

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-10500]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by June 15, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number; Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the

proposed collection(s) summarized in this notice, you may make your request using one of the following:

1. Access CMS' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10500 Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey

Under the 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 requires federal agencies to publish a 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:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey; *Use:* The information collected in the national implementation of Outpatient/Ambulatory Surgery Patient Experience of Care Survey (A/ASPECS) will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries to

help them make informed decisions for outpatient surgery facility selection; (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; and (3) provide us with information for monitoring and public reporting purposes. *Form Number:* CMS-10500 (OMB control number: 0938-1240); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 633,304; *Total Annual Responses:* 633,304; *Total Annual Hours:* 153,592. (For policy questions regarding this collection contact Memuna Ifedirah at 410-786-6849).

Dated: April 11, 2018.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018-07872 Filed 4-13-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: National Human Trafficking Training and Technical Assistance Center.

Title: National Human Trafficking Training and Technical Assistance Center (NHTTAC) Consultant and Evaluation Package.

OMB No.: New.

Description: The Trafficking Victims Protection Act of 2000 (PL 106-386), Section 106(b), as amended at 22 U.S. Code § 7104 and 22 U.S. Code § 7105(c)(4) authorizes The Office on Trafficking in Persons (OTIP), an office of The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) to establish and carry out human trafficking public awareness programs and training for government personnel. Under this authority, OTIP is proposing a data collection through the National Human Trafficking Training and Technical Assistance Center (NHTTAC).

NHTTAC hosts a variety of services, programs, and facilitated sessions to improve service provision to individuals who have been trafficked or who are at risk of trafficking, including The Human Trafficking Leadership Academy (HTLA); the Survivor Fellowship Program; the NHTTAC Customer Support Center; short-term and specialized T/TA requests (requests that take less than 3 hours or 3 or more

hours to fulfill, respectively); OTIP-funded grantees; and information through NHTTAC's website, resources, and materials about trafficking.

Assessment, evaluation, and quality improvement are essential components of NHTTAC T/TA delivery and requires data collection from NHTTAC T/TA participants, consultants, and other stakeholders that are involved in NHTTAC activities. Data will be collected after each T/TA event to provide a feedback mechanism to improve the availability and delivery of coordinated and trauma-informed services before, during, and after an individual's trafficking exploitation. Whenever possible, data will be collected from participants and consultants electronically via a survey tailored to the specific T/TA event to maximize convenience and minimize the burden for participants. When appropriate, focus groups and interviews will also be leveraged to obtain contextual information about NHTTAC activities. The types of information collected tie directly to the outputs, short-term, and long-term objectives of NHTTAC.

Respondents: NHTTAC consultants and T/TA participants are from a diverse background with a wide range of experiences within the trafficking and public health fields, including health and human service providers.

Human Trafficking Leadership Academy (HTLA): Participants in the HTLA comprise survivors of trafficking and anti-trafficking service providers.

Survivor Fellowship Program: Participants are representatives from health and human service organizations and survivors of trafficking.

Customer Support Center: Respondents are primarily health and human service providers requesting

materials or T/TA on trafficking service provision.

Short-Term and Specialized T/TA: NHTTAC follows up with participants 3 to 6 months after specialized T/TA activities to measure the outcomes of the T/TA.

OTIP Grantees: NHTTAC supports OTIP grantees by providing information, facilitating information sharing, and hosting meetings and webinars.

NHTTAC Website: NHTTAC hosts a website of information and resources; people who visit the website are asked for their feedback on how the website can be improved.

Conference and Meeting Support: NHTTAC supports conferences to share information, promising practices, and evidence-based research on trafficking within the field. NHTTAC also supports the delivery of cluster meetings on behalf of OTIP.

National Advisory Council: NHTTAC supports the National Advisory Council on the Sex Trafficking of Children and Youth in the United States (NAC) by facilitating and coordinating meetings. NAC members are asked for their feedback following meetings regarding how well the group is working together and what could be improved in the future.

