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)
Primary care providers	Provider survey	40	1	10/60	7
Men ages 55–69	Patient eligibility screener	900	1	8/60	120
Men ages 55–69	Pre-exposure survey	900	1	20/60	300
Men ages 55–69	Post-exposure survey	900	1	20/60	300
Men ages 55–69	Post-clinic survey	300	1	18/60	90
Men ages 55–69	Usability survey	30	1	20/60	10
Men ages 55–69	User experience interview	900	1	20/60	300
Clinic coordinators	Clinic coordinator interview	4	1	30/60	2
Total					1,129

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. 2024–01550 Filed 1–25–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10887]

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 (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 March 26, 2024.

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–10887 The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Advantage Prescription Drug (MARx) System Updates for the Medicare Prescription Payment Plan Program

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:* New collection (Request for a new OMB control number); *Title of Information Collection:* The Medicare Advantage and Prescription Drug Programs: Part C and Part D Medicare Advantage Prescription Drug (MARx) System Updates for the Medicare Prescription Payment Plan Program; *Use:* The IRA amended the Act by adding section 1860D–2(b)(2)(E) which, beginning January 1, 2025, establishes the Medicare Prescription Payment Plan program (hereinafter referred to as the ''program''). Under this program, MA Organizations offering Part D coverage and Part D sponsors (collectively ''Part D plans'' or ''Plans'') are required to offer enrollees the option to pay their Part D cost sharing in monthly amounts spread out over the plan year based on the formulae described in section 1860D–2(b)(2)(E)(iv) of the Act.

To effectively monitor the program, Part D plans will be required to report data elements related to the program at the beneficiary, contract, and Plan Benefit Package (PBP)1 levels beginning in Contract Year (CY) 2025. In this information collection package, CMS addresses the proposal to require Part D plans to submit beneficiary-level data elements into the MARx system via a program-specific transaction (separate from the enrollment file). In accordance with the Plan Communication User Guide (PCUG), plans may submit multiple transaction files during any CMS business day, Monday through Friday. Plan transactions are processed as received; there is no minimum or maximum limit to the number of files that Plans may submit in a day. In general, transaction and processing occur throughout the Current Calendar Month (CCM). For CY 2025, CMS will not require independent data validation for this new MARx reporting requirement. *Form Number:* CMS–10887 (OMB control number: 0938-New); *Frequency:* Monthly; *Affected Public:* Private, Federal Government, Business or other for profits, Not-for-profits institutions; *Number of Respondents:* 856; *Total Annual Responses:* 3,200,856; *Total Annual Hours:* 59,958. (For policy questions regarding this collection contact Michael Brown at (872) 287–1370 or *michael.brown3@cms.hhs.gov.*)

Dated: January 23, 2024.

William N. Parham, III

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–01582 Filed 1–25–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3768]

Best Practices for Food and Drug Administration Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products; Final Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final document entitled ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products.'' The 21st Century Cures Act (Cures Act), enacted on December 13, 2016, requires that FDA make publicly available on its internet website best practices for certain postmarketing drug safety surveillance activities. This final document sets forth risk-based principles for FDA's conduct of ongoing postmarketing safety surveillance for human drug products and human biological products, in part, to address the Cures Act requirements. This document finalizes the draft document entitled ''Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff'' that was issued on November 7, 2019.

DATES: The announcement of the final document is published in the **Federal Register** on January 26, 2024.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–3768 for ''Best Practices for FDA Staff in the Postmarketing Safety Surveillance of Human Drug and Biological Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this document to the Division of Drug Information, Center for Drug