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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by November 21, 2022.

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.

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 Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Summary of Benefits and Coverage and Uniform Glossary; *Use:* This information collection will ensure that over 30 million consumers shopping for or enrolled in private, individually purchased, or non-federal governmental group health plan coverage receive the consumer protections of the Affordable Care Act. Employers, employees, and individuals will use this information to compare coverage options prior to selecting coverage and to understand the terms of, and extent of medical benefits offered by, their coverage (or exceptions to such coverage or benefits) once they have coverage. *Form Number:* CMS–10407 (OMB control number 0938–1146); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 90,805; *Number of Responses:* 10,507,165; *Total Annual Hours:* 204,140. (For policy questions regarding this collection contact Daniel Kidane at *daniel.kidane@cms.hhs.gov.*)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title:* Programs of All-Inclusive Care for the Elderly (PACE); *Use:* PACE is a pre-paid, capitated plan that provides comprehensive health care services to frail, older adults in the community, who are eligible for nursing home care according to state standards. PACE programs must provide all Medicare and Medicaid covered services; financing of this model is accomplished through prospective capitation of both Medicare and Medicaid payments. Upon approval of a PACE application, CMS executes a three-way program agreement with the applicant entity and the applicable state. With certain exceptions, this information collection addresses all operational components of the PACE program, as defined in 42 CFR part 460. *Form Number:* CMS–R–244 (OMB control number: 0938–0790); *Frequency:* Once and occasionally; *Affected Public:* Private sector (business or other for profits and not-for-profit institutions); *Number of Respondents:* 179; *Total Annual Responses:* 121,407; *Total Annual Hours:* 97,069. (For policy questions regarding this collection contact Lauren Brandow at 410–786–9765.)

Dated: October 18, 2022.

William N. Parham, III,

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

[FR Doc. 2022–22949 Filed 10–20–22; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Trafficking Victim Assistance Program Data (OMB #0970–0467)

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, U.S. 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 requesting to renewal with revisions of an approved information collection: Trafficking Victim Assistance Program (TVAP) Data (OMB #0970–0467).

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: OTIP proposes to continue 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 captures information on participant demographics (*e.g.,* age, gender identity, race/ethnicity, country of origin), type of trafficking experienced (sex, labor, or both), types of services and benefits provided, along with aggregate information on the amount of money spent on each type of service provided, outreach activities conducted, subrecipients enrolled, and the types of trainings provided to relevant audiences. Minor updates have been made to performance indicators under this collection in consultation with existing grant recipients and stakeholders, to reduce respondent burden, strengthen client privacy and confidentiality, and to bring the collection into alignment with program requirements under the revised TVAP. Specifically, to reduce burden and strengthen client privacy and confidentiality, the following TVAP client-level indicators have been removed: Type of Intake, Date of Birth, Services Requested at Intake, Benefits Requested at Intake, Trafficker Relationship to Victim, and Employment Status at Case Closure. To reduce respondent burden, additional proposed outreach and subrecipient indicators have also been removed: Screening Tool Used During Outreach, Goal of Subrecipient Partnership, Type of Subrecipient Partnership; Services Provided by Subrecipient (In-House) and Services Provided by Subrecipient (by Referral) have been collapsed into one category: Services Provided By Subrecipient. To bring the collection into alignment with the revised TVAP requirements, outreach-specific indicators have been added, specifically: Number of Outreach Activities Conducted, Date of Outreach Activity, Outreach Settings, Target Population(s), Number of Victims Identified. The TVAP Spending Form was renamed to Categories of Assistance and categories have been simplified to reduce reporting burden.

Respondents: TVAP Grant Recipients and Clients of those programs, specifically the: TVAP (HHS–2022–ACF–IOAS–OTIP–ZV–0150), Aspire: Child Trafficking Victim Assistance Demonstration Program (HHS–2022–ACF–IOAS–OTIP–TV–0099), Victims of Human Trafficking Services and Outreach Program—Pacific Region Demonstration Program (VHT–SO Pacific) (HHS–2022–ACF–IOAS–OTIP–ZV–0038) and the Lighthouse: Services, Outreach, and Awareness for Labor Trafficking (Lighthouse) Demonstration Program (HHS–2022–ACF–IOAS–OTIP–ZV–0059).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Program Entry	6600	1	0.75	4950	1650
Client Case Closure	6600	1	0.167	1102.2	367.4
Barriers to Service Delivery and Monitoring	386	4	0.167	257.85	85.95
Client Service Use and Delivery	6600	1	0.25	1650	550
Victim Outreach	386	4	0.3	463.2	154.4
Training	386	4	0.5	772	257.3
Subrecipient Enrollment	193	2	0.167	64.5	21.5
Categories of Assistance	193	1	0.5	96.5	32.2

Estimated Total Annual Burden Hours: 3118.75.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–22842 Filed 10–20–22; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6528]

Refusal of Inspection by a Foreign Food Establishment or Foreign Government; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Refusal of Inspection by a Foreign Food Establishment or Foreign Government.'' The guidance will provide information for foreign food establishments subject to our inspection, as well as foreign governments, on when we may consider that a foreign food establishment or a government of a foreign country has refused to permit an inspection by us as provided in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on October 21, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets