to schedule site visit activities prior to each annual site visit.

- *Two Site Visit Discussion Guides:* To systematically document the approaches and strategies used by the first two cohorts of CWCC grantees (fiscal year (FY) 18 and FY 19 awardees), the evaluation team will conduct follow-up interviews with: (1) Project Directors from lead grantee organizations and leaders from partner organizations, and (2) Staff from the lead and partner organizations. These interviews will take place during site visits. Each grantee will participate in four site visits in total. As noted above, the first two have already been completed.

*Respondents:* Leadership and staff from CWCC lead (grantee) organizations and from partner organizations.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents (over request period) | Number of responses per respondent (total over request period) | Average burden hours per response (in hours) | Total burden (in hours) | Annual burden (in hours) |
|---|---|---|---|---|---|
| **Cohort 1 Data Collection for FY 18 grantees** | | | | | |
| Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Follow-Up Interviews | 12 | 1 | 1.5 | 18 | 9 |
| Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Follow-Up Interviews | 36 | 1 | 1 | 36 | 18 |
| Survey Invitee Template | 4 | 1 | 1 | 4 | 2 |
| Annual Collaboration Survey | 268 | 1 | .5 | 134 | 67 |
| Site Visit Planning Template | 4 | 1 | 2 | 8 | 4 |
| **Cohort 2 Data Collection for FY19 grantees** | | | | | |
| Site Visit Discussion Guide for Project Directors and Leaders from Partner Organizations—Follow-Up Interviews | 27 | 2 | 1.5 | 81 | 41 |
| Site Visit Discussion Guide for Staff from Lead and Partner Organizations—Follow-Up Interviews | 81 | 2 | 1 | 162 | 81 |
| Survey Invitee Template | 9 | 2 | 1 | 18 | 9 |
| Annual Collaboration Survey | 990 | 2 | .5 | 990 | 495 |
| Site Visit Planning Template | 9 | 2 | 2 | 36 | 18 |

*Estimated Total Annual Burden Hours:* 744.

*Comments:* The Department specifically requests comments on (a) whether the proposed continued 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:* Section 105(b)(5) of the Child Abuse Prevention and Treatment Act of 1978 (42 U.S.C. 5106(b)(5)), as amended by the CAPTA Reauthorization Act of 2010 (Pub. L. 111–320).

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2022–18327 Filed 8–24–22; 8:45 am]

**BILLING CODE 4184–29–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–N–0370]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Medical Devices; Foreign Letters of Approval

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by September 26, 2022.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0264. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Export of Medical Devices; Foreign Letters of Approval

*OMB Control Number 0910–0264—Extension*

Section 801(e)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is

intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device.

An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or Agency of the United States. Respondents to this collection of information are companies that seek to export medical devices.

In the **Federal Register** of January 28, 2022 (87 FR 4609) we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity and FD&C Act section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours | Total operating and maintenance costs |
|---|---|---|---|---|---|---|
| Foreign letter of approval—801(e)(2) ..... | 36 | 1 | 36 | 2 | 72 | $8,250 |

[1] There are no capital costs associated with this collection of information.

Our estimate of the reporting burden is based on our experience with the information collection and reflects an overall decrease of 27 hours and a corresponding increase of three responses. We attribute this adjustment to an increase in the number of submissions received.

Dated: August 17, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–18326 Filed 8–24–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Proposed Collection: Public Comment Request

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than October 24, 2022.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information collection request title for reference.

*Information Collection Request Title:* Membership Forms for Organ Procurement (OPTN) and Transplantation Network OMB No. 0915–0184 – Revision.

*Abstract:* Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, *et seq.,* the OPTN final rule, OPTN Policies, and OPTN Bylaws. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b–8 (section 1138) requires that hospitals in which transplants are performed by members of, and abide by, the rules and requirements of the OPTN (that have been approved by the Secretary of HHS) as a condition of participation in Medicare and Medicaid.

*Need and Proposed Use of the Information:* The application materials are needed to ensure that all members and prospective members of the OPTN submit evidence that they meet the required qualifications for membership. These materials provide the OPTN with information to permit the OPTN to confirm and demonstrate that applicants meet OPTN membership application requirements and to create a record of the application review process and resulting actions for consideration by the Secretary of HHS if an applicant subsequently appeals a membership rejection by the OPTN.

This is a request to revise the current OPTN data collection associated with transplant hospitals, organ procurement organizations, transplant histocompatibility laboratories, medical/scientific and public organizations, business organizations, and individuals to meet or sustain requirements for OPTN membership to include data collection forms for OPTN member hospitals requesting HIV Organ Policy Equity (HOPE) Act Variances and Kidney Paired Donation Pilot Program (KPDPP) contact update form. This revision also includes changes to the existing OMB data collection forms. HRSA is submitting the following changes to the Membership forms to clarify requirements and eliminate redundancy while adding more explanatory language and instruction to the applications, which include:

(1) Adding two new data collection forms for HOPE Act Variance Request and KPDPP contact update form. The HOPE Act Variance Request is for any OPTN member transplant program that wishes to start a variance to receive HIV-positive organs for their HIV-positive patients. The KPDPP contact