various revisions to CNMI's primacy program. For the revision covered by this action, EPA promulgated the GWR at 40 CFR subpart S on November 8, 2006 (71 FR 65574). The GWR provides protection against microbial pathogens in public water systems using ground water sources. EPA has determined that the GWR requirements were adopted into the CNMI Commonwealth Register, Section 2141 (alternatively published as Northern Mariana Islands Administrative Code, Title 65, Chapter 20) in a manner that CNMI's regulations are comparable to and no less stringent than the federal requirements. EPA has also determined that CNMI's program revision request meets all of the regulatory requirements for approval, as set forth in 40 CFR 142.12, including a side-by-side comparison of the Federal requirements demonstrating the corresponding CNMI authorities, additional materials to support special primacy requirements of 40 CFR 142.16, a review of the requirements contained in 40 CFR 142.10 necessary for CNMI to attain and retain primary enforcement responsibility, and a statement by the CNMI Attorney General certifying that CNMI's laws and regulations to carry out the program revision were duly adopted and are enforceable. The Attorney General's statement also affirms that there are no environmental audit privilege and immunity laws that would impact CNMI's ability to implement or enforce the CNMI laws and regulations pertaining to the program revision. Therefore, EPA approves this revision of CNMI's approved primacy program. The Technical Support Document, which provides EPA's analysis of CNMI's program revision request, is available by submitting a request to the following email address: *R9dw-program@epa.gov.* Please note ''Technical Support Document'' in the subject line of the email.

Public Process. Any interested person may request a public hearing on this determination. A request for a public hearing must be received or postmarked before February 2, 2022, and addressed to the Regional Administrator of EPA Region 9, via the following email address: *R9dw-program@epa.gov,* or by contacting the EPA Region 9 contact person listed above in this notice by telephone if you do not have access to email. Please note, ''State Program Revision Determination'' in the subject line of the email. The Regional Administrator may deny frivolous or insubstantial requests for a hearing. If a timely request for a public hearing is made, then EPA Region 9 may hold a public hearing. Any request for a public hearing shall include the following information: 1. The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; 2. A brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such hearing; and 3. The signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or other entity.

If EPA Region 9 does not receive a timely request for a hearing or a request for a hearing was denied by the Regional Administrator for being frivolous or insubstantial, and the Regional Administrator does not elect to hold a hearing on their own motion, EPA's approval shall become final and effective on February 2, 2022, and no further public notice will be issued.

Authority: Section 1413 of the Safe Drinking Water Act, as amended, 42 U.S.C. 300g–2 (1996), and 40 CFR part 142 of the National Primary Drinking Water Regulations.

Dated: December 23, 2021.

Deborah Jordan,

Acting Regional Administrator, EPA Region 9.

[FR Doc. 2021–28330 Filed 12–30–21; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2021–06; Docket No. 2021–0002, Sequence No. 30]

Calendar Year (CY) 2022 Privately Owned Vehicle (POV) Mileage Reimbursement Rates; CY 2022 Standard Mileage Rate for Moving Purposes

AGENCY: Office of Government-Wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice.

SUMMARY: GSA is updating the mileage reimbursement rate for privately owned automobiles (POA), airplanes, and motorcycles as required by statute. This information will be available in FTR Bulletin 22–05, which can be found on GSA's website at *https://gsa.gov/ftrbulletins.*

DATES: *Applicability date:* This notice applies to travel and relocation performed on or after January 1, 2022 through December 31, 2022.

FOR FURTHER INFORMATION CONTACT: For clarification of content, please contact Ms. Cheryl D. McClain-Barnes, Program Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–208–4334, or by email at *travelpolicy@gsa.gov.* Please cite Notice of FTR Bulletin 22–05.

