

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*: Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act; *Use*: Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program (the “Negotiation Program”), codified in sections 1191 through 1198 of the Social Security Act (“the Act”). The Act establishes the Negotiation Program to negotiate maximum fair prices (“MFPs”), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the first year of the Negotiation Program, the Secretary of Health and Human Services (the “Secretary”) will select 10 Part D high expenditure, single source drugs for negotiation.

The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. These data include the data required to calculate non-FAMP for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A), and the negotiation factors outlined in section 1194(e)(1) for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B). Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in section 1194(e)(1) and 1193(a)(4) must be submitted by the Primary Manufacturer.

Section 1194(e)(2) requires CMS to consider certain data on alternative treatments to the selected drug. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in 1194(e)(2) to ensure consideration of such factors.

Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may optionally submit evidence about alternative treatments. *Form Number*: CMS–10847 (OMB control number: 0938–New); *Frequency*: Occasionally; *Affected Public Sector*: Individuals and Households, Private Sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents*: 3,300; *Total Annual Responses*: 3,300; *Total Annual Hours*: 17,000. (For policy questions regarding this collection contact Lara Strawbridge at 410–786–6880).

Dated: March 16, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; SOAR (Stop, Observe, Ask, Respond) to Health and Wellness Training (SOAR) Demonstration Grant Program Data (NEW COLLECTION)

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new grant program: SOAR (Stop, Observe, Ask, Respond) to Health and Wellness Training (SOAR) Demonstration Grant Program Data.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting

“Currently under 30-day Review—Open for Public Comments” or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The SOAR

Demonstration Grant Program was developed in response to the Trafficking Victims Protection Act (TVPA) of 2000 (Pub. L. 106–386), § 106(b), as amended (22 U.S.C. 7104(b)(1)) and 22 U.S.C. 7105(b)(1)(B), which calls on agencies to “increase public awareness of the dangers of trafficking and the protections that are available for victims of trafficking” and provide “services to assist potential victims of severe forms of trafficking in persons.” The program’s goal is to fund the implementation of SOAR trainings and capacity building efforts to identify, treat, and respond to patients or clients who have experienced severe forms of human trafficking as defined by the TVPA of 2000, as amended, among their patient or client population. SOAR is a nationally recognized, accredited training program delivered by OTIP’s National Human Trafficking Training and Technical Assistance Center (NHTTAC) and designed to help target audiences identify and respond to those who are at risk of, are currently experiencing, or have experienced trafficking and connect them with needed resources. OTIP proposes to collect information to measure grant project performance, provide technical assistance to grant recipients, assess program outcomes, inform program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection will capture information on organizations enrolled in each grant recipient’s multidisciplinary network of providers serving individuals who have experienced, or are at-risk of experiencing, a severe form of trafficking in persons, and clients served. Data elements are designed to capture information about organizational providers (e.g., number of individuals trained to identify and respond to trafficking, types and number of trainings offered, types of services provided, number of clients enrolled in services, organizational barriers to service delivery and implementation, and total funds spent by category of assistance) and client

demographics (e.g., total number of clients enrolled in services by providers within the recipient's multidisciplinary network by client age, sex, gender identity, sexual orientation, race/ethnicity, and language spoken).

Respondents: Healthcare, behavioral health, and social service delivery professionals.

Annual Burden Estimates: Recipients will be awarded funding for a 5-year period. This request is for the first 3

years of data collection. We will request an extension to continue data collection beyond 3 years.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Provider Capacity Building Indicators	75	4	1	300	100
SOAR Demonstration Grant Participant Training Form	4,500	1	0.75	3,000	1,125
Client Demographics Indicators	2,000	4	1	8,000	2,667
Human Trafficking Response Protocol (HTRP) Indicators ..	75	4	2.5	750	250
Multidisciplinary Network Provider Indicators	75	4	0.5	150	50
Categories of Assistance Form	75	1	2.5	188	63

Estimated Total Annual Burden Hours: 4,255.

(Authority: 22 U.S.C. 7104)

John M. Sweet, Jr.

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB Budget No. 0970-0510]

Proposed Information Collection Activity; Refugee Support Services Federal Financial Report (Standard Form-425); Supplemental Data Collection

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) Office of Refugee Resettlement (ORR) plans to submit a generic information collection (GenIC) request under the umbrella generic: Generic Clearance for Financial Reports used for ACF Mandatory Grant Programs (0970-0510). This request is to include instructions for ORR Refugee

Support Services grant recipients to provide supplemental financial information when submitting the already required Federal Financial Report (Standard Form (SF)-425), which is approved under Office of Management and Budget (OMB) number 4040-0014.

DATES: *Comments due within 14 days of publication.* 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 above and below.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF programs require detailed financial information from their grantees that allows ACF to monitor various specialized cost categories within each program, to closely manage program activities, and to have sufficient financial information to enable periodic thorough and detailed audits. Generic Clearance for Financial Reports used for ACF Mandatory Grant Programs allows ACF programs to efficiently develop and receive approval for financial reports that are tailored to specific funding recipients and the

associated needs of the program. For more information about the umbrella generic, see: https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202108-0970-002.

This specific GenIC request applies to all ORR Refugee Support Services grantees awarded regular base and “set-aside” funding, all funding received under the Afghanistan Supplemental Appropriation, and funds received under the Ukraine Supplemental Appropriations Act, 2022, and other appropriations as communicated. All grantees must complete reporting in accordance with Statute. Currently grantees use the SF-425 to report standard required federal expenditure data (OMB #: 4040-0014). The SF-425 requests grantees to report one cumulative amount for all expenditures. ORR is proposing to request that grantees break out expenditure data by financial account and program category/set aside by providing more detailed instructions for Box 12 of the SF-425 which designated for additional remarks. The proposed supplemental instructions will provide guidance and assist grantees with submitting the additional detail about federal expenditure data reported on the SF-245. The analysis of this data would further support adherence to program requirements.

Respondents: States, State Agency Grantee Designees.

ANNUAL BURDEN ESTIMATES

Title of information collection	Number of respondents	Annual frequency of responses	Hourly burden per response	Annual hourly burden
RSS SF-425 Supplemental Data Collection	53	4	4	212

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