

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Employees and Representatives	Health Hazard Evaluation Request Form.	175	1	12/60	35
Employers	Health Hazard Evaluation Request Form.	75	1	12/60	15
Employees	Health Hazard Evaluation specific interview example.	1,470	1	15/60	368
Employees	Health Hazard Evaluation specific questionnaire example.	2,100	1	30/60	1,050
Employees	HHE specific informed consent form ...	60	1	30/60	30
Employees	Contact information post card	1,225	1	5/60	102
Employees and Representatives; Employers—Year 1 (on-site evaluation).	First Followback Survey	140	1	10/60	23
Employees and Representatives; Employers—Year 1 (on-site evaluation).	Second Followback Survey	140	1	20/60	47
Employees and Representatives; Employers—Year 2 (on-site evaluation).	Third Followback Survey	140	1	15/60	35
Employees and Representatives; Employers—Year 1 (without on-site evaluation).	First Followback Survey	94	1	10/60	16
Employees and Representatives; Employers—Year 2 (without on-site evaluation).	Second Followback Survey	94	1	15/60	24
Total	1,745

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

[FR Doc. 2023-16221 Filed 7-31-23; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10241]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are

invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 2, 2023.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10241 Survey of Retail Prices
Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Survey of Retail Prices; *Use:* This information collection request provides for a survey of the average acquisition costs of all covered outpatient drugs purchased by retail community pharmacies. CMS may contract with a vendor to conduct monthly surveys of retail prices for covered outpatient drugs. Such prices represent a nationwide average of consumer purchase prices, net of discounts and rebates. The contractor shall provide notification when a drug product becomes generally available and that the contract includes such terms and conditions as the Secretary shall specify, including a requirement that the vendor monitor the marketplace. CMS has developed a National Average Drug Acquisition Cost (NADAC) for states to consider when developing reimbursement methodology. The NADAC is a pricing benchmark that is based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchmark is based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey is conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date. *Form Number:* CMS-10241 (OMB control number 0938-1041); *Frequency:* Monthly; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 72,000; *Total Annual Responses:* 72,000; *Total Annual Hours:* 36,000. (For policy questions regarding this collection contact: Robert Giles at 667-290-8626.)

Dated: July 27, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-16281 Filed 7-31-23; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare and Medicaid Services, Center for Medicare and Medicaid Innovation (CMMI), has modified its organizational structure.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services and took effect on July 27, 2023.

FOR FURTHER INFORMATION CONTACT: Joe Kane at (410) 786-0655; 7500 Security Blvd., Baltimore, MD.

SUPPLEMENTARY INFORMATION: Part F of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) (last amended at **Federal Register**, Vol. 88, No. 107, pp. 36586-36587, dated June 5, 2023) is further amended to reflect the establishment of the Division of Drug Innovation within the Center for Medicare and Medicaid Innovation (CMMI). Part F, Section FC. 10 (Organization) is revised as follows: Center for Medicare and Medicaid Innovation (CMMI), Seamless Care Models Group, Seamless Care Models Group, Division of Health Plan Innovations

Part F, Section FC. 20 (Functions) for the new organization is as follows:

Centers for Medicare & Medicaid Services

Office of the Administrator

Center for Medicare and Medicaid Innovation

Seamless Care Models Group

Division of Drug Innovation

- Directs, designs and implements models to test alternative approaches to payment for drugs in Medicare Part B, Part D, and Medicaid to optimize access to high quality, affordable drugs.

- Seeks and develop opportunities to include Part B and Part D drugs in alternative payment models, including accountable care models, and addresses regulatory and operational issues that arise when trying to develop a model crossing different parts of the Medicare program.

- Builds relationships within CMS and HHS, with States and Medicaid agencies, and with both governmental and non-governmental entities to develop, implement, and operate innovative Medicare Part B, Part D, and Medicaid models.

- Meets with model participants and other interested parties, including relevant Government officials, representatives from the pharmaceutical industry, payers, providers, academia, and consumer advocates regarding their perspectives on innovative models, research, and ideas for new models.

- Conducts formative research studies to inform innovative payment models.

- Provides technical expertise to various CMS and non-Governmental entities on innovative Medicare Part B, Part D, and Medicaid payment and service delivery models to optimize access to affordable drugs.

Authority: 44 U.S.C. 3101.

Xavier Becerra,

Secretary of Health and Human Services.

[FR Doc. 2023-16280 Filed 7-31-23; 8:45 am]

BILLING CODE 4150-28-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-P-1574]

Determination That Progesterone Injection, USP, 50 Milligrams/Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Progesterone Injection, USP, 50 milligrams/milliliter (mg/mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Iris Masucci, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-3600, Iris.Masucci@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and