Exhibit 2 shows the annualized cost burden to submit the Online Submission Form. The cost burden is estimated to be $7,449.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Total burden hours	Average hourly wage rate *	Adjusted hourly wage rate **	Total cost burden
OSF	50	$74.49	$148.98	$7,449
Total	50	N/A	N/A	7,449

* Occupational Employment Statistics, May 2024 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. Based on the mean wages for *Public Relations and Fundraising Managers, 11–2030,* the occupational group most likely tasked with completing the OSF. *http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.*

** The Adjusted Hourly Rate was estimated at 200% of the hourly wage.

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: September 15, 2025.

Mamatha Pancholi,

Deputy Director.

[FR Doc. 2025–18156 Filed 9–18–25; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10595, CMS–10834 and CMS–10511]

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 November 18, 2025.

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–10595—QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods

CMS–10834—Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

CMS–10511—Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies

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 Collections

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* QHP Issuers Data Collection for Notices for Plan or Display Errors Special Enrollment Periods; *Use:* The Patient Protection and Affordable Care Act (Pub. L. 111–148) and Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), collectively referred to as the PPACA, established new competitive private health insurance markets called Marketplaces, or Exchanges, which gave millions of Americans and small businesses access to qualified health plans (QHPs), including stand-alone dental plans (SADPs)—private health and dental insurance plans that have been certified as meeting certain standards.

In the final rule, the Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 (CMS–9937–F), we finalized 45 CFR 156.1256, which requires QHP issuers, in the case of a material plan or benefit display error included in 45 CFR 155.420(d)(12), to notify their enrollees of the error and the enrollees' eligibility for a special enrollment period (SEP) within 30 calendar days after the issuer is informed by an Federally-facilitated Exchange (FFE) that the error is corrected, if directed to do so by the FFE. This requirement provides notification to QHP enrollees of errors that may have impacted their QHP selection and enrollment and any associated monthly or annual costs, as well as the availability of an SEP under § 155.420(d)(12) for the enrollee to select a different QHP, if desired.

The original approved information collection request (ICR) (OMB #: 0938–1301) titled Third Party Payment of QHP Premiums and Additional Notices for QHP Issuers Data Collection was approved on 9/13/2016. The ICR was approved with change on 1/3/2020 and most recently approved on 03/01/2023. This ICR serves as the formal request for an extension without change of a currently approved clearance. *Form Number:* CMS–10595 (OMB control number 0938–1301); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profit institutions) *Number of Respondents:* 394; *Number of Responses:* 394; *Total Annual Hours:* 152.50. (For questions regarding this collection, contact Emily Martin at 301–492–4423).

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Requirement for Electronic Prescribing for Controlled Substances (EPCS) for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan; *Use:* Section 2003 of the SUPPORT for Patients and Communities Act of 2018 requires that prescribing of a Schedule II, III, IV, and V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. In the calendar year (CY) 2021 and 2022 Physician Fee Schedule (PFS) final rules, CMS finalized the electronic prescribing for controlled substances (EPCS) requirements and exceptions at 42 CFR 423.160(a)(5). Compliance for prescribers not in long-term care facilities begins in CY 2023. Compliance for prescribers in long-term care facilities begins in CY 2028.

EPCS requirements do not require prescribers or pharmacies to submit additional data to CMS; however, CMS did finalize one exception that requires data collection. The EPCS exception, at § 423.160(a)(5)(iii), requires a prescriber to apply for a waiver if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. This collection of information is necessary to provide adequate and timely exception from the EPCS requirements if the prescriber is unable to conduct EPCS due to circumstances beyond the prescriber's control. *Form Number:* CMS–10834 (OMB control number: 0938–1455); *Frequency:* Annually; *Affected Public:* Public sector (State, Local or Tribal Governments), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 306; *Total Annual Responses:* 306; *Total Annual Hours:* 52. (For policy questions regarding this collection contact Carrie Sena at 410–786–8003.)

3. *Type of Information Collection Request:* Extension of a currently approved information collection; *Title of Information Collection:* Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies; *Use:* Section 1862(m) of the Social Security Act (and regulations at 42 CFR Subpart B (sections 405.201–405.215) allows for payment of the routine costs of care furnished to Medicare beneficiaries in a Category A investigational device exemption (IDE) study and authorizes the Secretary to establish criteria to ensure that Category A IDE trials conform to appropriate scientific and ethical standards. Medicare does not cover the Category A device itself because Category A (Experimental) devices do not satisfy the statutory requirement that Medicare pay for devices determined to be reasonable and necessary. Medicare may cover Category B (Non-experimental) devices, and associated routine costs of care, if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

Under the current centralized review process, interested parties (such as study sponsors) that wish to seek Medicare coverage related to Category A or B IDE studies have a centralized point of contact for submission, review and determination of Medicare coverage IDE study requests. In order for CMS (or its designated entity) to determine if the Medicare coverage criteria are met, as described in our regulations, CMS (or its designated entity) must review documents submitted by interested parties or study sponsors. Such information submitted will be a FDA IDE approval letter, IDE study protocol, IRB approval letter, National Clinical Trials (NCT) number, and Supporting materials as needed. *Form Number:* CMS–10511 (OMB control number: 0938–1250); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 118 *Total Annual Responses:* 118; *Total Annual Hours:* 236. (For policy questions regarding this collection contact Xiufen Sui at 410–786–3136.)

William N. Parham, III,

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

[FR Doc. 2025–18216 Filed 9–18–25; 8:45 am]

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