

the requirements of the applicable statutes and regulations. This draft guidance, when finalized, will contain both binding and nonbinding provisions.

As we develop any final guidance on this topic, FDA will consider comments on the applicability of Executive Order 14192, per OMB guidance M–25–20, and in particular, on any costs or cost savings.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological

Health guidance documents is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products>. This guidance document is also available at <https://www.regulations.gov>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>. Persons unable to download an electronic copy of “Electronic Submission Template for Medical Device Q-Submissions” may send an email request to [CDRH-Guidance@](mailto:CDRH-Guidance@fda.hhs.gov)

[fda.hhs.gov](mailto:fda.hhs.gov) to receive an electronic copy of the document. Please use the document number GUI00007041 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA Form	Topic	OMB control No.
“Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program”.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756

Dated: May 22, 2025.

**Grace R. Graham,**  
*Deputy Commissioner for Policy, Legislation, and International Affairs.*  
[FR Doc. 2025–09615 Filed 5–28–25; 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).

FOR FURTHER INFORMATION CONTACT: CAPT George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, HHS by mail at 5600 Fishers Lane, 08–W25A, Rockville, Maryland 20857; or call (301) 443–9350.

SUPPLEMENTARY INFORMATION: Section 100.2 of the 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**. The Secretary delegated this responsibility to the Director of the Division of Injury Compensation Programs. This figure is calculated using the most recent Medical Expenditure Panel Survey–Insurance Component 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 Employer Health Benefits Survey.

In 2024, the Medical Expenditure Panel Survey–Insurance Component, available at [www.meps.ahrq.gov](http://www.meps.ahrq.gov), published the annual 2023 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$8,182. This figure is divided by 12 to determine the cost per month of \$681.83. The \$681.83 figure is increased or decreased by the percentage change reported by the most recent Kaiser Family Foundation Employer Health Benefits Survey, available at [www.kff.org](http://www.kff.org). The increase from 2023 to 2024 was six percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is \$722.74.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$722.74 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 January 7, 2025.

**George Reed Grimes,**  
*Director, Division of Injury Compensation Programs.*  
[FR Doc. 2025–09694 Filed 5–28–25; 8:45 am]  
BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business: Bioengineering, Device Development and Neurosurgery.  
*Date:* June 25–26, 2025.  
*Time:* 9:00 a.m. to 7:00 p.m.  
*Agenda:* To review and evaluate grant applications.