

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Administration for Children and Families****Submission for OMB Review; Request for Certification of Adult Victims of Human Trafficking**

AGENCY: Office on Trafficking in Persons; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF), Office on Trafficking in Persons (OTIP), is requesting a 3-year extension of the Request for Certification of Adult Victims of Human Trafficking (RFC) form (Office of Management and Budget (OMB) #: 0970-0454, expiration 2/28/22). Minor revisions have been made to the form, including the addition of a few fields that will enable OTIP to be more responsive to congressional inquiries, federal reporting requirements, and the needs of victims.

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. All emailed requests should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The U.S. Department of Health and Human Services (HHS) provides letters of certification to foreign national victims of severe forms of trafficking in persons under the authority of the Trafficking Victims Protection Act of 2000 (TVPA), as amended 22 U.S.C. Section 7105(b)(1)(C) and (E). HHS delegated this authority to OTIP. Certification is required for foreign national adult victims of human trafficking in the United States to apply for federally funded benefits and services.

OTIP developed a form for potential victims and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives to provide the required information for certification to HHS in accordance with the TVPA of 2000, as amended. The RFC form (formerly titled Trafficking Victims Tracking System) was renamed in order to create continuity between the RFC and Request for Assistance for Child Victims of Human Trafficking (RFA)

forms (OMB Control Number 0970-0362).

Since the RFC form originally received clearance, OTIP modernized its request process and launched Shepherd, an online case management system, to process requests for certification and assistance on behalf of foreign national adult and minor victims of trafficking. The PDF version of the form should only be used in exceptional circumstances when the online case management system is inaccessible. If a requester encounters issues submitting a request through Shepherd, they may submit the RFC form to OTIP as a password protected PDF to Trafficking@acf.hhs.gov. The form asks the requester for their identifying information, identifying information for the foreign national adult in the event the form is submitted by a case manager, and information describing the victim's case management service needs. The minor revisions made to this form enable OTIP to better fulfill its mandate in accordance with the TVPA of 2000, as amended. These revisions also enable OTIP to be more responsive to congressional inquiries, federal reporting requirements, and the needs of victims, as the information provided will be factored into policy and program development efforts.

Respondents: Potential victims of a severe form of trafficking in persons and their advocates, including case managers, attorneys, law enforcement officers, service providers, and other representatives.

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
Request for Certification of Adult Victims of Human Trafficking	1,300	1	1	1,300	433

Estimated Total Annual Burden Hours: 433.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2020-D-1564]

Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation; Guidance for Industry and Food and Drug Administration Staff, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.” FDA encourages the collection, analysis, and integration of patient perspectives in the development, evaluation, and surveillance of medical devices, including digital health technologies. Patient-reported outcome (PRO) instruments facilitate the systematic