, public health, etc.), and the topic/subject matter. Oral comments must be presented in-person and not via phone/webinar.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify David S. de la Cruz at the address and phone number listed above at least 10 days prior to the meeting. Since this meeting occurs in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 10 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–25105 Filed 11–16–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 10⅛%, as fixed by the Secretary of the Treasury, is certified for the quarter ended September 30, 2018. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))'' and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

Dated: October 10, 2018.

David C. Horn,

Director, Office of Financial Policy and Reporting.

[FR Doc. 2018–25204 Filed 11–16–18; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Activities Deemed Not To Be Research: Public Health Surveillance, 2018 Requirements

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled, ''Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements.''

DATES: Submit written comments by December 19, 2018.

ADDRESSES: Submit written requests for a single copy of the draft guidance document entitled ''Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements,'' to the Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–453–6909. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance documents.

You may submit comments identified by docket ID number HHS–OS–OPHS–2018–0015 (Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements), by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Enter the docket ID number and click on ''Search.'' On the next page, click the ''Comment Now'''' action and follow the instructions.
- *Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]:* Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

Comments received, including any personal information, will be posted without change to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Irene Stith-Coleman, Ph.D., Office for Human Research Protections, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, 240–453–6900; email *Irene.Stith-Coleman@hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Overview

OHRP, Office of the Assistant Secretary for Health, is announcing the availability of a draft guidance document entitled ''Activities Deemed Not to Be Research: Public Health Surveillance, 2018 Requirements.'' This guidance document applies to activities that are conducted or supported by HHS. It is intended to help entities determine whether a planned activity constitutes a public health surveillance activity deemed not to be research under the 2018 Requirements (the revised subpart A of 45 CFR part 46, effective July 19, 2018). The draft guidance document, when finalized, will represent OHRP's current thinking on this topic. OHRP obtained input from HHS agencies and the Common Rule departments and agencies in developing the draft guidance document.

II. Electronic Access

Persons with access may obtain the draft guidance documents on OHRP's website at *https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/index.html*.

Dated: November 8, 2018.

Julie Kaneshiro,

Deputy Director, Office for Human Research Protections.

[FR Doc. 2018–25202 Filed 11–16–18; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board Public Teleconference

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human