

quality and cost performance categories in a manner that applies the combined performance of all the MIPS eligible clinicians in the virtual group to each MIPS eligible clinician in the virtual group for the applicable performance period; and (2) be scored for the quality and cost performance categories based on such assessment. *Form Number:* CMS–10652 (OMB control number: 0938–1343); *Frequency:* Yearly; *Affected Public:* Individuals and Households, Private Sector, Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 16; *Total Annual Responses:* 16; *Total Annual Hours:* 160 (For policy questions regarding this collection contact Renee O’Neill at 410–786–8821.)

**3. Type of Information Collection**  
*Request:* Revision of a currently approved collection. *Title of Information Collection:* Quality Improvement Strategy Implementation Plan, Progress Report, and Modification Summary Supplement Forms. *Use:* Section 1311(c)(1)(E) of the Affordable Care Act requires qualified health plans (QHPs) offered through an Exchange must implement a quality improvement strategy (QIS) as described in section 1311(g)(1). Section 1311(g)(3) of the Affordable Care Act specifies the guidelines under Section 1311(g)(2) shall require the periodic reporting to the applicable Exchange the activities that a qualified health plan has conducted to implement a strategy as described in section 1311(g)(1). CMS intends to have QHP issuers complete the appropriate QIS forms annually for implementation and progress reporting of their quality improvement strategies. The QIS forms will include topics to assess an issuer’s compliance in creating a payment structure that provides increased reimbursement or other incentives to improve the health outcomes of plan enrollees, prevent hospital readmissions, improve patient safety and reduce medical errors, promote wellness and health, and reduce health and health care disparities, as described in Section 1311(g)(1) of the Affordable Care Act.

The QIS forms will allow: (1) the Department of Health & Human Services (HHS) to evaluate the compliance and adequacy of QHP issuers’ quality improvement efforts, as required by Section 1311(c) of the Affordable Care Act, and (2) HHS will use the issuers’ validated information to evaluate the issuers’ quality improvement strategies for compliance with the requirements of Section 1311(g) of the Affordable Care Act. *Form Number:* CMS–10540 (OMB control number: 0938–1286); *Frequency:* Annually; *Affected Public:* Public sector

(Individuals and Households), Private sector (Business or other for-profits and not-for-profit institutions); *Number of Responses:* 250; *Total Annual Responses:* 250; *Annual Hours:* 4,933. (For policy questions regarding this collection, contact Preeti Hans at 301–492–1444).

Dated: January 10, 2024.

**William N. Parham, III**

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

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**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Expedited Office of Management and Budget Review and Public Comment: Office of Community Services Affordable Housing and Supportive Services Demonstration Data Collection (New Collection)

**AGENCY:** Office of Community Services, Administration for Children and Families, U.S. Department of Health and Human Services

**ACTION:** Request for public comments.

**SUMMARY:** The Office of Community Services (OCS), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting expedited review of an information collection request from the Office of Management and Budget (OMB) and inviting public comments on the proposed collection. The Affordable Housing and Supportive Services Demonstration was appropriated by the Departments of Labor, Health and Human Services, and Related Agencies Appropriations Bill, 2023 through the Social Services Research Demonstration program (SSRD). The House report language directs ACF to provide a report on the findings of this demonstration within 1 year after grants are awarded. ACF is soliciting public comment within the next 30 days and requesting expedited approval from OMB to collect information to study the implementation of this demonstration program to inform this report. Following initial approval, ACF will request an extension of approval within 6 months. This extension process will include additional commenting opportunities.

