

45 CFR 156.280(e)(5)(ii), each QHP issuer that offers coverage of abortion services for which public funding is prohibited must submit to the State Insurance Commissioner a segregation plan describing how the QHP issuer establishes and maintains separate allocation accounts for any QHP covering abortion services for which public funding is prohibited, and pursuant to § 156.280(e)(5)(iii), each QHP issuer must annually attest to compliance with PPACA section 1303 and applicable regulations. This segregation plan is used to verify that the QHP issuer's financial and other systems fully conform to the segregation requirements required by the PPACA.

The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with the segregation plan requirement under 45 CFR 156.280(e)(5)(ii). The burden estimates for this collection of information renewal reflect the time and effort for QHP issuers to submit a segregation plan that demonstrates how the QHP issuer segregates QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget (OMB) and guidance on accounting of the Government Accountability Office. CMS is also renewing the ICR in connection with the annual attestation requirement under 45 CFR 156.280(e)(5)(iii). The burden estimate for this ICR reflects the time and effort associated with QHP issuers submitting an annual attestation to the State Insurance Commissioner attesting to compliance with section 1303 of the PPACA. *Form Number:* CMS-10400 (OMB control number: 0938-1156); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits and not-for-profits institutions); *Number of Respondents:* 1,617; *Number of Responses:* 1,617; *Total Annual Hours:* 5,508.75. (For questions regarding this collection, contact Agata Pelka at 667-290-9979).

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Disclosure Requirement for the In-Office Ancillary Services Exception; *Use:* Section 6003 of the ACA established a disclosure requirement for the in-office ancillary services exception to the prohibition of physician self-referral for certain imaging services. This section of the ACA amended section 1877(b)(2) of the Social Security Act by adding a requirement that the referring physician informs the patient, at the time of the

referral and in writing, that the patient may receive the imaging service from another supplier. The implementing regulations are at 42 CFR 411.355(b)(7). Physicians who provide certain imaging services (MRI, CT, and PET) under the in-office ancillary services exception to the physician self-referral prohibition are required to provide the disclosure notice as well as the list of other imaging suppliers to the patient. The patient will then be able to use the disclosure notice and list of suppliers in making an informed decision about his or her course of care for the imaging service. CMS would use the collected information for enforcement purposes. Specifically, if we were investigating the referrals of a physician providing advanced imaging services under the in-office ancillary services exception, we would review the written disclosure in order to determine if it satisfied the requirement. *Form Number:* CMS-10332 (OMB control number 0938-1133); *Frequency:* Occasionally; *Affected Public:* Private Sector, Business or other for-profits and Not-for-profits institutions; *Number of Respondents:* 974,557; *Total Annual Responses:* 974,557; *Total Annual Hours:* 18,107. (For policy questions regarding this collection contact Sabrina Teferi at 404-562-7251 or Sabrina.Teferi@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 Community Living

Intent To Award a Single-Source Supplement for the Expanding the National Capacity for Person-Centered, Trauma-Informed (PCTI) Care: Services and Supports for Holocaust Survivors and Other Older Adults With a History of Trauma and Their Family Caregivers Program

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) announces the intent to award a single-source supplement to the current cooperative agreement held by the Jewish Federations of North America for the project "Expanding the National Capacity for Person-Centered, Trauma-

Informed (PCTI) Care: Services and Supports for Holocaust Survivors and Other Older Adults with a History of Trauma and Their Family Caregivers" program. The purpose of this program is to advance the development and expansion of PCTI supportive services for Holocaust survivors living in the U.S. Additionally, the project is advancing the capacity of the broader aging services network to deliver services of this type to any older adult with a history of trauma and their family caregivers.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this program supplement, contact Greg Link, U.S. Department of Health and Human Services, Administration for Community Living, Administration on Aging, Office of Supportive and Caregiver Services: telephone (202) 795-7386; email greg.link@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: The goals of the program are as follows:

1. Increase the number and type of innovations in PCTI care for Holocaust survivors, older adults with a history of trauma, and their family caregivers, and
2. Expand the capacity of the Aging Network to provide PCTI care to the populations it serves.

The administrative supplement for FY 2024 will be in the amount of \$3,454,500, bringing the total award for FY 2023 to \$8,389,500. The supplement will provide sufficient resources to enable the grantee and their partners, JFNA, to accomplish the following:

- Continue to address the significant needs of Holocaust survivors living in the United States and other older adults with histories of trauma and their family caregivers by:
 - Further expanding Innovations Program, deepening its focus on existing programs to make them more PCTI, and expand the program to additional communities;
 - Continued expansion of the Critical Supports Initiative to federation agencies and aging services providers together to identify and address the most critical needs and allocate additional resources accordingly to those needs. This component of the program allows each participating community to determine how to best allocate the resources available to meet the needs and form new partnerships to prevent emergencies; and
 - Growing the National Networks program to scale PCTI approaches to multiple locations/cities.
- For all of these programs, the supplement will increase outreach, evaluation, technical assistance, and

sub-grantee monitoring and financial oversight activities.