SUPPLEMENTARY INFORMATION: GSA is required by statute to set the mileage reimbursement rate for privately owned automobiles (POA) as the single standard mileage rate established by the Internal Revenue Service (IRS). The IRS mileage rate for medical or moving purposes is used to determine the POA rate when a Government-furnished automobile is authorized and also represents the privately owned vehicle (POV) standard mileage reimbursement rate for official relocation. Finally, GSA conducts independent reviews of the cost of travel and the operation of privately owned airplanes and motorcycles on an annual basis to determine their corresponding mileage reimbursement rates. These reviews evaluate various factors, such as the cost of fuel, depreciation of the original vehicle cost, maintenance and insurance, state and Federal taxes, and consumer price index data. FTR Bulletin 22–05 establishes and announces the new CY 2022 POV mileage reimbursement rates for official temporary duty and relocation travel. This notice is the only notification to agencies of revisions to the POV mileage rates for official travel and relocation, in addition to the changes posted on GSA's website at *https://gsa.gov/mileage.*

Krystal J. Brumfield,

Associate Administrator, Office of Government-Wide Policy.

[FR Doc. 2021–28450 Filed 12–30–21; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed

information collection project ''Online Application Order Form for Products from the Healthcare Cost and Utilization Project (HCUP).''

DATES: Comments on this notice must be received by March 4, 2022.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Online Application Order Form for Products From the Healthcare Cost and Utilization Project (HCUP).

The Healthcare Cost and Utilization Project (HCUP, pronounced ''H-Cup'') is a vital resource helping the Agency achieve its research agenda, thereby furthering its goal of improving the delivery of health care in the United States. HCUP is a family of health care databases and related software tools and products developed through a Federal-State-Industry partnership and sponsored by AHRQ. HCUP includes the largest collection of longitudinal hospital care data in the United States, with all-payer, encounter-level information beginning in 1988. The HCUP databases are annual files that contain anonymous information from hospital discharge records for inpatient care and certain components of outpatient care, such as emergency care and ambulatory surgeries. The project currently releases eight types of databases created for research use on a broad range of health issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels. HCUP also produces a large number of software tools to enhance the use of administrative health care data for research and public health use. Software tools use information available from a variety of sources to create new data elements, often through sophisticated algorithms, for use with the HCUP databases.

HCUP's objectives are to:

- Create and enhance a powerful source of national, state, and all-payer health care data.
- Produce a broad set of software tools and products to facilitate the use of HCUP and other administrative data.
- Enrich a collaborative partnership with statewide data organizations (that voluntarily participate in the project) aimed at increasing the quality and use of health care data.
- Conduct and translate research to inform decision making and improve health care delivery.

This project is being conducted by AHRQ through its primary contractor and subcontractor, IBM Watson Health and Pantheon Software, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the outcomes, cost, cost-effectiveness, and use of health care services and access to such services. 42 U.S.C. 299a(a)(3).

Method of Collection

The project currently creates eight types of restricted access public release databases and related files that are released to authorized users under the terms of the HCUP Data Use Agreement (DUA). These HCUP databases and files are used by researchers for a broad range of health issues, including cost and quality of health services, medical practice patterns, access to health care programs, and outcomes of treatments at the national, State, and local market levels.

HCUP achieves the restricted access public release and tracking of the HCUP databases through the Online Application Form for HCUP Products (*https://www.distributor.hcup-us.ahrq.gov/SpecialPages/Shoppingcart.aspx*). To access the eight types of database, HCUP users are required to complete the Online Application Form for HCUP Products which includes three components, the application, HCUP DUA training (*https://www.hcup-us.ahrq.gov/DUA/dua/index.html*) and signing a HCUP DUA. Users are required to sign one of two DUAs: (1) Nationwide or (2) state (hereafter referred to collectively as the HCUP DUA) after they complete the HCUP DUA training.

Information collected in the HCUP Online Application Form process will be used for two purposes only:

1. *Business Transaction:* In order to deliver the HCUP databases to the applicants, contact information is necessary for shipping the data on disk (or any other media used in the future) and payment collection.

