

account the probable risks and benefits of currently available devices or alternative forms of treatment.

Respondents may submit a humanitarian device exemption (HDE) application seeking exemption from the effectiveness requirements of sections 514 and 515 of the FD&C Act as authorized by section 520(m)(2). The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2)

whether to exempt an HUD from the effectiveness requirements under sections 514 and 515 of the FD&C Act, provided that the device meets requirements set forth under section 520(m) of the FD&C Act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine

whether the holder of an HUD is in compliance with the HUD provisions under section 520(m) of the FD&C Act.

In the **Federal Register** of October 16, 2017 (82 FR 48096), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Request for HUD designation—814.102	19	1	19	40	760
HDE Application—814.104	3	1	3	320	960
HDE Amendments and resubmitted HDEs—814.106	6	5	30	50	1,500
HDE Supplements—814.108	110	1	110	80	8,800
Notification of withdrawal of an HDE—814.116(e)(3)	1	1	1	1	1
Notification of withdrawal of Institutional Review Board approval—814.124(b)	1	1	1	2	2
Periodic reports—814.126(b)(1)	35	1	35	120	4,200
Total					16,223

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeping	Total annual records	Average burden per recordkeeping	Total hours
HDE Records—814.126(b)(2)	247	1	247	2	494

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notification of emergency use—814.124(a)	22	1	22	1	22

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents in tables 1, 2, and 3 of this document are an average based on data for the previous 3 years, *i.e.*, fiscal years 2014 through 2016. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects 35 respondents with approved HUD applications. Under § 814.126(b)(2) in table 2, the estimated number of recordkeepers is 247.

The number of respondents has been adjusted to reflect updated respondent data. This has resulted in an overall decrease of 2,971 hours to the total estimated annual reporting burden. There have been no program changes and the estimated Average Burden per Response has not changed for any of the

information collections since the last OMB approval.

Dated: January 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection

Activities: Proposed Collection: Public Comment Request Information
Collection Request Title: Office for the Advancement of Telehealth Outcome Measures, OMB No. 0915–0311—Revision

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

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 March 12, 2018.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the

information request collection title for reference.

Information Collection Request Title: Office for the Advancement of Telehealth Outcome Measures, OMB No. 0915-0311—Revision.

Abstract: In order to help carry out its mission, the Office for the Advancement of Telehealth (OAT) created a set of performance measures that grantees can use to evaluate the effectiveness of their services programs and monitor their progress through the use of performance reporting data.

Need and Proposed Use of the Information: As required by the Government Performance and Review Act of 1993 (GPRA), all federal agencies must develop strategic plans describing their overall goal and objectives. OAT has worked with its grantees to develop performance measures used to evaluate and monitor the progress of the grantees. Grantee goals are to improve access to needed services, reduce rural practitioner isolation, improve health system productivity and efficiency, and improve patient outcomes.

In each of these categories, specific indicators were designed to be reported

through a performance monitoring website. New measures are being added to the Telehealth Network Grant Program and all measures speak to OAT's progress toward meeting the goals, specifically telehealth services delivered through rural schools.

Likely Respondents: Telehealth Network Grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Performance Improvement Measurement System (PIMS) ..	21	1	21	7	147
Total	21		21		147

HRSA specifically requests comments on: (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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018-00253 Filed 1-9-18; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 12-13, 2018.

Closed: February 12, 2018, 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: February 12, 2018, 10:30 a.m. to 4:45 p.m.

Agenda: Discussion of program and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: February 13, 2018, 8:30 a.m. to 10:30 a.m.