

*** Program directors hold various roles and responsibilities and, therefore, have varied salaries. For the purpose of this estimate, the hourly wages for the following managerial and post-secondary occupational codes were averaged: 11-3131, 11-1021, 11-9030, 11-9033, 11-9039, and 11-9199.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 6, 2020.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2020-05027 Filed 3-11-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Refugee Support Services (RSS) and RSS Set Aside Sub-Agency List (New Collection)

AGENCY: Office of Refugee Resettlement; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) seeks approval for a new information collection requesting Refugee Support Services (RSS) grantees and RSS Set Aside grantees to provide the agency name, city, state, phone number, and funding amount for each contracted sub-grantee.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be

forwarded by emailing *infocollection@acf.hhs.gov*. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This new data collection will request RSS grantees and RSS Set Aside grantees to provide the agency name, city, state, phone number, and funding amount for each contracted sub-grantee. Without having this information regarding RSS sub-grantees, the ACF Office of Refugee Resettlement (ORR) does not know whether an agency is, or is not, receiving ORR funds. This makes it difficult to ensure communications with, provide access to targeted assistance for, and keep abreast of the activities of all ORR-funded refugee service providers.

Respondents: State governments and replacement designees.

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
RSS and RSS Set Aside Sub-grantee List	56	3	2	336	112

Estimated Total Annual Burden Hours: 112.

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 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.

Authority: Refugee Act of 1980 [Immigration and Nationality Act, Title IV, Chapter 2 Section 412 (e)] and 45 CFR 400.28.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020-05035 Filed 3-11-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2565]

The 510(k) Third Party Review Program; Guidance for Industry, Food and Drug Administration Staff, and Third Party Review Organizations; 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 “510(k) Third Party Review Program.” This guidance provides a comprehensive look into FDA’s current thinking regarding the 510(k) Third Party (3P510k) Review Program authorized under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Under the FDA Reauthorization Act of 2017 (FDARA), FDA was directed to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The 3P510k Review Program is intended to allow review of devices by 3P510k Review Organizations in order to provide manufacturers of these devices an alternative review process that allows FDA to best utilize our resources on higher risk devices.

DATES: The announcement of the guidance is published in the **Federal Register** on March 12, 2020.

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-2016-D-2565 for “510(k) Third Party Review Program.” 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 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 made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “510(k) Third Party Review Program” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Gregory Pishko, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3441, Silver Spring, MD 20993-0002, 240-402-6635.

SUPPLEMENTARY INFORMATION:

I. Background

FDA’s implementation of section 523 of the FD&C Act (21 U.S.C. 360m) establishes a process for recognition of qualified third parties to conduct the initial review of premarket notification (510(k)) submissions for certain low-to-moderate risk devices eligible under the 3P510k Review Program. Under FDARA (Pub. L. 115-52), the criteria used to establish device eligibility in the 3P510k Review Program changed and FDA was directed to issue guidance on the factors that will be used in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person. The objectives of this guidance are to describe the factors FDA will use in determining device type eligibility for review by 3P510k Review Organizations; to outline FDA’s process for the recognition, rerecognition, suspension and withdrawal of recognition for 3P510k Review Organizations; and to ensure consistent quality of work among 3P510k Review Organizations through Medical Device User Fee Amendments IV commitments authorized under FDARA in order to eliminate the need for routine, substantive re-review by FDA. This guidance also outlines FDA’s current thinking on leveraging the International Medical Device Regulators Forum’s requirements for Regulatory Reviewers under the Good Regulatory Review Practices and the Medical Device Single Audit Program.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of September 14, 2018 (83 FR 46742). FDA revised the

guidance as appropriate in response to the comments. This guidance supersedes “Implementation of Third Party Programs Under the FDA Modernization Act of 1997; Final Guidance for Staff, Industry, and Third Parties” issued on February 2, 2001, and “Guidance for Third Parties and FDA Staff; Third Party Review of Premarket Notifications” issued on September 28, 2004.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the 510(k) Third Party Review Program. It does not establish any rights for any person and

is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of “510(k) Third Party Review Program” may send an email request to *CDRH-*

Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 17–028 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807	Medical Devices: Third-Party Review under FDAMA.	0910–0375
807, subpart E	Premarket notification	0910–0120
“Center for Devices and Radiological Health (CDRH) Appeals Processes”	CDRH Appeals Process	0910–0738
“Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff”.	Q-submissions	0910–0756

Dated: March 9, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–05080 Filed 3–11–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0419]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before May 11, 2020.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0419 60D, and project title for reference, to

Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov*, or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Acquisition Regulation Clause Patent Rights and Rights and Data.

Type of Collection: Extension.

OMB No. 0990–0419.

Abstract: The Department of Health and Human Services; Office of the Assistant Secretary for Financial Resources and Office of Grants and Acquisition Policy and Accountability, Division of Acquisition is requesting an approval by OMB for an extension of a previously approved information collection request, Acquisition Regulation Clause Patent rights and Rights in Data. HHS found that systematically, over a period of several

years, when Determination of Exceptional Circumstances(DEC) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR 27.306 were necessary A DEC is executed consistent with the policy and objectives of the Bayh-Dole Act, 35 U.S.C. 200, *et seq.*, to ensure that subject inventions made under contracts and subcontracts (at all tiers) are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations including universities; to ensure that the Government obtains sufficient rights in federally supported inventions to meet its needs; to protect the public against nonuse or unreasonable use of inventions; and in the case of fulfilling the mission of the U.S. Department of Health and Human Services, to ultimately to benefit the public health.

Likely Respondents: Administrative, technical, legal and management personnel.