

(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 establishment² (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/GuidanceComplianceRegulatoryInformation/Post-marketingPhaseIVCommitments/default.htm>.

Dated: November 13, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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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.

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.

In 2018, MEPS-IC, available at www.meeps.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.

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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