2. *Enforcement of the HCUP Data Use Agreement (DUA):* The HCUP DUA contains several restrictions on use of the data. Most of these restrictions have been put in place to safeguard the privacy of individuals and establishments represented in the data. For example, data users can only use the data for research, analysis, and aggregate statistical reporting and are prohibited from attempting to identify any persons in the data. Contact information on HCUP DUAs is retained in the event that a violation of the HCUP DUA takes place requiring legal remedy.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden associated with the applicants' time to order any of the HCUP databases. An estimated 1,800 persons will order HCUP data annually. Each of these persons will complete Online Application Order Form for HCUP products (30 minutes). The total burden for the Online Application Order Form is estimated to be 900 hours annually.

Exhibit 2 shows the estimated annualized cost burden associated with the applicants' time to order HCUP data. The total cost burden is estimated to be $39,879 annually.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Total for the HCUP Data Purchase Ordering Form	1,800	1	30/60	900

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Total	1,800	900	$44.31	$39,879

* *Based upon the mean of the average wages for Life Scientists, All Other (19–1099), National Compensation Survey:* Occupational Employment Statistics, May 2020 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *https://www.bls.gov/oes/current/oes_nat.htm#19-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: December 28, 2021.

Marquita Cullom,

Associate Director.

[FR Doc. 2021–28441 Filed 12–30–21; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA), Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Tobacco Products (CTP) have modified their organizational structures. These new organizational structures were approved by the Deputy Secretary of Health and Human Services and effective on November 24, 2021.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD 20705–4304, 301–796–3843.

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect the Food and Drug Administration's reorganizations of CBER, CDER's Office of Medical Policy (OMP), Office of Prescription Drug Promotion (OPDP), CDRH's Office of Product Evaluation and Quality, and CTP's Office of Compliance and Enforcement and Office of Science.

This reorganization will help to enhance these organization's ability to advance FDA's mission and streamline operations and support functions.

The Center for Biologics Evaluation and Research's organizational changes in the Office of the Center Director (OD), the Office of Management, and the Office of Communications, Outreach, and Development refocus functions that support CBER's product offices to better support the expected growth in those offices. The OD's functions are streamlined into those that require intensive engagement from the Center Director and have no other natural home. Several responsibilities are realigned or consolidated to leverage synergies with other functions. Harnessing the power of real-world evidence is a priority in the FDA Priority Framework, the 21st Century Cures Act, and the PDUFA commitment letter. The changes proposed to CBER's Office of Biostatistics and Epidemiology (OBE) position the center to advance real-world evidence priorities for biologics.

The 21st Century Cures Act established the Regenerative Medicine Advanced Therapy (RMAT) designation program, in Office of Tissues and Advanced Therapies (OTAT), and called on FDA to work to advance standards development for regenerative medicine products in order to support the development, evaluation, and review of regenerative medicine products. The RMAT program has generated tremendous industry interest, and CBER has granted 129 RMAT designations since program inception in December 2016.

One of FDA's key priorities is leveraging innovation to advance public health goals by continually improving the product development process and strengthening FDA's gold standard. CBER's portfolio of products is currently seeing an unprecedented level of innovation and growth. These innovations range from the development of new pathogen inactivation technology that has the potential to drastically improve how FDA promotes blood safety, the explosion in submissions for gene therapies that have the potential to transform patients' lives, innovations in approaches to managing serious food allergies, and advances in manufacturing technology for vaccines. The changes proposed in two of CBER's product offices: OTAT and the Office of Blood Research and Review (OBRR) along with the crosscutting functions in OBE and Office of Compliance and Biologics Quality are intended to ensure CBER's regulatory structures and processes are prepared to respond to innovation and development in the industry while upholding FDA's standards for safety and effectiveness for biological products. Establishing the Office of Regulatory Operations will help CBER support continued efficiency and effectiveness in CBER's regulatory processes and provide strategic direction as the Center works to modernize its supporting information technology (IT) infrastructure.

The Center for Drug Evaluation and Research's OMP, Office of Prescription