**DATES:** *Comments due within February 15, 2024.* In compliance with the requirements of the Paperwork

Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be submitted by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

*Description:* ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing. A request for review under normal procedures will be submitted within 180 days of the approval for this request. Given the Congressional directive for a report on the Affordable Housing and Supportive Services Demonstration within 1 year, OCS has prepared data collection instruments to study the implementation of this demonstration program with the intent to produce a robust report to Congress. Under normal circumstances, OCS would submit the data collection instruments through a standard information collection request with OMB. However, the short timeframe attached to the Congressional directive make it reasonably likely that the use of normal clearance procedures to comply with the Paperwork Reduction Act would cause this Congressional deadline to be missed. If OCS were to proceed with the normal timeline for OMB review and approval, OCS would be unable to collect, clean, analyze, and consolidate program data such that it would be accessible for the report to Congress due within 1 year. Thus, OCS is requesting emergency OMB approval of this data collection to ensure we can accommodate the Congressional request for a report on the findings of this demonstration within 1 year. OCS is hoping to center the study around three main research categories—implementation of supportive services in affordable housing, changes in participant access to supportive services in affordable housing, and overall participant experience and outcomes along several variables of interest. Ultimately, OCS hopes to illustrate how supportive services are implemented in affordable housing spaces by program directors and caseworkers, and also demonstrate participant experiences accessing those services in the affordable housing setting, as well as which services and supports worked to improve resident well-being and overall self-sufficiency. To answer these research questions, OCS will engage in the following activities:

- Collecting program official, caseworker, and resident beneficiary level data from the Affordable Housing and Supportive Services Demonstration.
- Conducting interviews with program officials and caseworkers that administer the supportive services to residents living in affordable housing units to better understand their program implementation efforts and responses to resident needs.
- Conducting focus groups with beneficiary residents to understand their needs and experiences with the

supportive services offered in their affordable housing residence.

- Administering a self-sufficiency matrix to beneficiary residents to assess any change or improvement in beneficiary resident reporting of overall self-sufficiency and wellbeing, which is measured using several indicators, with the receipt of additional supportive services in the affordable housing setting.

*Respondents:* There will be three types of respondents to the proposed instruments. First, the direct

beneficiaries living in the residential housing communities will respond to instruments 1, 2, and 3. Second, the program directors/administrative staff will respond to instruments 4, 5, 6, and 7. Finally, the caseworkers providing direct support to beneficiaries will respond to instrument 8. Caseworkers may also be asked to support the implementation and administration of instruments 1, 2, and 3.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
1—Self-Sufficiency Matrix .....	560	2	1.5	1,680
2—Service Receipt Questionnaire .....	560	2	.25	280
3—Resident Focus Group .....	25	1	1.5	37.5
4—Quarterly PPR Questions .....	9	4	2	72
5—Semi-Annual Report MANDATORY .....	9	2	3	54
6—Semi-Annual Report OPTIONAL .....	3	2	1	6
7—Interviews of Program Directors .....	18	1	1.5	27
8—Interviews of Caseworkers .....	18	1	1	18
Estimated Total Annual Burden Hours .....				2,174.5

*Comments:* The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication. Comments will be considered and any necessary updates to materials made prior to, and responses provided in, the submission to OMB that will follow this public comment period.

*Authority:* Sec. 1110, Social Security Act, 42 U.S.C. 1310.

**Mary B. Jones,**  
ACF/OPRE Certifying Officer.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
[Docket No. FDA-2024-N-0065]

**Notice of Approval of Product Under Voucher: Material Threat Medical Countermeasure Priority Review Voucher; FABHALTA**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a material threat medical countermeasure (MCM) priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved material threat MCM product applications that meet certain criteria. FDA is required to publish notice of the issuance of material threat MCM priority review vouchers as well as the approval of products redeeming a voucher. FDA has determined that FABHALTA (iptacopan) capsules, approved December 5, 2023, meets the redemption criteria.

**FOR FURTHER INFORMATION CONTACT:** Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-1394, email: *Cathryn.Lee@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Under section 565A of the FD&C Act (21 U.S.C. 360bbb-4a) FDA will report the issuance of material threat MCM priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the application for FABHALTA (iptacopan) capsules, approved December 5, 2023, meets the redemption criteria.

For further information about the material threat MCM Priority Review Voucher Program and for a link to the full text of section 565A of the FD&C Act, go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions#prv>. For further information about FABHALTA (iptacopan) capsules go to the “Drugs@FDA” website at <http://www.accessdata.fda.gov/scripts/cder/daf/>.

Dated: January 10, 2024.

**Lauren K. Roth,**  
Associate Commissioner for Policy.

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