- Continued expansion and support of the grantee staff to solidify the infrastructure and framework to realize Congress' intent for the establishment and operation of a national resource center to provide training and technical assistance to agencies in the aging network delivering services to older individuals experiencing the long-term and adverse consequences of trauma, as described in section 411(14) of the Older Americans Act of 1965, as amended. Doing so will enable JFNA to expand the reach and effectiveness of this project by broadening the technical assistance and capacity building activities in the following ways:

- *Growth and partnerships* are essential for PCTI approaches to take root. The supplement will be used to increase the ways in which this can be accomplished, including re-launching an Aging and Trauma Workgroup and an Educational Advisory Committee, ensuring the voices of Holocaust survivors, other older adults with histories of trauma and their family caregivers are represented; enabling the grantee to develop and implement an action plan to work with foundations.

- *Thought leadership in the field of PCTI care* is greatly needed for it to take root as standard practice in the aging services network. The supplement will: (1) permit the expansion of the grantee's PCTI training program; (2) provide the resources necessary to fund the development of a family caregiving roadmap to support PCTI approaches to implementing the National Strategy to Support Family Caregivers; and (3) further develop and expand the field and practice of PCTI evaluation approaches and practices already begun under this project, but on a limited basis.

- *Sustainability and efficiency* are key to any demonstration project. The supplement will enable JFNA to explore technology enhancements to streamline the sub-grant management process, bring on additional staff to manage expanded expectations and work, including growth, and enhance program oversight, monitoring, evaluation, and additional activities proportional to the increased funding and expectations resulting from this supplement.

Program Name: Expanding the National Capacity for Person-Centered, Trauma-Informed (PCTI) Care: Services and Supports for Holocaust Survivors and Other Older Adults with a History of Trauma and Their Family Caregivers.

Recipient: The Jewish Federations of North America.

Period of Performance: The supplement award will be issued for the third year of the five-year project period of September 1, 2020 through August 31, 2025.

Total Award Amount: \$8,389,500 in FY 2024.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: The Older Americans Act (OAA) of 1965, as amended, Public Law 109-365—title 4, section 411.

Basis for Award: The Jewish Federations of North America (JFNA) is currently funded to carry out the objectives of the project entitled "Expanding the National Capacity for Person-Centered, Trauma-Informed (PCTI) Care: Services and Supports for Holocaust Survivors and Other Older Adults with a History of Trauma and Their Family Caregivers" for the period of September 1, 2020 through August 31, 2025. Since project implementation began in late 2020, the grantee has accomplished a great deal. This supplement will enable the grantee to carry their work even further, serving more Holocaust survivors, other older adults with histories of trauma, family caregivers and to train more professionals in the principles of PCTI. The additional funding will not be used to begin new projects or activities.

The JFNA is uniquely positioned to complete the work called for under this project. JFNA's partners on this project include the Network of Jewish Human Services Agencies, KAVOD, the Conference on Material Claims Against Germany (the Claims Conference), USAging, the Health Foundation for Western and Central New York, LeadingAge, Habitat for Humanity International, University of Buffalo School of Social Work Institute on Trauma & Trauma-Informed Care, National Council on Aging, Campaign for Trauma-Informed Policy and Practice, and SAGE represent a broad cross-section of the aging services networks with equities in this area.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the Holocaust survivors and other older adults currently being served by this project could be negatively impacted by a service disruption, thus posing the risk of re-traumatization and further negative impacts on health and wellbeing. If this supplement is not provided, the project would be less able to address the significant unmet health and social support needs of additional Holocaust survivors and other older adults with histories of trauma.

Similarly, the project would be unable to expand its current technical assistance and training efforts in PCTI concepts and approaches, let alone reach beyond traditional providers of services to this population to train more "mainstream" providers of aging services. Finally, providing this supplement to JFNA will allow for the greater realization of Congress' intent in section 411(14)(A) of the Older Americans Act, as amended, which calls for the establishment of a national resource center to provide training, technical assistance and sub-grants in this area.

Dated: June 11, 2024.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-2422]

Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability on its website of the proposed administrative order (proposed order) entitled "Amending Over-the-Counter Monograph M013: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use."

DATES: Submit electronic comments on the administrative order by July 29, 2024.

ADDRESSES: Instructions for submitting comments are contained in the proposed order OTC000035. Comments must be submitted electronically on or before July 29, 2024. Comments submitted after this time will not be considered.

FOR FURTHER INFORMATION CONTACT:

Helen Lee, Center for Drug Evaluation and Research (HFD-600), Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-0138.