Organizational Scholarships: An organizational survivor scholarship may be awarded to organizations for conferences that support OTIP's stated goals and work with individuals who have been trafficked and/or at risk of trafficking.

Professional Development Scholarships: Eligible individuals include child welfare experts, public health professionals, medical service providers, behavioral health professionals, advocates, service providers, and individuals who have

been trafficked. Federal, tribal, state, and local agencies and multidisciplinary teams are also eligible.

SOAR to Health and Wellness (SOAR): Tier I trainings of SOAR engage respondents through a variety of modalities: (1) SOAR Online is available to the public and comprises multiple modules. (2) SOAR trainings at select national and regional conferences or similar meetings. (3) SOAR resources will help inform practitioners and professionals who work in the public health field. (4) SOAR training for U.S. Department of Health and Human Services (HHS) personnel is similar to SOAR Online but tailored to HHS staff. (5) Emerging issues webinars are available to the public but targeted to public health professionals, including health and human service providers.

Tier II of SOAR targets respondents through a blended online training to individuals who plan to incorporate the content into their organization's policies and best practices. Organizations can also add the SOAR Online training to their learning management systems.

Tier III of SOAR engages respondents through intensive, in-person T/TA via SOAR for Communities. The goal is to provide strategic planning and goal setting in communities looking to improve their response to trafficking.

NHTTAC Consultants: T/TA expert consultants are subject matter experts with at least 7 years of relevant professional experience. Survivor impact consultants are individuals who have experienced human trafficking. Each category has distinct qualifications and eligibility requirements that are fielded through an online application process.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survivor Fellowship Organization Feedback Form	10	1	.250	2.50
Survivor Fellowship Fellow Feedback Form	10	1	.250	2.50
Website Feedback Form	300	1	.083	24.90
Consultant Feedback Form	50	1	.083	4.15
Coordination Feedback Form	100	1	.050	5.00
Focus Group Demographic Survey	25	1	.033	.825
Focus Group Guide	25	1	.750	18.75
Follow-up Feedback Form	300	1	.133	39.90
General Training Feedback Form	150	1	.133	19.95
Interview Guide	25	1	.750	18.75
Pilot Feedback Form	25	1	.150	3.75
Requester Feedback Form	75	1	.117	8.78
Resource Tool Feedback Form	500	1	.033	16.50
SOAR Blended Learning Participant Feedback Form	30	1	.150	4.50
SOAR Conference Feedback Form	500	1	.200	100.00
SOAR Online Participant Feedback Form	1500	1	.100	150.00
SOAR Organizational Feedback Form	20	1	.133	2.66

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SOAR Specialized T/TA Feedback Form	200	1	.150	30.00
Webinar Participant Feedback Form	1000	1	.067	67.00
Survivor Impact Consultant Application	20	1	.283	5.66
Expert T/TA Consultant Application	20	1	.267	5.34
Organizational Scholarship Application	10	1	.317	3.17
Professional Development Survivor Scholarship Application	30	1	.333	9.99
Total Annual Burden	5,908	689.15

Estimated Total Annual Burden Hours: 689 Hours.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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 information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–07843 Filed 4–13–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–4764]

Policy Clarification and Premarket Notification Submissions for Ultrasonic Diathermy Devices; Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled “Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices; Guidance for Industry and Food and Drug Administration Staff.” This guidance clarifies FDA’s policy related to compliance with applicable performance standards and conformance to International Electrotechnical Commission (IEC) consensus standards for ultrasonic diathermy devices. This guidance provides recommendations for information to provide in 510(k) submissions for ultrasonic diathermy devices.

DATES: The announcement of the guidance is published in the **Federal Register** on April 16, 2018.

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 Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2017–D–4764 for “Policy Clarification and Premarket Notification [510(k)] Submissions for Ultrasonic Diathermy Devices; Guidance for Industry and Food and Drug Administration Staff.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be