submission consists of the Plan Benefit Package (PBP) software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits.

CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. CMS uses this data to review and approve the benefit packages that the plans will offer to Medicare beneficiaries. This allows CMS to review the benefit packages in a consistent way across all submitted bids during with incredibly tight timeframes. This data is also used to populate data on Medicare Plan Finder, which allows beneficiaries to access and compare Medicare Advantage and Prescription Drug plans. *Form Number:* CMS–R–262 (OMB control number: 0938–0763); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 785; *Total Annual Responses:* 8,337; *Total Annual Hours:* 46,026. (For policy questions regarding this collection contact Kristy Holtje at 410–786–2209 or *kristy.holtje@cms.hhs.gov.*)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Dual Eligible Special Needs Plan Contract with the State Medicaid Agency; *Use:* Special needs plans (SNPs) are Medicare Advantage (MA) plans created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) that are specifically designed to provide targeted care and limit enrollment to special needs individuals. Under section 1859(b)(6) of the Act, D–SNPs restrict enrollment to individuals entitled to medical assistance under a State plan under title XIX of the Social Security Act (hereinafter referred to as the Act).

Section 1859(f)(3)(D) of the Act and 42 CFR 422.107 established the requirement for D–SNPs to have contracts with State Medicaid agencies in addition to other contracting requirements that that apply to all MA plans. MA organizations with D–SNPs and States use the information in the contract to provide benefits, or arrange for the provision of Medicaid benefits, to which an enrollee is entitled. CMS reviews the D–SNP contract with the State Medicaid agency to ensure that it meets the minimum contract requirements at § 422.107(c)&(d). CMS uses the attestations and matrices in the appendices of this package to identify the types of D–SNPs an MA organization(s) offers and the location of the contract requirements in the document. *Form Number:* CMS–10796 (OMB control number: 0938–1410); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 886; *Total Annual Responses:* 893; *Total Annual Hours:* 17,403. (For policy questions regarding this collection contact Marla Rothouse at 410–786–8063 or *Marla.rothouse@cms.hhs.gov.*)

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement; Notice of Change of Eligibility

AGENCY: Administration for Children and Families (ACF), HHS.

ACTION: Notice of change of eligibility period.

SUMMARY: In accordance with ORR regulations, the Director of ORR is announcing the shortening of the Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA) eligibility period from 12 months to four months of assistance for participants who become eligible for ORR benefits 45 days after publication of this notice. For 30 years, ORR had not increased the RCA and RMA eligibility period. In 2022, during a surge in refugee admissions, ORR increased the eligibility period from eight months to 12 months. ORR has determined that it must shorten the RCA and RMA eligibility period to four months to avoid a significant budget shortfall.

DATES: The changes described in this **Federal Register** notice are effective 45 days after the date of publication—exceeding the minimum permitted by 45 CFR 400.211(b).

FOR FURTHER INFORMATION CONTACT: Colleen Mahar-Piersma, Refugee Policy Unit, Division of Policy and Procedures, Office of the Director, Office of Refugee Resettlement, Administration for Children and Families, by phone at (202) 260–5493, and email at *refugeepolicy@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: The 1980 Refugee Act (8 U.S.C. 1522(e)(1)) authorized the Director of ORR (hereinafter ''the Director'') to provide RCA and RMA during the first 36 months after a refugee's arrival in the United States. For the first two years, ORR provided refugees with RCA and RMA for the first 36 months after a refugee's arrival. Thereafter, due to reduced appropriations, ORR had to decrease this assistance, first to 18 months, then to 12 months, and finally, in FY 1992, to eight months. RCA and RMA remained at eight months until FY 2022. In FY 2022, ORR expanded the RCA and RMA eligibility period to 12 months. However, ORR is unable to sustain this expansion based on current and projected congressional appropriations and the number of refugees eligible for RCA and RMA. Accordingly, the time-eligibility period for RCA and RMA will be changed to four months.

