

use of RWE to: (1) Help to support the approval of a new indication for a drug approved under section 505(c) of the FD&C Act (21 U.S.C. 355(c)); and (2) help to support or satisfy postapproval study requirements. This section also requires that FDA use the program to inform guidance for industry on the circumstances under which sponsors of drugs may rely on RWE and the appropriate standards and methodologies for the collection and analysis of RWE submitted to evaluate the potential use of RWE for those purposes. Further, under the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), FDA committed to the goal of publishing draft guidance on how RWE can contribute to the assessment of safety and effectiveness in regulatory submissions.

FDA is issuing the draft guidance as part of a series of guidance documents to satisfy the Cures Act mandate and the PDUFA VI goal. The RWE Program will cover clinical studies that use real-world data sources, such as information from routine clinical practice, to derive RWE.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have

been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Renewal for the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, HHS is hereby giving notice that the Advisory Committee on Infant Mortality has been renamed the Advisory Committee on Infant and Maternal Mortality (ACIMM) and has been renewed.

DATES: The effective date of the charter renewal is September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Vanessa Lee, MPH, Designated Federal Official, HRSA, Maternal and Child Health Bureau, 5600 Fishers Lane, 18N84, Rockville, Maryland 20857; (301) 443–0543; or VLee1@hrsa.gov.

SUPPLEMENTARY INFORMATION: ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended, (5 U.S.C. App. 2), which sets forth standards for the formation and use of Advisory Committees. ACIMM advises the Secretary of HHS on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before,

during, and after pregnancy. The Committee provides advice on how best to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, and maternal health, as well as influence similar efforts in the private and voluntary sectors. ACIMM provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The charter renewal and name change for ACIMM was approved on September 30, 2021, which will also stand as the filing date. Renewal of the ACIMM charter gives authorization for the ACIMM committee to operate until September 30, 2023.

A copy of the ACIMM charter is available on the ACIMM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is <http://www.facadatabase.gov/>.

Maria G. Button,

Director, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information
Collection Request Title: The HRSA Community-Based Outreach Reporting Module, OMB #0906–0064, Revision

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

ACTION: Notice.