Prior to 1993, ORR would change the text in the Code of Federal Regulations each time it changed the number of months for cash and medical assistance. In 1993, ORR drafted regulations removing the specific duration of RCA and RMA from the regulatory text and instead added 45 CFR 400.211(a) establishing a methodology by which the Director to determines the time-eligibility period for RCA and RMA each year based on the appropriated funds available for the fiscal year. 58 FR 64499 (Dec. 8, 1993). The preamble explained that the methodology in the regulation was the substantive rule regarding how to determine RCA and RMA duration but future determinations of the actual months using the methodology would be interpretive rules. *Id.*

In recent years, annual refugee admissions have been high, resulting in an expanding pool of refugees and other eligible populations in need of services. As of March 3, 2025, approximately 109,800 refugees and other eligible populations have been resettled in the U.S. since October 1, 2024. In addition, approximately 714,000 ORR-eligible individuals were admitted to the U.S. in FY 2024. The open border policies of the Biden Administration have caused

budgetary shortfalls, requiring supplemental appropriations or transfers from other essential programs each year since FY2022. In fiscal year 2024, Congress decreased appropriations for Refugee and Entrant Assistance by more than 35% The level of funds appropriated for services has not kept pace with arrivals over the past two years, making it difficult to serve all refugees in need of services with available resources. Pursuant to 45 CFR 400.211, ORR calculated the costs of providing RCA and RMA to current recipients and the estimated number of future recipients at 12, nine, eight, six, and four months, and determined that it must shorten the period of eligibility for RCA and RMA to four months.

ORR acknowledges the reasoning articulated in its March 28, 2022, notice expanding the eligibility period for RCA and RMA. 87 FR 17312. Namely, that a longer eligibility period would ''positively impact refugees'' by allowing them to address medical and mental health conditions in order to become self-sufficient and allowing them to focus on learning English and secure employment. *Id.* at 17312–13. But such reasoning is not a basis to stay with the 12-month eligibility period, due to both legal considerations and practical considerations. First, the determination of the eligibility period is, by ORR's own regulation, supposed to be straightforwardly derived from the available appropriations. 45 CFR 400.211(a); *see also* 58 FR at 64502. Second, as a practical reality, the beneficial effects referenced in the 2022 notice must be weighed against resource constraints. As explained above, budget shortfalls require an adjustment of the eligibility period in order to ensure adequate coverage of the entire population of ORR-eligible individuals. Furthermore, the effective date of this notice has been set to account for reliance interests, in that the new eligibility period will only come into effect for those individuals who become eligible in the future.

Refugees whose date of eligibility for ORR benefits is on or after 45 days following publication of this notice are subject to the shortened RCA and RMA eligibility period.

(Authority: 45 CFR 400.211)

Angie Salazar,

Acting Director, Office of Refugee Resettlement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0648]

Over-the-Counter Monograph Drug User Fee Program—Facility Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the over-the-counter (OTC) monograph drug facility (MDF) fee rates under the OTC monograph drug user fee program (OMUFA) for fiscal year (FY) 2025. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OTC monograph order requests (OMORs). This notice publishes the OMUFA facility fee rates for FY 2025.

DATES: These facility fees are effective on October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at *OO-OFBA-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC OMORs. The OTC OMOR fee rates for FY 2025 were published on July 31, 2024.[1] OMUFA fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include various FDA activities associated with OTC monograph drugs. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);
- An OTC MDF is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act); and
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2025 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the fee-liable period from January 1, 2024, through December 31, 2024.[2] Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees for FY 2025 are due on June 2, 2025 (see section 744M(a)(1)(D)(ii) of the FD&C Act).[3]

As discussed in greater detail below:

- OTC monograph drug facilities are exempt from FY 2025 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2023 (see section 744M(a)(1)(B)(i) of the FD&C Act).
- Entities that registered with FDA during the Coronavirus Disease 2019 (COVID–19) pandemic whose sole activity with respect to OTC monograph drugs during the pandemic consisted of manufacturing OTC hand sanitizer

[1] *https://www.federalregister.gov/documents/2024/07/31/2024-16878/over-the-counter-monograph-drug-user-fee-program-otc-monograph-order-request-fee-rates-for-fiscal.*

[2] Under section 744M(a)(1) of the FD&C Act, ''Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility.'' For purposes of FY 2025 facility fees, that time period is January 1, 2024, through December 31, 2024.

[3] Assuming that, as we anticipate, the FY 2025 fee appropriation will occur prior to June 3, 2025. Under section 744M(a)(1)(D)(ii), the FY 2025 facility fees are due on the later of: (1) the first business day of June 2025 (*i.e.,* June 3, 2025) or (2) the first business day after the enactment of an appropriations Act providing for the collection and obligation of FY 2025 OMUFA fees.